Opioid Regulations Are Widely Misunderstood

BY BRUCE K. DIXON
Chicago Bureau

SALT LAKE CITY — State laws governing the availability and use of opioid analgesics are becoming less onerous, but confusion and misunderstanding persist among regulators and practitioners, according to David E. Joranson.

"There are some positive aspects of policies being developed over the last several years because [states] are more affirmatively recognizing how valuable opioids are in medical practice," said Mr. Joranson, director of the University of Wisconsin Pain and Policy Studies Group in Madison.

The group's mission is to "achieve more balanced international, national, and state policies so that patients' access to pain medications is not compromised by efforts to prevent diversion and drug abuse," he said.

'If a physician knows the laws, he should be perfectly comfortable prescribing opioids for chronic pain.'

MR. JORANSON

A large number of physicians don't have a clear understanding of federal and state regulations governing pain management and overestimate state and federal restrictions on opioid use, a lapse that can contribute to unreasonable fear of regulatory scrutiny and unnecessary conservatism in prescribing, he said at the annual meeting of the American Academy of Hospice and Palliative Medicine and the Hospice and Palliative Nurses Association.

"The major organizations advocating for improved pain management in palliative care should focus the attention of their members on better understanding how policies can improve patient care, and then work to bring change to those policies that are hindering treatment," Mr. Joranson said in an interview.

"If a physician knows the laws, he should be perfectly comfortable prescribing opioids for chronic pain. If he doesn't know the law, he might be concerned," he added.

During a luncheon presentation, attendees participated in an electronic survey that showed significant gaps in knowledge.

For example, more than half of the 300 survey participants, which included physicians and nurses, said that the Drug Enforcement Administration limits prescriptions for schedule II controlled substances such as morphine to a 30-day supply, when in fact the DEA permits an unlimited supply (though the agency is currently finalizing a 90-day supply limit).

Many of the participants in the survey also were unaware that several states recently adopted pain policies and eliminated restrictions on drug quantity, Mr. Joranson said. This same survey drew similar results at the recent annual meeting of the American Academy of Pain Medicine in New Orleans, he added.

The Wisconsin Pain and Policy Studies Group conducted a 6-year evaluation and analysis of each state's policies.

The group's efforts culminated in a "report card," which was issued in 2006. The overall grade improved over the period of the study in 19 states.

Mr. Joranson said that, unfortunately, 16 states confuse physical dependence and addiction, and at least one state contradicts itself. The Pennsylvania Uniform Controlled Substances Act defines a drug-dependent person as someone "who is using a drug, controlled substance, or alcohol, and who is in a state of psychic or physical dependence, or both. . . . This definition shall include those persons commonly known as 'drug addicts.' "

Yet the Pennsylvania State Board of Medicine guideline says physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

"So if you have a physically dependent pain patient in Pennsylvania, depending on which definition you look at, that person either is an addict or is definitively not an addict," Mr. Joranson said.

Other states that confuse physical dependence with addiction are Arizona, Colorado, Georgia, Hawaii, Idaho, Indiana, Louisiana, Maryland, Missouri, Nevada, New Jersey, North Carolina, Oklahoma, Tennessee, and Wyoming.

States that have no statutes relating to pain management and no regulations or guidelines from the state medical or pharmacy boards are Alaska, Delaware, Illinois, and Indiana, Mr. Joranson said.

A model policy is available from the Federation of State Medical Boards, summarized as follows:

- Controlled substances are necessary for public health.
- People should have access to appropriate and effective pain relief.
- Pain management is part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness.
- Physicians should not fear regulatory sanctions.
- Physical dependence is not synonymous with addiction.

"Obviously, some of the laws that have the potential to confuse patients and practitioners need to be changed," Mr. Joranson said.

"This is an opportunity for physicians to come forward and explain to policy makers the importance of making those changes," he added.

Mr. Joranson has received honoraria from A.L. Pharma Inc. and Abbott Laboratories, and he has received grant support from Endo Pharmaceuticals and Purdue Pharma L.P. ■

For more information and links to other resources, go to www.painpolicy.wisc.edu/index.htm.

Cancer Patients With Part D Need Extra Help to Pick Plans

BY CHRISTINE KILGORE
Contributing Writer

WASHINGTON — Physicians treating older cancer patients must actively help them choose Medicare Part D prescription drug plans with formularies that best cover not only current medications but future needs as well, health care consultant Mary Kruczynski said at a conference sponsored by Elsevier Oncology.

"Get online and check their formulary, and if [your patient] hasn't chosen a plan, think outside the box and list all the drugs they'll possibly need in the future," said Ms. Kruczynski, a policy analyst and board member of the Community Oncology Alliance, a Washington-based lobbying group.

Although most physicians do not have time for such legwork, "the current reality is, you can't afford not to. … If we don't, our patients can't get treated," said Ms. Kruczynski, who is based in Langhorne, Pa.

Get online and check their formulary, and if your patient hasn't chosen a plan, think outside the box and list all the drugs they'll need in the future.

"If [your patients] go to the drug store and get told 'it's not on the formulary,' they come back to you," she said.

When cancer drugs appear on multiple formularies, pricing variations can be significant—and physicians and staff might even want to help patients navigate such variations, especially as more and more oral drugs for cancer become available.

A recent cost study of seven oral cancer drugs in three markets documented significant variations, Ms. Kruczynski noted.

The cost of Arimidex (anastrozole), for instance, was 72% higher in Portland than in Virginia Beach (Commun. Oncol. 2006;3:753-5).

Formularies under Medicare Part D also are increasingly restrictive. Many insurers have added coverage of generic drugs and reduced coverage of brand-name drugs; some also are adopting new techniques to control the use of certain drugs.

"They're asking for data, blood counts, medical records … and checking doses," Ms. Kruczynski said. "Some carriers now require you to get every prescription authorized."

Those physicians who care for patients with cancer, in the meantime, have "been bending over backwards to try to get every drug our patients need for them, even if they have to switch them from Part D to Part B … even if they get them to their doughnut hole," or coverage gap, "and bring them into the office for an infusible under Part B," Ms. Kruczynski commented.

The Medicare Payment Advisory Commission (MedPAC) recognized such actions in its January 2007 report, she said.

The report, which focuses on Medicare payments for Part B drugs and also includes some commentary on Part D drugs, notes the word of those physicians who work with their patients to determine whether it is more beneficial to prescribe the drugs under Medicare Part D or under Part B.

One option might be preferable to the other, Ms. Kruczynski said, depending upon the patient's Part D plan and coverage. The value of one choice over another could also depend on the patient's spending relative to the doughnut hole and any catastrophic coverage that the patient might have.

The MedPAC report also relates physician accounts of patients who reach the doughnut hole and either neglect their treatment or try to stretch out their drug regimens until coverage starts again.

Concerns about patients "brown bagging" physician-administered drugs so that they can be covered under Part D—as well as observations that some physicians have established in-house pharmacies to remedy the problem—also are mentioned in the MedPAC report, Ms. Kruczynski said.

Insurance companies also are "changing their formularies midstream," she said. That is, although Medicare drug plans are indeed permitted to retain the same name while substantially changing costs and benefits each year, the plans sometimes fail to send out the required change notices.

The UnitedHealth Group, which serves the largest segment of the Medicare Part D market, has done this in the past.

The issue of formulary changes has been included in at least some of the 42 House and 31 Senate bills addressing problems with Medicare Part D, Ms. Kruczynski noted.

MedPAC also is expected to weigh in this year with a report focused on the program.

For now, she said, "it's coming down to us again."

By helping patients navigate Part D, "we're essentially administering the plans of private insurance carriers for free."

In the meantime, she emphasized, that help is essential for the health of patients.

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