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Board of Medical Licensure & Supervision

Issues&Answers

Preventing Drug Overdoses in Oklahoma

Drug overdose deaths in Oklahoma have risen sharply during the past decade, according to Oklahoma City Addiction Medicine physicians Hal Vorse, MD, and Billy Stout, MD.

Between 2002 and 2010, the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBN) reports the number of overdose deaths in the state rose from 470 to 814 per year. Preliminary data indicates there were at least 795 drug overdose deaths in Oklahoma in 2011. Seventy-seven percent of the deaths were due to the use of prescription drugs in combination with other prescription drugs or alcohol.

Drug overdose deaths now annually outnumber automobile accident fatalities in the Sooner State.

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Many physicians consider such drugs as benzodiazepines, hydrocodone and carisoprodol relatively harmless when used alone. When used in combination, however, they can become very lethal. All drugs which depress the central nervous system become synergistic in their toxicity when used together.

The Oklahoma State Medical Examiner's Office reported the following drug overdose death statistics for 2009:

- 351 single agent deaths.
- 441 two or more agent deaths.
- Benzodiazepines (Xanax, Valium), 10 single agent deaths; 181 deaths with one or more other agents.
- Carisoprodol (Soma), 2 single agent deaths; 46 deaths with one or more other agents.
- Tramadol (Ultram, Ultracet), 5 single agent deaths; 14 deaths with one or more other agents.
- Hydrocodone (Lortab, Vicodin, Norco), 20 single agent deaths; 124 deaths with one or more other agents.

Since the Drug Enforcement Agency (DEA) classifies hydrocodone as a Schedule III rather than a more tightly controlled Schedule II drug, some physicians may conclude that it is safer to use. It is not safer, particularly when used with other depressant drugs.

The State of Oklahoma only recently designated Tramadol and cariosprodol as controlled dangerous substances (CDS). Therefore many physicians may

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assume they are relatively harmless. However, they are addictive and also carry a significant risk of overdose.

Many overdose deaths are preventable. Here are a few recommendations that could save hundreds of lives:

- Check the OBN's Prescription Monitoring Program's (PMP) history report on all patients, particularly those taking controlled substances. Be sure patients are not receiving prescriptions from other providers.
- Determine if the patient has a history of substance abuse.
- Make sure patients understand they must never take two or more substances at the same time—including alcohol—which depress the central nervous system.
- Do not prescribe opiates and benzodiazepines at the same time or decrease the dosage of each if they must be given together.

**See "Upcoming CME Programs" on back page*

Extended-release / Long-acting Opioids REMS

While extended-release and long-acting (ER/LA) opioid analgesics are approved for the management of moderate to severe chronic pain in appropriately selected patients, these medications also are associated with serious risks and are the center of a major public health crisis due to increased misuse, abuse, addiction, overdose and death.

Therefore, the United States Food and Drug Administration (FDA) has required a Risk Evaluation and Mitigation Strategy (REMS) for ER/LA opioid analgesics. A REMS is a strategy to manage known, or potential, serious risks associated with a drug product and is required by the FDA to ensure that the benefits of a drug outweigh its risks. The drug products subject to this REMS include all extended-release oral-dosage forms containing hydromorphone, morphine, oxycodone, oxymorphone, or tapentadol; fentanyl and buprenorphine-containing transdermal delivery systems; and methadone tablets and solutions that are indicated for use as analgesics.

The FDA and manufacturers of ER/LA opioids are developing Continuing Medical Education programs for prescribers.

Under the conditions of this REMS, prescribers of ER/LA opioid analgesics are strongly encouraged to do all of the following:

- **Educate Yourself -** Complete REMS-compliant CME courses when they become available.
- **Counsel Your Patients** - Discuss the safe use, serious risks, storage and disposal of ER/LA opioid analgesics with patients and/or their caregivers every time you prescribe these medicines. You may download the Patient Counseling Document on Extended-Release/Long-Acting Opioid Analgesics (and also learn more about this REMS) at er-la-opioidrems.com.
- **Emphasize Patient and Caregiver Understanding of the Medication Guide** - Stress to patients and caregivers the importance of reading the Medication Guide they will receive from their pharmacist every time an ER/LA opioid is dispensed to them.
- **Consider Using Other Tools** - In addition to the Patient Counseling Document there are other publicly available tools to improve patient, household and community safety, as well as compliance with conditions of treatment, including Patient-Prescriber Agreements and risk assessment instruments.

To report all suspected adverse reactions associated with the use of ER/LA opioid analgesics contact the manufacturer of the specific product and/or notify the FDA MedWatch program: 800-332-1088 or www.fda.gov/medwatch/report.htm.

To learn more about the ER/LA Opioid REMS program, call 800-503-0784 or er-la-opioidrems.com.

**See "Upcoming CME Programs" on back page*

Investigational Drug Compounding

Drugs listed as "investigational" or "investigational new drug" (IND) by the United Stated Food and Drug Administration (FDA) must be prescribed or ordered by a licensed prescriber who has a FDA-sanctioned IND for a recipient/ patient who also is part of the IND study.

(This statement does not apply to a FDA-approved drug which is used for an unapproved indication.)

The FDA defines the term IND as meaning an unapproved drug or biological drug that may be used in a clinical investigation study. The term may also include a biological product that is used in vitro for diagnostic purposes.

The Medical Board may not consider a prescription for an "investigational only" drug ordered by a licensed practitioner to be a valid prescription unless the physician is part of an investigational study for an "investigational only" drug and the patient for whom the prescription is written is part of the investigational study. Physicians who are not part of an investigational study who are found on prescription audits to have prescribed investigational-only drugs will be referred to the Medical Board for appropriate action.

A pharmacy and/or pharmacist found to be compounding and dispensing such prescriptions will be referred to the FDA enforcement office, in addition to the Oklahoma Board of Pharmacy, for possible disciplinary action.

FDA policy requires that for a patient to gain access to an investigational drug outside a clinical trial, the patient must have a serious or immediately life-threatening disease or condition and no comparable or satisfactory therapeutic alternatives. **Additionally, the drug manufacturer and the patient's physician must make special arrangements to obtain the drug for the patient. These arrangements must be authorized by the FDA.** These safeguards are in place to avoid exposing patients to unnecessary risks.

Medical Board Pioneers Use of QR Codes

Oklahoma State Board of Medical Licensure and Supervision (Medical Board) is the first in the nation to incorporate QR (quick response) codes on the medical licenses of physicians and other medical professionals. QR codes are two-dimensional bar codes first designed for the automotive industry in Japan. They can contain more information than a regular bar code and may be read by devices many people already own, such as smart phones and tablets. The ubiquitous black and white square box will now appear in the lower right hand corner of all newly issued or renewed physician licenses in Oklahoma.

Scanning the code will provide direct, instant access to a physician's information page as it appears on the Board's website, www.okmedicalboard.org. Some of the data available includes the doctor's education, medical specialty and board certification, office address, telephone and office hours, hospital privileges, insurance participation and board status. In the same way that traditional UPC bar codes changed the way we pay for groceries, the QR codes will allow for rapid check-in of medical professionals at training events, clinics, hospitals, etc.

The QR code on medical licenses should provide a real service during emergencies, according to Board Deputy Director Reji Varghese.

"Law enforcement or emergency medical personnel establishing an incident command system at the scene of an accident or emergency will be able to immediately identify and confirm that the Good Samaritan offering assistance is indeed a licensed medical doctor," he said.

Treating Addicted Colleagues

IT'S ILLEGAL AND UNETHICAL TO ENABLE ADDICTED COLLEAGUES.

It is against the law for Oklahoma physicians to prescribe, sell, administer, distribute, order or give "any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug for other than medically accepted therapeutic purposes." (Oklahoma Medical Practice Act 435: 10-7-4 [24].) It is also illegal, "except as otherwise permitted by law," to prescribe, sell, administer, distribute, order or give "to a habitué or addict or any person previously drug dependent, any drug legally classified as a controlled substance or recognized as an addictive or dangerous drug." (Oklahoma Medical Practice Act 435: 10-7-4 [25]). Inappropriately prescribing Controlled Dangerous Substances (CDS) to patients known to be addicts is unprofessional conduct for which physicians, if found guilty, may be disciplined, which can include the possibility of losing their medical licenses.

> "...doctors face difficult, often uncomfortable, ethical decisions when the addicted patient is another physician or health professional."

In addition to the legal consequences, doctors face difficult, often uncomfortable, ethical decisions when the addicted patient is another physician or health professional. When treating a member of the public who is an addict, physicians may simply dismiss that patient from their practices if the patient refuses to follow medical advice. Treating the addicted colleague presents both an ethical and legal dilemma. Physicians cannot skirt their ethical responsibility to the public and their profession by simply refusing to treat a non-compliant addicted colleague.

What is a physician to do when treating another health professional who may be an addict?

First, when treating a colleague, DO NOT rule out the diagnosis of addiction because of misdirected professional respect or courtesy. It is human nature for a treating physician to presume a colleague/patient is being honest. That's not always the case under normal conditions and particularly when dealing with an addict. If symptoms and clinical judgment seem to indicate addiction, that course of treatment must be pursued. Order a urinalysis and other appropriate drug screening tests. The treating physician should attempt to learn if the colleague/patient is in a good recovery mode, attends AA meetings, counseling sessions, etc. If possible, have a third party verify the recovery status. All this should be made a part of the colleague/patient's medical record.

Secondly, if the treating physician is certain that the colleague/patient is doing well in documented, solid recovery and poses no "threat to the public" when practicing medicine, then the treating physician DOES NOT have any obligation to report the colleague to the licensing board or any other entity. Doctor/patient confidentiality remains in effect. Appropriately document in the chart the reason for treating with CDS and informed consent.

Thirdly, if the treating physician knows the colleague/patient is a substance abuser, a threat to the public and not in a good recovery, the treating physician has two options.

A. The treating physician can counsel the colleague/patient and provide information on the programs available in Oklahoma to assist and advocate for health professionals with substance abuse issues. The treating physician can encourage the colleague/patient to call the appropriate program and ask for an intervention and/or assessment to determine the current status of substance use, abuse, or abstinence. ALL THIS MAY BE DONE WITHOUT ANY NOTIFICATION TO A LICENSING BOARD OR OTHER ENTITY, provided that the colleague/patient follows through with the process, agrees to and follows the program's recommendations, including any required treatment and long-term recovery activities. All of the recovery programs will report to the appropriate licensing board if the colleague/patient does not participate in the assessment, treatment and recovery recommendations and process.

Programs available to Oklahoma health professionals are:

Oklahoma Health Professionals Program (OHPP) Robert Westcott, MD, 405-601-2536 (MD, DO, DDS,PA and DVM)

Nursing Peer Assistance Program (NPAP)
Laura Clarkson, RN, 405-525-2277
(RN, NP, CNS, NMW, CRNA)

Allied Professional Peer Assistance Program (APPA)
Billy Stout, MD, 405-962-1450
(PT, RC, OT, AT, LD, RT, RE, AA, RA, PED, O&P)

Oklahoma Pharmacists Helping Pharmacists (OPHP)
Kevin Rich, 1-800-260-7574 Ext. 5773
(RPhD)

B. If the treating physician knows that the colleague/patient is a substance abuser, a threat to the public and not in a good recovery mode and the colleague/patient REFUSES to contact the professional assistance program, then the treating physician has a professional, legal and ethical obligation to the profession and the public to report the colleague/patient to the proper authorities under the Oklahoma Medical Practice Act, 435:10-7-4 (42,43), which states a physician can be cited for unprofessional conduct for:

(42) "Failure to inform the Board of a state of physical or mental health of the licensee or any other health professional which constitutes or which the licensee suspects constitutes a threat to the public."

And:

(43) "Failure to report to the Board unprofessional conduct committed by another physician."

In Oklahoma, the authorities are:

Oklahoma Board of Medical Licensure and Supervision
405-962-1400, 1-800-381-4519, okmedicalboard.org

Oklahoma State Board of Osteopathic Examiners
405-528-8625, ok.gov/osboe

Oklahoma State Board of Pharmacy
405-521-3815, ok.gov/OSBP

Oklahoma Board of Nursing
405-962-1800, ok.gov/nursing

Oklahoma Bureau of Narcotics and Dangerous Drugs Control
1-800-522-8031, ok.gov/obndd

Oklahoma Offices U.S. Drug Enforcement Agency
Oklahoma City: 405-475-7500
Tulsa: 918-459-9600

New Ban on Hydrocodone Refills Effective November 1st

Effective November 1, 2013, prescriptions for any medication containing Hydrocodone may not be refilled. This applies even if the prescription was written prior to November 1st. Transfers are considered to be a refill of a pre-existing prescription and are not allowed. Partial fills would be permitted (i.e. a prescription is written for 100 but the patient only wants to purchase 20 at a time). Documentation for partial fills would be required in accordance with OAC 475:30-1-12. Hydrocodone combination medications are still classified as a CIII product and may be phoned in. Mid-level practitioners (nurse practitioners, physician assistants, etc.) may continue to prescribe Hydrocodone combination medications at this time.

Board CME Efforts Recognized

The Oklahoma Medical Board staff received Honorable Mention Best of the Boards Award at the national meeting of Administrators in Medicine (AIM) for its ongoing public and licensee educational outreach initiative, "It Takes a Village…to Put on a Great CME Program."

AIM Best of the Boards Awards recognize programs and initiatives that demonstrate outstanding "best practices" or innovations. The Award allows state boards to share the benefit of their accomplishments with colleagues and receive recognition for their hard work.

The Oklahoma Board was recognized for its efforts to ease the delivery and increase the frequency of educational programs through the use of both new technology and traditional face-to-face CME programs. The Board also was commended for its commitment to collaboration through strong partnerships with the Osteopathic Board, OU College of Medicine, Oklahoma State University College of Osteopathic Medicine, Oklahoma State Medical Association, Oklahoma Osteopathic Association and professional liability carriers.

Upcoming CME Offerings

* **Safe Practical Pain Management for Primary Care Physicians & ER/LA Opioid REMS: Achieving Safe Use While Improving Patient Care** September 20, 2013, 8 AM - 4:30 PM St. Luke's United Methodist Church, 222 NW 15th St, OKC. Registration $75
www.okmedicalboard.org/#bill-pay
6.5 AMA PRA Category 1 Credits for entire conference.

A Day With The Judges
Pain Management, Telemedicine, EHR, Judicial System and Official Disability Guidelines
November 15, 2013, 8:30 AM – 4:15 PM
Conference Center, INTEGRIS Baptist Medical Center, 3300 NW Expressway, OKC Registration $125.
http://sssanbar.wix.com/baptist
7 Hours CME

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