



Oregon State Board of Pharmacy

800 NE Oregon St, Suite 150
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Published to promote voluntary compliance of pharmacy and drug law.

No. 404: New Continuing Education Requirement: Pain Management

In 2001, legislation was adopted that required certain categories of health care practitioners and providers to complete continuing education (CE) in the area of pain management. This was due in part to recent research and reports provided to legislators indicating widespread underdiagnosis and undertreatment of pain, and a lack of adequate professional training and expertise in the areas of pain and symptom management. Pharmacists were not included in the list of providers subject to this requirement. Since pharmacists already have a requirement to obtain a minimum of 15 hours of CE annually, it was argued that CE in the subject of pain and symptom management is, and will continue to be, available to pharmacists with or without the new legislation.

In 2005, the legislature passed another pain and symptom management CE requirement, this time adding pharmacists to the list. The requirement provides for a minimum total of seven hours, including the one-hour online program developed by the Oregon Pain Management Commission (OPMC). The OPMC program can be accessed via the Commission's Web site at www.oregon.gov/DHS/pain/index.shtml.

The 2001 legislation required CE to be completed within 24 months of the first license renewal after January 1, 2006. The 2005 legislation did not adjust the deadline for pharmacists. Therefore, all pharmacists licensed in Oregon on or before June 30, 2006, must complete the CE by May 31, 2008.

The 2005 legislation also required the Oregon State Board of Pharmacy to adopt rules to administer the new CE mandate for pharmacists. The Board was reminded in a September 13, 2006 letter from Senator Bill Morrisette, chair of the Senate Interim Public Health Committee, to request pharmacists to participate in the training. The Board adopted a temporary rule on August 9, 2006, in order to notify pharmacists because of the limited time frame for completion. Language has also been proposed by the Board

for permanent rule making, which is expected to be presented for adoption at the December Board meeting following the September 2006 public rule making and rule making hearing notices and the November 1, 2006 public hearing. CE providers are being contacted and programs are being developed to ensure that pharmacists will have plenty of opportunity to comply with the new requirement. Pain management CE will be considered in the category of "Therapeutics."

No. 405: Other Proposed Rules

Notice was also issued by the Board regarding several other proposed rules to be presented at the November 1, 2006 hearing and voted on at the December Board meeting. These include:

- ◆ definition of "Shared Pharmacy Services";
- ◆ changes to the pharmaceutical wholesaler registration requirements, distribution and chain of custody documentation, prohibited practices, and penalties; and
- ◆ changes to rules for manufacturers of prophylactics and contraceptives deleting the requirement for manufacturers of condoms to provide samples to the Board for testing.

No. 406: Oregon Patient Safety Commission Begins Safety and Quality Effort

By Dave Widen, MBA, RPh, and Leslie Ray, PhD, RN

The Patient Safety Commission has begun working with retail pharmacies in Oregon to develop a voluntary and confidential reporting program to reduce the risk of adverse drug events. The Commission is a semi-independent state agency governed by a 17-member board of directors appointed by the governor and confirmed by the Senate. It is the only organization in Oregon exclusively dedicated to promoting a culture of patient safety with an emphasis on shared data, quality improvement, and quick absorption of new approaches. It is explicitly nonregulatory and nonpunitive.

Continued on page 4



FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- ◆ the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- ◆ read the label and follow the directions carefully and correctly;
- ◆ two medicines with the same active ingredient should not be used at the same time; and
- ◆ measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl

may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm*. October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

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error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical**[®], **Micalcin**[®]) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP**[®]), sumatriptan (**Imitrex**[®]), and zolmitriptan (**Zomig**[®]).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing

ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register*, FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors[®] accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

Continued from page 1

The Commission has already experienced significant success with its hospital reporting program, where 51 of 57 hospitals have signed participation agreements. These 51 hospitals provide 98% of all hospital care in Oregon. Now well on its way to introducing a reporting program for retail pharmacies, the Commission represents a safe haven where pharmacies can share confidential patient safety information without fear of legal consequence.

It is known that most medication dispensing errors occur with refills rather than new prescriptions and that distractions and interruptions are major impediments to accuracy. However, much is unknown about errors in the retail environment as compared to hospital settings. The potential risks are real and growing as the profession of pharmacy struggles with fewer pharmacists and aging baby boomers requiring greater numbers of medications. The goal for the retail pharmacy adverse event reporting program is to better understand where and how adverse events occur, then to create and share strategies for reducing the risk of patient harm.

In developing the reporting program, the Patient Safety Commission established an advisory group with representation from retail pharmacy chains, independent pharmacies, Oregon State University College of Pharmacy, and the Oregon State Pharmacy Association. The advisory group and others helped the Commission define adverse events; create a safe, confidential nonpunitive reporting framework; and pilot the program to test its feasibility. The group also helped draft administrative rules to guide the reporting program. The next step is to gain public comment on the rules (available on the Commission's Web site at www.oregonpatientsafety.org). The Commission encourages pharmacists to review the proposed rules and to offer ways that we might work together for patient safety.

The health care quality and patient safety movement is making itself felt within the pharmacy world, and Oregon is one of the first states to respond. With more than 700 retail pharmacies statewide, the Commission and Oregon's

pharmacists have an unparalleled opportunity to demonstrate creative leadership by implementing effective programs to increase pharmacy accuracy and decrease adverse events.

No. 407: Proposed Rule Change: DWD Reporting Requirements

The Department of Human Services Public Health Division issued a Notice of Proposed Rule Making to announce its proposed revisions to Oregon Administrative Rules Chapter 333, Division 009 §0000-0030 (Reporting Requirements of the Oregon Death with Dignity Act). The comment period for these revisions ended November 1, 2006. Board of Pharmacy staff reviewed the proposed changes and did not provide any comments back to Department of Human Services Public Health Division since the changes related to reporting by dispensers appear to be only technical in nature.

The major change to the pharmacist's reporting requirement is the timing of the report. The current rule states, ". . . upon dispensing medication pursuant to the Death with Dignity Act. . ." The proposed new rule states, ". . . within 10 days of dispensing medication pursuant to the Death with Dignity Act, the dispensing health care provider shall file a copy of the 'Pharmacy Dispensing Record Form' . . ." When the final rule is adopted, the complete rule will be posted on the Board of Pharmacy's Web site at www.pharmacy.state.or.us.

Page 4 – November 2006

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