February 2017

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 572: Board's Compliance Director Retires

Oregon State Board of Pharmacy Compliance Director Gary Miner announced his retirement, effective Friday, January 13, 2017. Gary joined the Board as a compliance officer in 2004 and was appointed compliance director the following year. Gary has been an instrumental figure and mentor to many throughout his tenure with the Board. Gary's steadfast commitment to his maxim of "Compliance Through Education" is central to the Board's policymaking, outreach, and disciplinary approaches of today. Under Gary's leadership, the Board has worked diligently to improve communications and relationships with licensees. He created the Oregon Pharmacist In Charge (PIC) Training Program as a way to introduce newly appointed PICs to the Board's pharmacy compliance expectations. To date, more than 2,000 people have taken the course. Gary also helped promote the daily dedication of an inspector/investigator to staff the phones in order to be available to address compliance circumstances and inquiries from licensees and consumers.

Gary's devotion to education and outreach is evident in many of the Board's regular activities. He initiated the creation of the Board as a unique Advanced Pharmacy Practice Experience elective rotation site, one of the first of its kind in the country. Students have the opportunity to gain firsthand experience at the Board office, learning how rules and regulations affect policies and pharmacy practice, which provides invaluable insights into their future professional endeavors. Board staff members routinely teach educational presentations to the students at Pacific University School of Pharmacy and Oregon State University College of Pharmacy. Additionally, you will regularly see the Board at the state and local pharmacy association meetings, providing information at the booth and presenting the lively law update that many look forward to each year!

As a result of Gary's foresight and ability to anticipate the evolution of the practice of pharmacy, the Board is well poised to continue to adapt to the momentous changes to the profession in the coming years, with a continued focus on the public health and safety of its citizens. Best wishes, Mr Miner!

No. 573: Pharmacist Board Member Opportunity

The Board will have one pharmacist member position available for appointment effective July 1, 2017. For qualifications, more information, and how to apply, please visit the Board's website at *www.oregon.gov/pharmacy/Pages/Employment.aspx.*

The Board encourages all interested and qualified people to apply sooner rather than later, but no later than March 30, 2017, as the governor's office may close the applicant pool without notice.

No. 574: Schedule II Prescriptions – New Partial Fill Allowance

In July 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law. One of the provisions of the law amended the Controlled Substances Act to allow a pharmacist to partially fill a prescription for a Schedule II controlled substance (CS) for ambulatory patients under certain circumstances. Previously, this was only permissible if the pharmacist was unable to supply the full quantity as issued on the original prescription, and the pharmacist was required to complete the balance within 72 hours. Partial filling has been allowed for nursing home patients in a nursing home setting and terminally ill patients.

CARA allows for the partial filling of a Schedule II drug if the following conditions are met:

- It is not prohibited by state law (ie, it is not prohibited by Oregon Administrative Rules (OARs));
- The prescription is written and filled in accordance with federal and state law;
- The partial fill is requested by the patient or the practitioner who wrote the prescription; and
- The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

The new law requires that the remaining portion(s) of a partially filled Schedule II prescription may be filled no later than 30 days after the date on which the prescription was written (original date). For additional information, please visit *www.congress.gov/bill/114th-congress/senate-bill/524.* Per Drug Enforcement Administration (DEA), the Code of Federal Regulations will not reflect this change until the new edition is issued in April 2017.

Though the intent of the law is to decrease the amount of unwanted and unused prescription opioid medications in

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

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DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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households across the country, the law change is applicable to all Schedule II prescriptions. Leftover prescription medications being diverted continues to be a major issue with drug overdoses and abuse. This law change creates the opportunity for increased dialogue with practitioners and enhanced patient care and safety.

No. 575: Pharmacies Still Requesting NPI and DEA Registration Numbers

The Oregon Veterinary Medical Association (OVMA) continues to hear from veterinarians who are being asked by some pharmacists to provide a National Provider Identifier (NPI) number or the licensee's DEA registration number in order to fill the veterinarian's prescription for a non-scheduled drug. It is important to note that these are not prescription requirements, per Board rules. Rather they are pharmacy company policy/procedure or sometimes simply a computer field that a system will not allow the user to move through until something is entered. This creates confusion and inappropriate communications between pharmacists and their fellow practitioners.

NPI Number for Veterinary Prescriptions

Pharmacists and pharmacy system developers must be aware that veterinarians **do not qualify** for an NPI number. The federal government has clarified that veterinarians are not eligible to have an NPI number. Therefore, pharmacists and technicians should not ask a veterinarian for an NPI number.

DEA Registration Number and Veterinary Prescriptions

Some pharmacies also routinely ask for the veterinarian's DEA number for non-CS prescriptions as a means to prevent fraudulent prescriptions called in by non-veterinarians. The DEA field office in Portland, OR, recommends against prescribers sharing this number when issuing non-scheduled drug prescriptions.

Pharmacists, use your professional judgment when complying with the rules related to this topic. OAR 855-019-0210(2) states that a pharmacist receiving a prescription is responsible for "[u]sing professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist, in their professional judgment, believes that the prescription was issued without a valid patient-practitioner relationship. In this rule, the term practitioner shall include a clinical associate of the practitioner or any other practitioner acting in the practitioner's absence. The prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice . . . "

Additionally, a component of OAR 855-041-1105(2) states that "Each pharmacy must document the following information:

(a) The name of the patient for whom or the owner of the animal and the species of the animal for which the drug is dispensed;

(b) The full name and, in the case of controlled substances, the address and the Drug Enforcement Administration registration number of the practitioner . . . "

The DEA number is not required for a pharmacist when receiving an oral prescription for a non-controlled medication. For prescriptive authority confirmation, you may consider asking for the veterinarian's state veterinary license number or another proper identifier.

If this creates a problem for your computer processing systems, you can address the computer configurations with your corporate leadership. The Board expects that these types of issues will not interfere with providing safe, effective care for all patients. Computer systems and automated processes should assist the practice of pharmacy, not interfere with it. Certainly, these issues should never cause a delay in care for any patient.

To help facilitate these conversations, OVMA has developed material on veterinary prescriptions to help professionals better understand the shared commonalities between pharmacies and veterinarians. This information can be found at *https://oregonvma.org/resources/pharmacies-and-prescriptions*.

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