



Oregon State Board of Pharmacy

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No. 565: Board Business

The Oregon State Board of Pharmacy and Board staff would like to thank outgoing member Brad Fujisaki, who served on the Board from July 1, 2012, to June 30, 2016. Brad brought a unique voice to the Board's conversations during his years of service. His focus on the practicality of the information technology angle on contemporary issues facing the pharmacy profession today regularly helped inform the Board and its policy discussions. Some of the Board's accomplishments during his tenure include the establishment of the drug outlet conduct rules and receipt of the 2013 Fred T. Mahaffey Award from the National Association of Boards of Pharmacy® for exceptional contributions to the health and welfare of the public. Additionally, the Board established new types of outlet registrations to keep up with evolving technology in the industry, including consulting or drugless pharmacies, remote processing and central fill, and the Technician Checking Validation Program, all with strong advocacy and input from Brad. His contributions have been invaluable, and he will be greatly missed!

The Board would also like to introduce its new pharmacist member, Rachael DeBarmore, who graduated from the Oregon State University (OSU) College of Pharmacy in 1998. Rachael has gained well-rounded exposure to community pharmacy practice through work experiences at different levels within organizations in this state. Rachael started her career as a pharmacy technician and has worked through the tiers of management from ground level pharmacy management to the director of pharmacy. She has worked in a mass merchant operation and grocery/pharmacy organization and currently is a pharmacy district manager with Rite Aid. Rachael has been actively involved in the pharmacy community; she has served as a board of directors member of the Oregon State Pharmacy Association, participates in the Oregon Pharmacy Coalition, and interacts regularly with students and faculty at both OSU and Pacific University. Rachael currently resides in Keizer, OR, with her husband and three sons.

In other business, are you aware that you can attend the Board's open session meetings, **and** that you can earn continuing education (CE) credit as an added bonus for attending? Up to 0.4 Oregon CEUs (four contact hours) per day are issued (two hours for the morning and two hours for the afternoon). Please consider this great way of getting CE related to law, licensure, and policy. The Board meets about every other month, typically over two to three days, in February, April, June, August, October, and December. Occasionally, these meetings take place outside the Portland, OR area. For dates and locations, please visit www.oregon.gov/pharmacy/Pages/Meetings.aspx. The Board looks forward to seeing you!

No. 566: CPTs Transition to Biennial Licensure

New rules related to Oregon pharmacy technicians are now filed and in effect. The rules state that a Certified Oregon Pharmacy Technician (CPT) license will be valid for up to two years and will be renewed biennially (every two years). The CPT licenses issued henceforth will expire on June 30 in **even-numbered** years. There are also changes to CE requirements. CPTs must complete 20 CE hours during the period from July 1 through June 30 of each biennial license renewal cycle. This means that upon renewal in 2016, a CPT license will expire June 30, 2018, in this shift to biennial licensure. CPT licenses issued beginning on July 1, 2016, will expire June 30, 2018, and so on every even-numbered year. Additionally, these rules bring clarification to license requirements and update parameters for CPT licensure reinstatement. A full set of the rules are available at www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx.

The Board realizes this is a big transition for our licensees and has created some frequently asked questions (FAQs) to assist persons seeking information. Because the CPT license being renewed this year in 2016 was previously a one-year license, the CE requirements for this cycle are different than they are in future biennial license cycles. For this reason, please understand that these FAQs **specifically relate to this year's (2016) license renewal process.**

Q1: How many hours of CE do I have to have completed in order to renew my Board CPT license for this year's renewal?

A1: Your CE must be completed in the period of September 1, 2015, to August 31, 2016, and prior to submitting your renewal. Required CE includes one hour of pharmacy law, one hour of patient safety or medication error prevention, and eight hours of your choice of relevant pharmacy CE or Board-approved on-site training.

Q2: Does my Pharmacy Technician Certification Board or National Healthcareer Association national certification have to be active to renew my CPT (state license)?

A2: No. The Board no longer requires maintenance of national certification for licensure **renewal**; however, it is still required for the **initial** CPT license.

Q3: Do I have to do the law CE on the Board website?

A3: No. The pharmacy law CE on the Board website is one option available for your law CE, but is not required.

Q4: Does my CE have to be "live" or "technician-specific" to count for my CPT?

A4: No. Oregon does not require live or technician-specific CE; however, it is encouraged that your CE be relevant to your

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.

More Selected Medication Safety Risks to Manage in 2016

 *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.

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as $154 \text{ mEq}/0.9\% = x/3\%$ and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256–257 mEq of sodium chloride for a 500 mL bag ($77 \text{ mEq}/0.9\% = x/3\%$).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,¹⁻³ and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.⁶ The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



most of these errors happened within the first 14 days after discharge.⁵ The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).⁴

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røsstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res.* 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
5. Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc.* 2013;61(11):1894-1899.
6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at www.usp.org in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, 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.

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at www.fda.gov/Drugs/DrugSafety/ucm489676.htm.

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.

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practice setting. Additionally, the national certification entities may have extra requirements.

Q5: My initial CPT license was issued after October 1, 2015. Was I supposed to complete the 10 CE hours?

A5: No. Oregon Administrative Rule (OAR) 855-025-0015(2)(c) states that the CE requirement “does not apply to Certified Oregon Pharmacy Technicians applying for the first renewal of their license if they have not been licensed by the Board for at least one year prior to October 1 of the renewal period.”

Q6: I am ready to begin preparing for my next CPT license renewal. In what time frame do I need to do my 20 hours of CE for the 2018 renewal?

A6: Twenty hours of CE must be completed from July 1, 2016, to June 30, 2018, for the renewal cycle in spring 2018. CE requirements are doubled from the annual renewal requirement (two hours of law, two hours medication safety, and 16 “other”/approved on-site training hours).

Q7: How do I change my address with the Board?

A7: When completing the online renewal, simply type in the correct information. Outside the renewal cycle you may submit an email or fax, or use the online electronic address/employment change form available at www.oregon.gov/pharmacy/Pages/Address_Change.aspx.

Important note: The Board performs random CE audits for every renewal cycle. If selected this year, you will be required to provide proof of CE completed between the dates of September 1, 2015, and August 31, 2016, and prior to submitting your license renewal. If you are audited and it is found that you did not complete the required CE, **you will be subject to disciplinary action.** Please be sure to contact Board staff if you need clarification.

No. 567: Compliance Pearls – To Fill or Not to Fill

The Board’s compliance department receives many inquiries related to expectations of how a pharmacist is expected to evaluate a new prescription for validity. This article describes some tools and methods one can use.

The duties of a pharmacist receiving a prescription are outlined in OAR 855-019-0210. It states that a pharmacist must ensure that all prescriptions, prescription refills, and drug orders are correctly dispensed or prepared for administration in accordance with the prescribing practitioner’s authorization. Additionally, a pharmacist receiving a prescription order is responsible for using professional judgment in dispensing only pursuant to a valid prescription. A pharmacist shall not dispense a prescription if the pharmacist in his or her professional judgment believes that the prescription was issued without a valid patient-practitioner relationship. The prescription must be issued for a

legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice and not result solely from a questionnaire or an internet-based relationship.

Prescriptions Written by Practitioners for Themselves or Family Members

Pharmacists regularly inquire about the legality of filling prescriptions written by a practitioner for him/herself or a family member. The Board does not regulate other licensed health care professionals. However, it can refer to the guidance other boards have given. For example, the Oregon Medical Board states that it is “generally unwise to treat oneself or a family member” and “cautions licensees against self-prescribing” and “suggests that a practitioner never prescribe narcotics or benzodiazepines under these circumstances.” (*Oregon Medical Board Report*, Winter 2011.) Additionally, the Medical Board provides guidance in a newsletter FAQ article that asks, “May I prescribe medication to my spouse or family member when her/his physician is unavailable?” The answer states, “Yes, if you don’t make it a habit, **and** you evaluate and chart your workup . . . just like any other patient, **and** it’s not for a scheduled drug.” (*Oregon Medical Board Report*, Summer 2008.) While there are certainly times that exceptions can be made for emergent circumstances, a pharmacist is expected to utilize professionalism when faced with this type of situation.

Prescriptions Written by and Refills Authorized Prior to a Practitioner Retiring

Pharmacists often question whether they can fill or refill a prescription written by a prescriber who is no longer in practice. The answer is based upon common sense and on the pharmacist’s judgment. As long as the prescription was valid when originally issued to the patient, and as long as the condition for which the drug was prescribed still applies to the patient, it may be dispensed. The pharmacist should evaluate each patient and each situation individually to allow reasonable time for the patient to establish care with another practitioner. There is no “exact science” or “legal time frame” to follow. Determinations are based on professional judgment. Document what you do and understand that refilling prescriptions beyond a reasonable time period without medical supervision is not appropriate.