February 2019

News

Oregon State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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No. 605 Oregon State Board of Pharmacy Appoints New Executive Director

The Oregon State Board of Pharmacy is pleased to announce its new director, Joseph "Joe" Schnabel, PharmD, RPh, BCPS. Dr Schnabel comes to the Board after serving for over 30 years at Salem Hospital, where he had been the director of pharmacy since 2011.

Dr Schnabel's strong leadership is founded on a career of serving Oregonians. He previously served as a member of the Board from 1992 to 2000. Dr Schnabel brings experience that translates well to the Board's mission to promote, preserve, and protect public health, safety, and welfare by ensuring high standards in the practice of pharmacy and by regulating the quality, manufacture, sale, and distribution of drugs.

Dr Schnabel will start his new role with the Board on Monday, February 4, 2019. The Board, staff, partners, and stakeholders welcome him to the helm, and at the same time thank Interim Director Brad Avy for leading the Board during the director search.

No. 606 License Renewal – CE Reminder

During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed 30 hours of continuing education (CE) prior to submission of the license renewal. A minimum of at least two hours of CE credit must be earned in the area of pharmacy and drug law. A minimum of two hours of CE credit must be earned in the area of patient safety or medication error prevention.

In accordance with Oregon Administrative Rule (OAR) 855-021-0005(2), pharmacists applying for the **first renewal** of their license have to complete CE if they have been licensed by the Board for at least one year prior to July 1 of the renewal period. However, a pharmacist reciprocating into Oregon will not be required to submit proof of continuing pharmacy education during the initial license cycle, per OAR 855-021-0025.

- **Pharmacists initially licensed between July 1, 2018, and June 30, 2019, do not have to complete the CE requirements for the 2019 renewal.**
- **Pharmacists initially licensed between July 1, 2017, and June 30, 2018, must complete the CE requirements for the 2019 renewal.** (Note: this does not apply to initial licensure by reciprocity.)

Additionally, Oregon has a one-time pain management CE requirement, which must be completed within 24 months of your first license renewal. Per OAR 855-021-0016, a pharmacist shall complete seven hours of CE in pain management, which must include the Oregon Pain Management Commission's one-hour course, as well as six additional pain management-related programs (see *www.oregon.gov/pharmacy/pages/ce_resources.aspx)*. This pain management CE can be counted toward the 30-hour total required.

No. 607 Fifty-Year Pharmacists

The Board is pleased to acknowledge the pharmacists who have been licensed in Oregon for 50 years. The Board recognizes their many years of service and contributions to the profession and to the health and well-being of the citizens of Oregon. These distinguished individuals should be proud of their accomplishments and they deserve the recognition and acknowledgement of their profession. The following pharmacists reached this milestone in 2017 and 2018:

- Patrick Ackerman, Salem, OR
- Gordon Bertelsen, Medford, OR
- Robin Bolton, Portland, OR

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National Pharmacy Compliance News

February 2019

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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- Frederick Campbell, Snohomish, WA
- Douglas Gregory, Portland, OR
- David Maloney, Clovis, CA
- Douglas Rude, Bend, OR
- Stephen Semling, St Helens, OR
- Sara J. White, Mountain View, CA
- Patricia E.Woolsey, Los Altos Hills, CA

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