



# Nevada State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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Jade Jacobo, PharmD, JD, RPh, Las Vegas .... Board Member

## **Retirement of the Executive Secretary**

With much excitement and some sadness, the Nevada State Board of Pharmacy announces the retirement of Larry L. Pinson, PharmD, RPh, from his position as executive secretary of the Board. Dr Pinson has served as the Board’s executive secretary since September 2005.

Dr Pinson began his pharmacy career in 1973, after graduating with a doctor of pharmacy degree from the University of California Medical Center in San Francisco, CA. He practiced clinical pharmacy at St Mary’s Hospital in Reno, NV, for five years before going on to own and operate his store, Silverada Pharmacy, for 22 years. Dr Pinson also worked from time to time as a consultant pharmacist in northern Nevada.

Prior to becoming the executive secretary of the Board, Dr Pinson served as a Board member with appointments to serve from two governors, allowing him to serve on the Board for the statutory maximum of nine years. He was elected to serve as the Board’s president for eight of those years. In total, Dr Pinson has served the state of Nevada in association with the Board for over 23 years. During that time, Dr Pinson oversaw the evolution of the Nevada Prescription Monitoring Program (PMP) into the valuable tool it is today. He also advanced the Board through numerous regulatory amendments, including major updates of the Board’s compounding and wholesaler regulations.

Under Dr Pinson’s direction, the Board twice received the National Association of Boards of Pharmacy®

(NABP®) Fred T. Mahaffey Award, first in 2005 for its work regarding prescription drug pedigrees, and again in 2010 for its “inspecting for safety” initiative. Dr Pinson served NABP and the pharmacy community in various other capacities as well, including service on the Task Force on Licensing of Pharmacy Benefit Managers, the Committee on Constitution and Bylaws, and the Committee on Law Enforcement/Legislation. Dr Pinson currently serves on the committee overseeing NABP’s .Pharmacy Verified Websites Program.

Outside of his Board service, Dr Pinson has served his community and his profession continually. Dr Pinson has spoken and presented before various professional organizations. At NABP conferences he presented on pedigrees and diversion prevention issues, discipline, and compounding. Before the American Society for Pharmacy Law, Dr Pinson presented on navigating regulatory inspections and on how a pharmacy or pharmacist should present before a regulatory board. Dr Pinson has also presented or spoken before numerous state legislative committees, industry and community organizations, and practitioner groups.

During his pharmacy career, Dr Pinson was appointed as an adjunct professor for the schools/colleges of pharmacy at Creighton University and Idaho State University. He served as a preceptor for students from both of those schools/colleges, as well as for students at Chicago State University and Roseman University of Health Sciences. Dr Pinson also served in various capacities with the University of California, San Francisco School of Pharmacy, including as president of its Alumni Association Board of Governors.

In addition to his service directly to the profession, Dr Pinson somehow found time to serve at both the state and local levels. That service includes collaborating with Governor Brian Sandoval on his work with the National Governors Association to address Nevada and the nation’s opioid crisis. Dr Pinson also served on the Nevada attorney general’s Substance Abuse Working Group. Outside

*continued on page 4*

# National Pharmacy Compliance News

January 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](http://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 Con-

trolled 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](http://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](http://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](http://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](http://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](http://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](http://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](http://www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm).

*continued from page 1*

of pharmacy, he served his community on a local level, including service as a local board member of the American Cancer Society and the Washoe County School District's Gifted and Talented Program, and as a leader in the Boy Scouts of America.

Last, but certainly not least, Dr Pinson has been a loving husband and father throughout the entire length of his career. He married his wife, Kathy, in March 1972, and raised two children, his son, Scott, and daughter, Kelly. In his retirement, he looks forward to spending time with his granddaughters, Madelyn and Finley.

The Board appreciates and thanks Dr Pinson for all of his years of service. The Board is excited for the new opportunities his retirement will bring but will also miss him and his magnetic personality. The Board wishes you and your family the best going forward, Larry!

### **New Reno Office**

In January 2019, the Board will move its Reno office to 985 Damonte Ranch Parkway, Suite 206, Reno, NV 89521. The Board's telephone, fax, and email contacts will remain the same. The Board's hours of operation will continue to be from 8 AM to 5 PM, Monday through Friday, except for all state holidays, when the Board is closed. Notice of the exact move date can be found on the Board's website, [www.bop.nv.gov](http://www.bop.nv.gov).

### **Board Member Update**

Board staff is delighted to welcome Jade Michelle Jacobo, PharmD, JD, RPh, as Governor Sandoval's newest appointment to the Board for a three-year term. Dr Jacobo received her doctor of pharmacy degree from Mercer University College of Pharmacy in Atlanta, GA. She went on to achieve a juris doctor degree from John Marshall Law School. Dr Jacobo is currently employed as a pharmacy manager by Walmart in Las Vegas, NV. She has also worked as a hospital pharmacist in the Las Vegas area. Throughout her career she has focused on community outreach to provide awareness of the practice of pharmacy.

Governor Sandoval also reappointed Board Member Wayne Mitchell to another three-year term, as well as Board President Leo Basch to his third three-year term.

Yenh Long, PharmD, RPh, BCACP, CPM, has been hired as the new deputy executive secretary of the Board. Dr Long was promoted from her position as the Nevada PMP administrator. During her time with the Board, she has overseen several critical projects and mandates, including Nevada Senate Bill 459 and Assembly Bill 474, which consisted of extensive work with law enforcement regarding prescription misuse, and naloxone training for officers and first responders. Dr Long has also focused on improving Nevada's PMP data and has presented on proper management of state PMPs throughout the United States.

Congratulations, Jade, Mitch, Leo, and Yenh!

## **Nevada Medicaid Initiates Antibiotics Prior Authorization Criteria**

*By Holly M. Long, Social Services Specialist, Nevada Department of Health and Human Services*

Nevada, along with the rest of the nation, is struggling with the antimicrobial resistance crisis. According to the Centers for Disease Control and Prevention, our state leads the country in a number of resistance phenotypes, including fluoroquinolones and third-generation cephalosporins. These are important antibiotic classes used to treat serious, complicated infections. Our resistance patterns over time suggest we may reach a point when these antibiotics are no longer effective, leaving us with very few options.

One of the drivers of advancing antibiotic resistance is overuse. Studies have shown that the restriction of antibiotic use can reduce the levels of resistance over time. Soon, Nevada's Division of Health Care Financing and Policy (DHCFP) will be implementing a policy to require prior authorization in the outpatient care setting for the prescription of oral fluoroquinolones and third-generation cephalosporins. This policy will require demonstration of medical necessity based on current Infectious Diseases Society of America national guidelines or specific data such as culture-sensitivity results.

The DHCFP Pharmacy Program will be providing further information and provider education regarding this implementation in the form of web announcements, a work group, and a webinar. You may check for upcoming announcements at <https://www.medicaid.nv.gov/providers/rx/rxinfo.aspx>.

Our overall goal is that together, we can preserve our ability to save lives with antibiotics and begin to turn the tide of antibiotic resistance for Medicaid recipients through excellent stewardship.

**Disclaimer:** This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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Page 4 – January 2019

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