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Nevada State Board of Pharmacy News

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Board Members

Reappointment of Jason Penrod

The Nevada State Board of Pharmacy staff is happy to report the announcement by Governor Brian Sandoval of the reappointment of Jason Penrod to a second term on the Board. Jason is a tireless Board member with a true compassion for the well-being of patients. The Board congratulates him and looks forward to continue working with him over the next three years.

A New Era for Compounding Inspections

Following the New England Compounding Center meningitis outbreak in 2012, the inspection process for facilities that perform sterile compounding immediately became more detailed and rigorous. Unfortunately, on a national basis, we continue to see significant patient harm, including deaths from products that are being produced by sterile compounding facilities. Based on the continued potential for patient harm related to the compounding of sterile products, all sterile compounding facilities in Nevada can expect to see more changes in the near future related to their annual inspection process. Changes to the process will include updates to the existing sterile compounding inspection form, a sterile compounding reference guide, a comprehensive list of items that will need to be available for review during the inspection, visual observation of compounding, and detailed records review of all environmental monitoring data. Sterile compounding facilities should anticipate that the inspector may be present for six to eight hours to complete this comprehensive review. Two of the inspectors in Nevada have gone through a certification process with CriticalPoint that includes over 60 hours of both didactic and hands-on training specifically related to sterile compounding. It is the Board's intent that all inspectors will have successfully completed the certification process over the next 12 months. Board inspectors will work collaboratively with the Board's licensees to pass on the knowledge that they have obtained during the certification process.

Senate Bill 59 Makes Changes in Reporting to the Nevada PMP

The Board administers the Nevada Prescription Monitoring Program (PMP) pursuant to the provisions of Nevada Revised Statutes (NRS) Chapter 453. The PMP was instituted at the direction of the Nevada Legislature in 1997 to track the prescription and dispensation of controlled substances (CS) to prevent diversion, abuse, and overdose; however, some critical data is not currently entered into the PMP, including violations of NRS Chapter 453, reports of stolen prescription drugs, and prescription drug-related overdoses or deaths. Senate Bill 59 from the 79th Legislative Session, which took effect July 1, 2017, implements recommendations of the Nevada Substance Abuse Working Group to fix this deficiency.

Section 1.3 of the bill ensures that law enforcement agencies can effectively enter data on CS violations and reports of stolen prescription drugs into the PMP. Section 1.3 ensures that coroners and medical examiners also can effectively enter data on prescription drug-related overdoses or deaths to the PMP. Section 1.6 authorizes coroners and medical examiners to access the PMP to comply with these reporting requirements and to investigate the death of a person. Section 4 amends NRS 453.165, which already authorizes law enforcement agencies to access the PMP while investigating crimes related to prescription drugs, to further access the PMP to comply with these reporting requirements.

PMP Data Submission Accuracy Data

By Darla Zarley, Yehn Long, and Stacy Ward

The media publishes articles almost daily about the opioid crisis and the various strategies to combat the problem.

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National Pharmacy Compliance News

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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.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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The Nevada PMP is one essential tool designed to help health care providers fight this epidemic. The PMP works best when dispensers – eg, pharmacies and dispensing practitioners – submit accurate information to the PMP database regarding each CS they dispense. Most of that information is entered manually by pharmacists and pharmacy technicians. Errors in the data can result in inaccurate patient PMP reports, which can negatively impact patient care and even the prescriber's practice.

Roseman University of Health Sciences College of Pharmacy and the Board have partnered on a project designed to improve the quality of data in the PMP database. Over the last several months, that partnership has worked to analyze and verify the accuracy of the data that Nevada dispensers have submitted to the PMP. You may have felt an impact from that study during your pharmacy's last annual inspection when the Board inspector requested copies of randomly selected CS prescriptions dispensed by your pharmacy. The inspector requested those copies for auditing as part of this project.

After analyzing the prescriptions that Board inspectors collected, the PMP divided the errors it found into three classifications: minor (errors in "non-vital" fields), major, and severe (errors in "vital" fields).

Type of Error	Error
Minor (errors in "non-vital" fields)	Missing/incorrect/misspelled address or phone number of patient, incorrect days supply
Major	Incorrect quantity, incorrect date issued or date dispensed
Severe (errors in "vital" fields)	Missing/incorrect patient date of birth, misspelled patient name, wrong patient, incorrect drug name, missing/incorrect prescriber Drug Enforcement Administration number, wrong prescriber, prescription not reported to the PMP

Of the approximately 3,400 prescriptions that the PMP analyzed, 15% of the prescriptions (511 total) had data submission errors. Forty-five percent of those 511 errors fell within the minor classification, 40% qualified as major, and 15% of the errors were severe.

The most common minor error the PMP found was "missing or incorrect patient address." Incorrect dates ("incorrect date issued or date dispensed") were the most common major errors the PMP identified, and the most common severe errors the PMP identified were entry of the "wrong prescriber" or "prescription not reported to the PMP." Additionally, the Board found that chain pharmacies have a slightly higher error rate (15%) over independent pharmacies (14%). Dispensing practitioners' error submission rate was approximately 12%.

The PMP targeted only the severe data errors for correction. The PMP corrected those errors by notifying the appropriate dispenser with instructions to make the necessary corrections and retransmit the corrected prescription data back to the PMP. It followed up to ensure that each error was corrected.

Regardless of the number of CS prescriptions dispensed from any facility, the onus is on each dispenser to ensure that the prescription data submitted to the PMP is complete and accurate. Each pharmacy must account for each CS prescription. Each dispenser must ensure that it selects the correct prescriber when it enters the prescription data. Each dispenser must verify the patient's name, address, date of birth, and phone number and must enter the correct prescription issue date and the date it dispensed the prescription. If a facility does not dispense any CS prescriptions for any 24-hour period, it must still submit a "zero report" by the end of the next business day, indicating that no CS prescriptions were dispensed.

Roseman University, the Board, and the Nevada PMP thank you for your participation in this process and for assisting to improve the PMP's data integrity.

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