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Nevada State Board of Pharmacy News

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Board Members

Flash News!

Nevada State Board of Pharmacy staff has just received word that Governor Brian Sandoval has appointed Darla Zarley, PharmD, RPh, director of experiential education, associate professor of pharmacy practice at Roseman University of Health Sciences in Henderson, NV, to the Board. Governor Sandoval also reappointed Board Treasurer Kirk Wentworth to a third and final three-year term, as well as Board President Leo Basch to another three-year term. More information will follow.

Congratulations, Darla, Kirk, and Leo!

Senate Bill 459

By Yenh Long, Nevada PMP Program Administrator

The United States contains 4.6% of the world's population, yet it consumes 80% of the world's supply of opioids and 99% of the world's supply of hydrocodone.[1] According to the Centers for Disease Control and Prevention, the quantity of prescription pain medications sold nationally quadrupled from 1999 to 2010.[2] This steep increase in controlled substance (CS) use has been accompanied by an increase in overdose deaths. In 2013, Nevada had the fourth highest rate of drug overdose deaths in the US with 20.7 deaths per 100,000 people, an increase of 80% from 1999.[3] Faced with this epidemic of prescription drug abuse, Nevada policymakers have taken steps to decrease CS misuse, abuse, overdoses, and deaths.

The Nevada Prescription Monitoring Program (PMP) is one of the first tools to provide prescribers and dispensers with insight into their patients' prescription CS use history. Use of the PMP is now mandatory under Senate Bill (SB) 459, which was signed into law by Governor Sandoval in May 2015 with the goal of reducing CS misuse, abuse, overdoses, and deaths. Effective October 1, 2015, this bill addresses three primary topics: (1) the mandatory use of the Nevada PMP by prescribers, (2) the Good Samaritan Drug Overdose Act (GSDOA), and (3) next-day reporting to the PMP database.

Firstly, SB 459 requires prescribers to obtain and review a patient's CS history report (from the PMP) to assess whether a CS is medically necessary before prescribing it to a new patient, or to an existing patient if the prescription is for more than seven days and is part of a new course of treatment. This bill does not affect ongoing courses of treatments for established patients, nor does it apply to inpatient chart orders. Prescribers who fail to comply may be subject to professional discipline if their licensing board determines the violation is intentional. SB 459 also states that individual licensing boards may require all of their respective prescribers to complete at least one hour of training relating to the misuse and abuse of CS during each biennial CS licensing period.

The second area of emphasis is the GSDOA. This statute allows for licensed prescribers to prescribe and dispense an opioid antagonist to a patient's friend or family member, or to a person who could assist another person at risk for an opioid drug overdose, although this is not mandatory. Prescribers are immune from criminal and civil proceedings directly related to writing or declining to write the prescription. This law also allows persons with a standing order from a prescriber to possess and dispense opioid antagonists without a license from the Board as long as that person does not receive compensation for his or her services. Pharmacists may also dispense opioid antagonists without a prescription following standardized procedures, which are currently being written by the Board.

Lastly, this new law requires pharmacies and dispensing practitioners to report their dispensing to the PMP "not

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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later than the end of the next business day after dispensing a controlled substance." Next-day reporting to the PMP will provide users with more up-to-date patient information. It is crucial that the data submitted to the PMP are as accurate as possible, and the Board will establish administrative penalties for dispensers who fail to report this required information.[4]

These regulatory changes will hopefully help combat the epidemic of CS abuse, overdoses, and deaths. We can expect to see changes in the prescribing process of CS, as well as changes regarding our duties as pharmacists in educating and providing the public with opioid antagonists.

References

1. Manchikanti L, Singh A. Therapeutic opioids: A ten-year perspective on the complexities and complications of the escalating use, abuse, and nonmedical use of opioids. *Pain Physician.* 2008;11(2 Suppl):S63-S88.
2. Paulozzi LJ, Jones CM, Mack KA, Rudd, RA. Vital signs: Overdoses of prescription opioid pain relievers – United States, 1999-2008. *Morbidity and Mortality Weekly Report.* 2011;60(43):1487-92.
3. Trust for America's Health. Prescription drug abuse: Strategies to stop the epidemic. http://healthyamericans.org/reports/drugabuse2013/release.php?stateid=NV. Published October 2013. Accessed November 22, 2015.
4. SB 459 (as enrolled), Reg Sess 2015. https://www.leg.state.nv.us/App/NELIS/REL/78th2015/Bill/2161/Text.

DEA Number for Residents Working at a Hospital

It has come to the attention of Board staff that many residents working at various hospitals in Nevada are having a difficult time getting prescriptions issued by them honored at pharmacies. The Board encourages all pharmacists to review Title 21 Code of Federal Regulations §1301.22, which addresses this issue. Essentially, the resident may use the hospital Drug Enforcement Administration (DEA) registration number followed by an internal code established by the hospital for that individual, which is sometimes part of that resident's National Provider Identifier number.

2015 Pharmacist Renewal Update!

Nevada had another successful year with pharmacist renewals. Approximately 8,200 renewal forms were mailed, including both active and inactive licensed pharmacists. As of November 6, 2015, there were almost 7,500 pharmacists who renewed their license. Of those renewed, about 84% chose to renew online. Board staff wants to thank everyone for their patience during some tenuous moments, and appreciates all the consideration given. The Board office does not increase staff during renewals and still manages to remain fully operational, completing most expected duties. This is only possible through the use of its online renewal option, as paper renewals are more time-consuming due to having to manually ensure that each section is filled in properly.

Board staff is now gearing up for the audit of continuing education (CE). Letters will be mailed no later than February 2016. Only pharmacists who receive an audit letter will be required to provide **copies** of CE certificates. As of now, the Board is not tied into the National Association of Boards of Pharmacy® CPE Monitor® service; therefore, the onus lies with the pharmacist to provide copies upon request.

With that, October 2016 brings all other licenses due to renew, including pharmacy technicians, practitioners, wholesalers, and pharmacies, just to name a few.

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