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New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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In Memoriam

Ramon Rede: 1931 to 2016
Active Pharmacist License: 1957 to 2016
New Mexico Board of Pharmacy Member: 1976 to 1986

Ray was an asset to the profession of pharmacy. He was always highly regarded as a Board member and he continued to be a good friend to the Board after his term was over.
He will be greatly missed.

Disciplinary Actions

Joaquin Alaniz, RPh – License RP-7243. During the January 25-26, 2016 Board meeting, the Board accepted respondent's order accepting voluntary surrender of pharmacist registration. Must pay $100 fine.

Christina Coronado, PT – License PT-9571. Pharmacy technician license was revoked by default. Respondent did not respond to a notice of contemplated action issued as a result of obtaining controlled substances (CS) from the pharmacy where she worked without having a valid prescription. Respondent may not reapply for at least a 60-month period. Respondent must pay investigation costs of $400.

James Gonzales, RPh – License RP-7378. During the January 25-26, 2016 Board meeting, respondent entered into a stipulated agreement with the Board. Respondent's pharmacist license was voluntarily surrendered on September 12, 2014. Respondent's pharmacist license is on probation for a period of five years. Respondent shall successfully complete a five-year contract with the Monitored Treatment Program (MTP) and fully comply with the terms and conditions required by MTP. Respondent must notify employers of this agreement. Must pay investigative costs of $100. Must take and successfully complete the Multistate Pharmacy Jurisprudence Examination® (MPJE®).

Ronald Inkrott, RPh – License RP-7132. On November 19, 2015, respondent's pharmacist license was summarily suspended for failure to comply with the terms and conditions of the settlement agreement with the Board. During the January 25-26, 2016 Board meeting, respondent's pharmacist license was reinstated. Respondent must comply with terms and conditions of original Board settlement agreement.

Frances Wren Kennedy, CNP – License CS-217315. During the January 25-26, 2016 Board meeting, the Board accepted an order of voluntary surrender of CS registration. Must pay investigative costs of $600.

Rudy Nolasco RPh – License RP-4260. Respondent was the consultant pharmacist for a custodial care facility. Respondent had not been visiting the facility quarterly as required. Respondent was not destroying unwanted medications from the facility as required. Instead, a nurse from the facility was allowed to destroy unwanted medications. Respondent must take and pass the MPJE. Must pay fine of $2,500. Must pay $1,175 for the costs of investigation. Respondent is on probation for a period of three years.

Armin Quedzuweit, RPh – License RP-7774. During the January 25-26, 2016 Board meeting, respondent's pharmacist license was revoked. Respondent must comply with MTP. When MTP certifies that respondent is fit to practice, respondent may reapply with the Board, at which time, the Board will consider his application.

Continuing Pharmacy Education

Board regulations state that no less than 10% of registrants will be randomly selected each year by the Board for an audit of their certificates by the state drug inspectors. Failure to provide sufficient documentation of continuing pharmacy education (CPE) requirements may result in a $1,000 fine and the requirement to complete the deficient CPE.

Audit letters were mailed out recently. The results of the audit were poor. Therefore, with this *Newsletter* article, the Board is reminding pharmacists of their CPE requirements. In future months, expect audit letters to again be mailed. Also expect the Board to take action against pharmacists who have not completed sufficient CPE.

A minimum of 30 total hours are required each renewal period. A renewal period is from the first day of the pharmacist's birth month until the last day of the birth month two years later. During this 25-month period, all CPE must be completed. There are no carry-over hours.

Acceptable CPE hours are courses accredited by the Accreditation Council for Pharmacy Education (ACPE), the Accreditation Council for Continuing Medical Education, Board-approved courses, courses approved by other state boards of pharmacy, and pharmacy law programs offered by the Board. Pharmacists may request to obtain one CPE credit per year in the area of pharmacy law by attending one full day of a regularly scheduled Board meeting or serving on a Board-approved committee.

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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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Of the 30 CPE hours required each renewal period, the following is required:

(a) Ten CPE hours of live programs;
(b) Two CPE hours in the area of patient safety as applicable to the practice of pharmacy;
(c) Two CPE hours in the area of safe and appropriate use of opioids; and
(d) Two hours of pharmacy law. If you are residing or practicing in New Mexico, you must complete a law CPE course as offered by the Board. If you do not reside or practice in New Mexico, the law requirement must be ACPE-accredited.

An educational program consisting of a minimum of two CPE hours that addresses both patient safety as applicable to the practice of pharmacy and the safe and appropriate use of opioids will satisfy both requirements described in (a) and (b) above.

Pharmacists, after approval, may complete continuing professional development (CPD) hours. CPD hours may replace some or all of the required CPE hours. CPD hours will focus on a particular activity within the registrant's chosen field of pharmacy. For information on this pilot program, please visit the Board web page and click the link titled "Volunteers Sought For Continuous Professional Development Project."

Pharmacist clinicians must complete an additional 20 contact hours of live CPE each renewal period.

Pharmacists who elect to perform pharmacist prescriptive authority must complete an extra two hours of CPE each renewal period in each of the following areas in which he or she wishes to participate: vaccines, emergency contraception drug therapy, tobacco cessation drug therapy, and/or naloxone for opioid overdose. The CPE for both vaccines and naloxone for opioid overdose must be live. Failure to complete the CPE required for any of these areas, even for just one renewal period, will result in a pharmacist needing to repeat the initial required training in order to regain pharmacist prescriptive authority in the specific area for which CPE was not completed.

ACPE News

Board Northwest District Representative/Board Secretary LuGina Mendez-Harper, RPh, was appointed to the ACPE Board of Directors for a six-year term. ACPE accredits schools and colleges of pharmacy and providers of CPE. ACPE was founded and is overseen by a Board of Directors derived from the associations that started ACPE. The associations are the American Association of Colleges of Pharmacy, American Pharmacists Association, National Association of Boards of Pharmacy® (NABP®), and American Council on Education.

In similar news, Board Public Member Cathleen Wingert was invited as a designated observer for an evaluation team of ACPE. This ACPE team evaluated the doctor of pharmacy program at the University of New Mexico (UNM) College of Pharmacy on November 3-5, 2015.

And finally, congratulations to the UNM College of Pharmacy. The ACPE Board of Directors has extended its accreditation term for its doctor of pharmacy program until June 30, 2024. This represents the customary eight-year cycle between self-studies.

2016 Board Meeting Schedule

Please note on your calendars that the June 2016 Board meeting has been rescheduled. The new dates are Monday and Tuesday, June 27-28, 2016.

The current Board meeting dates for 2016 are:

- April 21-22, 2016
- June 27-28, 2016
- August 25-26, 2016 – Ruidoso, NM, meeting
- October 20-21, 2016

Prescription Monitoring Program

A public hearing of proposed changes to Regulation 16.19.29.8 NMAC, Mandatory Reporting of Prescription Information to the PMP, took place during the January 2016 Board meeting. This rule was amended to include a product identifier in the data set reported. Also, the rule was revised to make prescription monitoring program (PMP) regulation language uniform with national PMP and American Society for Automation in Pharmacy (ASAP) reporting. All information that should be submitted for each prescription, as well as the standards for how this information shall be formatted, is defined in the PMP Data Reporting Manual. This manual is available on the PMP website at *http://nmpmp.org* under PMP Resources.

Get ready for the ASAP 4.2 format! March should see the beginning of the implementation of the Board's Harold Rogers 2014 Grant enhancements for the PMP. The enhancements include the following.

Expansion of Proactive Alerts

Unsolicited reports will include pharmacy managers as well as prescribers. A new unsolicited alert will be provided when the results of a PMP request meet the same threshold used for unsolicited reporting. Currently, the threshold is any patients receiving any scheduled prescriptions from more than five prescribers and filled at more than five pharmacies within a six-month period.

Enhanced Dispenser Reporting

The Board will be changing to the ASAP 4.2 format for dispensers reporting data, which will support the Drug Enforcement Administration (DEA) suffix so that practitioners who prescribe under a master DEA number can be separated. In addition, this will allow for enhanced delinquent pharmacy reporting compliance monitoring. Make sure you are reporting daily as required by regulation; although you may receive a reminder of your failure and/or delinquency in reporting, these are merely a courtesy. Dispensers are required to know of and be compliant with reporting to the PMP or be subject to action by the Board.

Integration of NAR$_X$CHECK as an Optional PMP Report Format

NAR$_X$CHECK, owned by Appriss, Inc, provides a propriety "NAR$_X$CHECK score" as well as graphical representations of prescription history. Users will be able to quickly digest the sometimes dense PMP information of their patients. The PMP will implement the inclusion of the NAR$_X$CHECK report as an optional request report format within the PMP itself. New Mexico PMP web portal users will be able to set the NAR$_X$CHECK format as their default format for PMP request reports.

Help the PMP With a New Name

The Board is looking to increase its visibility and recognition. As catchy as "New Mexico PMP" may be, the Board is looking to improve upon it. You may have noticed other states have a more stylish name. For example: California – CURES 2.0 (Controlled Substance Utilization Review and Evaluation System); Kentucky – KASPER (Kentucky All Schedule Prescription Electronic Reporting); South Carolina – SCRIPTS

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(South Carolina Reporting & Identification Prescription Tracking System); and Wyoming – WORx (Wyoming Online Prescription Database). Please send in your recommendation for a new name for New Mexico's PMP.

PMP Website

The Board is currently working on updating the website. Please contact the Board at nm.pmp@state.nm.us for anything you cannot find or have questions about.

New Employee – PMP Director

The Board is pleased to introduce its new PMP director, Shelley Bagwell. Shelley was born in New Mexico, and graduated from the UNM College of Pharmacy in 1997. Since that time, she has worked in various aspects of pharmacy. Under Shelley's guidance, the Board is hoping to grow and improve the PMP. If you meet Shelley, please welcome her. She can be reached at shelley.bagwell@state.nm.us or at 505/222-9818.

Significant Adverse Drug Events

1. A 33-year-old female was prescribed medroxyprogesterone 2.5 mg but received trazodone 100 mg. The patient took one dose and experienced dizziness, light-headedness, and tiredness. The wrong medication was bagged for the patient. The pharmacist may have been bagging prescriptions for more than one patient at a time. Pharmacist recommends verifying medications for one patient at a time and then bagging the medication immediately.
2. A 41-year-old male received another patient's prescriptions for divalproex ER 500 mg and quetiapine 300 mg. The patient reported dizziness, upset stomach, incoherence, and being "out of it." The prescription was scanned in under the wrong patient. Pharmacist recommends verifying that the patient name and date of birth match correctly on the computer before scanning prescriptions, as well as while typing and verifying the medications.
3. A 36-year-old female was prescribed cefuroxime 250 mg but received levothyroxine 137 mcg. The patient experienced insomnia and muscle aches. The pharmacy technician looked for the patient's medication on the numbered shelf, but grabbed the adjacent bag containing a medication for another patient. The scan tag on the prescription would not scan for sale. The pharmacy technician assumed that it was due to the prescription having been rebilled, so then the pharmacy technician reprinted a new scan tag. Pharmacist states that standard company policies and procedures were bypassed. No recommendations for improvement were provided.
4. A 35-year-old female was prescribed butalbital/acetaminophen/caffeine 50/325/40 mg but was dispensed butalbital/aspirin/caffeine 50/325/40 mg. The patient reported no symptoms and no allergy to aspirin. Pharmacist reports that the error likely occurred during busy hours and because of the similarity of the two medications. No recommendations for improvement were provided.
5. A 65-year-old male was prescribed metoprolol succinate ER 50 mg but was dispensed metoprolol succinate ER 25 mg. The patient experienced migraines and dizziness. The incorrect medication strength was filled. The pharmacist reports that the error may have resulted from the handling of multiple prescriptions at a time, the barcode scanning system being overridden, improper training, the similarity in medication name and appearance, and/or the similarity in medication location. No recommendations for improvement were provided.
6. A 54-year-old female was prescribed anastrozole 10 mg, but the refill was partially filled with amitriptyline 10 mg. Patient experienced mild drowsiness. The refill was completed with two stock bottles of anastrozole and one stock bottle of amitriptyline. The pharmacist reports that the bottles of the two medications are by the same manufacturer and are the same size and color. Pharmacist recommends scanning the barcode of each stock bottle prior to filling and labeling, and exercising caution when putting up medication stock.
7. A 17-year-old female was prescribed Polytrim® 10,000 units/mL 0.1% and was dispensed polymyxin B sulfate/trimethoprim 10,000 units/mL 0.1%. The patient's mother reports that the patient experienced nausea, vomiting, and an increase in eye pressure. The patient was taken to the emergency room, and she felt better after flushing her eye. The patient's ophthalmologist reports having multiple conversations with the patient's mother regarding the patient's allergies and the differences between sulfa, sulfates, and sulfites. The patient's mother states that the patient's allergy is to sulfa antibiotics and not sulfates. The ophthalmologist also states that the increase in ocular pressure is due to a surgery and not to an allergic reaction to the medication. The pharmacist states that the patient allergy information was not updated at drop-off and therefore resulted in the pharmacist not catching the allergy at drug utilization review. The pharmacist also stated there was inadequate medication counseling. No recommendations for improvement were provided.
8. A 50-year-old male was prescribed zolpidem 10 mg but received a different medication. The patient took one dose and felt ill and tired. The patient had multiple medications and received the wrong medication from another patient with the exact same name. Pharmacist recommends verifying patient name and address before selling the medication.
9. A 67-year-old female received an incorrect medication for Eliquis® 5 mg. The patient stated that she felt tired all day. The wrong prescription was sold to the patient because it was for another patient with the same name. Pharmacist recommends verifying the address on every prescription, regardless of name.
10. A 65-year-old female was prescribed warfarin 5 mg and received a warfarin 5 mg prescription that was for a different patient with a similar name. The patient experienced palpitations and dizziness after 26 doses with one dose per day. The patient thought the symptoms were from her citalopram. Pharmacist recommends verifying at least two patient identifiers to match the patient.

Disclaimer: The suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. The New Mexico Board of Pharmacy may not necessarily agree with these suggestions.

The *New Mexico Board of Pharmacy News* is published by the New Mexico Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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