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New Mexico Board of Pharmacy News

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Regulation Changes

During the April 18-19, 2013 New Mexico Board of Pharmacy meeting, three regulation changes were made. These regulation changes are discussed as follows.

16.19.4.17 NMAC – Pharmacist Clinician. This regulation was revised to prohibit pharmacist clinicians from prescribing for themselves or immediate family members, except under emergency situations. The regulation revision also prohibits a pharmacist clinician from referring patients for the use of medical cannabis.

16.19.22 NMAC – Support Personnel and Pharmacy Technicians. This regulation was revised to allow support personnel (who are not pharmacy technicians) to place prescription drugs on the pharmacy shelf, in bins, or in a dispensing technology system in sites that utilize a barcode verification, electronic verification, or similar verification process to ensure correct selection of medication. In addition, the ratio of technicians to pharmacists was eliminated. According to the revised regulation, the permissible ratio of pharmacy technicians to pharmacists on duty is to be determined by the pharmacist-in-charge. And also, previously, a registered pharmacy technician must become certified within one year. The regulation revision made an exemption to this requirement for a pharmacy technician that is enrolled in a Board-recognized technician training program.

16.19.30.9 NMAC – Compounding of Nonsterile Pharmaceuticals; Operational Standards. This regulation revision states that a pharmacy may no longer compound for a prescriber's office use. The wording allowing for office use compounding was removed from the regulation. A compounded medication may be sold by a pharmacy by prescription only. The labeled compounded product is sold after receipt of a valid prescription is issued to a specific patient.

All Board regulation changes are heard in open session during Board meetings. Links to the proposed changes are available online. Go to the Board Web site and click on the agenda for the Board meeting. There you will find a link to a proposed regulation change. Public and professional comments are welcome. Please submit comments to the Board through written correspondence at least 15 days prior to the Board meeting, or you may appear in person to express your opinion.

Reminders

Did you do your annual controlled substance inventory? For most pharmacies, the inventory date is May 1, plus or minus four days.

Only a pharmacist or a pharmacist intern may counsel a patient. Counseling is required on all new prescriptions. Only a pharmacist, a pharmacist intern, or a pharmacy technician may query a patient if they would like counseling on a refill of a prescription. Non-registered support personnel may not query the patient as to whether or not they wish to be counseled by the pharmacist or pharmacist intern. With the new regulation revision regarding the ratio of pharmacy technicians to pharmacists, this should not be an issue.

Welcome and Congratulations

Carl Flansbaum, RPh, has accepted the newly created position of Prescription Monitoring Program (PMP) director. Carl is a New Mexico registered pharmacist. Graduating from the University of Pittsburgh in 1989, Carl has spent his pharmacy career working in hospitals and home health. After graduating, Carl worked about five years in California. Then, Carl spent 15 years working in Washington. Carl has computer knowledge, having worked for technology companies. Carl has also assisted in developing Web applications. Carl says that developing Web applications is his passion and interest. Carl has lived in New Mexico since October 2012.

Maria Gonzales, CPhT, has been promoted to fill the newly created position of PMP manager. Maria has been employed by the Board since November 2005 as administrative assistant. In her position as administrative assistant, Maria assisted many in registering for the PMP.

The Board welcomes Carl and congratulates Maria.

The application process for filling the position of administrative assistant with the Board has been completed.

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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Interviews for this position have taken place. As of the date of submission to this *Newsletter,* the Board has not filled this position. Look for an article in the next *Newsletter* for information on who was selected.

As previously announced, Larry Loring was promoted to the position of chief drug inspector/executive director of the Board. His former position, state drug inspector, currently has not been filled. If you are interested, please apply online at the New Mexico State Personnel Office Web page. Search for the job position titled, "State Drug Inspector (RLD #3952)." Information regarding this position is found at the same Web link.

New Board Members

Governor Susana Martinez recently appointed two new Board members. Please welcome and congratulate your new Board members.

Anise Yarbrough was appointed to serve as public member. Anise's grandfather and father owned a small chain of drug stores in the St Louis, MO, area and in Aspen, CO, where she was raised. In 1990, Anise received a bachelor of university studies degree from University of New Mexico (UNM), with a concentration in family studies and sociology. After graduating, Anise was a stay-at-home mother, raising three boys in the Albuquerque, NM, area. For the last four years, Anise was a history and religion middle school teacher at Frassati Academy. In 2012, Anise received an associate of applied science in culinary arts from Central New Mexico Community College. Anise plans on beginning a cooking ministry.

Chris Woodul, RPh, was appointed to serve the Southwest District. Chris graduated from UNM College of Pharmacy in 1992. Chris started his pharmacy career by working for Walgreens beginning in 1989. Chris worked for Walgreens for 23 years. Chris then opened his own store on October 1, 2012. The pharmacy is Sierra Blanca Pharmacy located in Ruidoso, NM.

The New Mexico Board of Pharmacy is now a full Board. The following is a list of the current Board members:

- Richard Mazzoni, RPh, Northeast District, Board Chairperson
- Amy Buesing, RPh, Hospital Representative, Board Vice Chairperson
- LuGina Mendez-Harper, RPh, Northwest District, Secretary
- Joe R. Anderson, RPh, Central District
- Allen Carrier, Public Member
- Danny Cross, RPh, Southeast District
- Buffie Saavedra, Public Member
- Chris Woodul, RPh, Southwest District
- Anise Yarbrough, Public Member

Contact the Board office if you would like information on how to reach your Board member.

From the DEA: CVS pays $11 Million to Settle Prescription Drug Case

By Randall Bencomo – Albuquerque District Office

National pharmacy chain CVS is settling a case with the United States government over charges the store manufactured and filed false records for prescriptions it filled. CVS has agreed to pay $11 million to settle civil penalty claims for violating the Controlled Substances Act and related regulations.

In a statement, Daniel Salter, acting special agent in charge of Drug Enforcement Administration's (DEA) Dallas Field Division, said, "This settlement reinforces the responsibilities of all pharmacies to prevent the diversion of dangerous drugs." He added, "This case highlights DEA's steadfast resolve to combat the growing prescription drug abuse problem in this country by ensuring that all DEA registrants, including nationwide pharmacy chains, are in compliance with the law." Each CVS pharmacy is registered with a unique number by the DEA to dispense prescription drugs. According to the suit, from October 2005 to October 2011, CVS stores created and filed false numbers, filled invalid prescriptions, and switched out doctor information on store records.

The pharmacy maintains the alleged violations were purely administrative. "Neither the DEA nor the U.S. Attorney claimed that any patient's health or safety was put at risk or that any false or fraudulent prescriptions for controlled substances were filled," CVS spokeswoman Carolyn Castel said in a statement. Castel added, "CVS has developed and implemented a new state-of-the-art retail electronic prescription management and recordkeeping system at a cost of several hundred million dollars that is designed to comply with DEA and other regulatory requirements." As a part of the settlement, CVS did not admit liability.

50-Year Pharmacists

Something the Board likes to do on occasion is to publish a list of pharmacists that have been licensed in New Mexico for at least 50 years. The following meet this criterion.

Joseph Abeyta	Robert McClelland
Joe Andrews	Joseph Mengoni
Jack Churchill	Lonnie Nunley
Durward Colbert	Edward Osborne
Ronald Dawes	Philip Parkhurst
George Downs	Dennis Pena
Lawrence Eherton	Tony Pesavento
Kenneth Fourcher	Walter Peyton
Edwin Gailbreath	Ramon Rede
John (Chris) Gallegos	James Reed
Robert Ghattas	Robert Shmaeff
Richard Gomez	Raymond Sierks
John Huffmyer	Larry Sparks
Dillard Irby	Elton Veralrud
Lowell Irby	Johnny Volpato

Significant Adverse Drug Events

1. A prescription for amoxicillin-pot clavulanate 600-42.9 mg/5 ml suspension may have been mixed incorrectly. The father of the seven-month-old infant stated that the antibiotic was written for a 10-day supply, but ran out after six days. The infant experienced diarrhea. Pharmacist recommends double checking directions before reconstituting medications.
2. A prescription for **hydralazine** 50 mg one tablet three times a day (TID) was entered into the system as **hydroxyzine** 50 mg one tablet TID. Patient received all doses over seven days in nursing home. As a result, the patient had uncontrolled high blood pressure. Pharmacist recommends being extra cautious when verifying look-alike and sound-alike medications.
3. A prescription for promethazine 25 mg tablets was incorrectly filled and dispensed with prednisone 5 mg tablets. The patient reported headache, increased agitation, difficulty sleeping, feeling "out of it," and buzzing in head. The error was attributed to the correct bottle being scanned while the other bottle was used to fill. The pharmacist recommends that technicians do not override National Drug Code (NDC) scans manually; make sure all original bottles are kept with the prescription in its tote basket; and open vials in order to verify contents versus stock bottle as well as computer image. Only a pharmacist is allowed to manually override an NDC that does not scan.
4. A prescription for Vyvanse® 20 mg one capsule every morning was entered incorrectly with directions to take one capsule every evening. The patient reported no symptoms since the mother noticed the error in the directions. Pharmacist recommends focusing on the task at hand and trying not to multitask.
5. A prescription for hydroxyzine 25 mg one tablet every eight hours as needed for itching was incorrectly entered and dispensed with hydrochlorothiazide 25 mg one tablet every eight hours. The patient took a total of 30 doses and was admitted to the hospital for dehydration and depleted potassium. Pharmacist recommends slowing down and handling only one prescription at a time. Also, be more wary of look-alike, sound-alike medications and pay closer attention to sig versus drug.
6. A vial correctly labeled for a patient's prescription of lorazepam 2 mg tablets contained both lorazepam 2 mg as well as promethazine tablets per patient report. The patient reported suffering from bleeding ulcer, rectal bleeding, and severe heart pain. Pain was relieved by taking lorazepam and aspirin. Patient stated she did not seek or receive any medical treatments. Pharmacist recommends increased training and attention to policy. Human error contributed to this incident. Pharmacist has evaluated all potential reasons why this could have happened and addressed with all technicians and pharmacist on staff.
7. A vial correctly labeled for a patient's prescription of zafirlukast 20 mg tablets was incorrectly filled with ziprasidone 20 mg capsules. The patient reported feeling lightheaded, dry mouth, insomnia, "wired," no focus, shakiness, sore throat, and suffered two asthma attacks. The pharmacist recommends that the product dispenser must not override any prescriptions in the work flow. All prescriptions must be scanned, and when not scanned, a visual verification of the NDC must be made by the pharmacist.
8. A prescription for Daypro® (oxaprozin) 600 mg tablets was incorrectly filled with oxcarbazepine 600 mg tablets. Patient reported upset stomach, feeling very tired, numbness in tongue, dizziness (no falls experienced), and complained that it took a lot of concentration to drive. No recommendations for improvement were given.
9. A prescription for Abilify® 20 mg ½ tablet twice a day (BID) was incorrectly entered and filled with Abilify 2 mg ½ tablet BID. Patient's mother reported "bad" behavior/mood. Pharmacist recommends to double check dosage and strength. Also, person reviewing the prescription should not be the same person who entered the prescription.
10. A prescription for hydroxyzine HCl 25 mg one tablet at bedtime as needed for itching was incorrectly entered and filled with hydrochlorothiazide 25 mg one tablet daily as needed for itching. The patient only reported increased urination during the night time. Patient was seen by a doctor and reported nothing was wrong. Pharmacist recommends slowing down and do not rely on the label as being perfect. Do not let guard down and check everything every time.

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, Inc, 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 the Foundation or the Board unless expressly so stated.

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