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New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

5200 Oakland Ave NE, Suite A • Albuquerque, NM 87113 • Tel: 505/222-9830 • Fax: 505/222-9845
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Volunteer CE Reminder!

In 2010 the New Mexico Board of Pharmacy authorized continuing education (CE) for pharmacists volunteering for the New Mexico Department of Health – Health Emergency Management (DOH HEM) for seasonal and H1N1 vaccination clinics and Point of Dispensing Sites operated by the New Mexico DOH HEM. You receive one hour of credit per three hours you volunteer with a maximum of two continuing education units per licensing cycle. New Mexico DOH HEM is required to send the New Mexico Board of Pharmacy a list of volunteers and their number of hours volunteered. The Board will issue a CE certificate.

Regulation Changes

April 12-13, 2012 Board Meeting

The Board modified Regulation 16.19.23 NMAC – Parental Responsibility Act Compliance. The changes will allow the Board to take action against all licensees who do not keep current with court ordered child support payments. Previous to the change, the Board could only take action against pharmacists, interns, and pharmacy technicians who become delinquent in their child support payments.

Law Update Schedule

The Board will hold the following updates at the Board office. All updates are on Fridays from 2 PM to 4 PM. Current dates for the Board-sponsored non-Accreditation Council for Pharmacy Education (ACPE) updates in Albuquerque, NM, are:

- July 27, 2012
- August 24, 2012
- September 14, 2012
- October 12, 2012
- November 2, 2012
- December 14, 2012

At least five updates are held each year in areas outside of Albuquerque. These updates are from 7 PM to 9 PM. The current schedule is:

- Wednesday, June 27, 2012 – Silver City, NM
- Tuesday, July 10, 2012 – Farmington, NM
- Tuesday, August 7, 2012 – Raton, NM
- Tuesday, September 18, 2012 – Clovis, NM
- Tuesday, October 23, 2012 – Carlsbad, NM
- Tuesday, November 6, 2012 – Alamogordo, NM

An ACPE-approved law update is done at each New Mexico Pharmacists Association (NMPhA) meeting and at the October New Mexico Society of Health-System Pharmacists (NMSHP) meeting. Please contact NMPhA or NMSHP to attend.

Please contact the Board office to reserve a spot for one of the non-ACPE law updates. By doing so, you make sure a seat will be available for you. Also, especially for the updates outside of Albuquerque, the Board will be able to pre-print your certificate.

Do You Know?

If anybody has something they feel all pharmacists should know, but many do not, please contact the Board so that it can be included in the *Newsletter*. Following is this quarter's "Do You Know?"

Do you know that New Mexico is currently number one in the country regarding overdose death? This includes both intentional overdose and accidental overdose. The latest figures show that New Mexico is about 28 deaths per 100,000. The national average is about 14 per 100,000. As a result the Board and others in New Mexico are focusing on ways to reduce this number. The Board has formed a Substance Abuse/Harm Reduction Committee that has already submitted suggested rule changes that it believes will help prevent harm/death as a result of controlled substance abuse.

There are also a large number of forged prescriptions presented and filled within New Mexico. The majority of these prescriptions are for oxycodone 30 mg.

Pharmacists have a corresponding responsibility, along with the prescriber, for prescriptions. This includes verifying that the prescription is for a legitimate medical purpose written within the prescriber's usual course of practice.

When a pharmacist is notified that a prescription they filled is a forgery, it is easy to say "Well, I guess that one got by me." But did you do all you were required to do prior to filling that prescription? Did you obtain the patient's complete medication

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

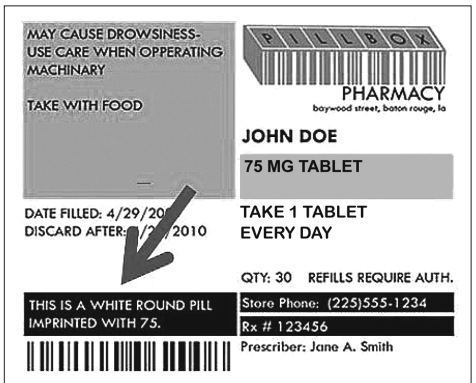
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies 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.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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history? Whenever you fill a prescription, you should know all medications a patient is on. This includes herbs and over-the-counter medications. Generally, a patient is not started on oxycodone 30 mg. Do you know why the patient is taking the prescribed medication? Oxycodone is used for pain, but does this patient have cancer? Did the patient recently have surgery? Does the patient also have high blood pressure or diabetes? These are all things you should know and document.

If a single pharmacy is filling a large number of forgeries, criminal charges may be filed. The Drug Enforcement Administration (DEA) has charged other pharmacies around the country, but none in New Mexico yet. Charges could be filed against the pharmacy owners, the pharmacist-in-charge, or the filling pharmacist.

There are some clues that forgers might exhibit. One such clue is they are willing to pay cash. If you fill a forged prescription, it is not unusual to be presented with multiple other similar prescriptions. If you filled a prescription and realize that the customer paid cash or anything else is unusual, you can verify the prescription after the fact. If you just say "Well that one got by me," please do not let the next five similar prescriptions "get by you."

Prescription Monitoring Program Changes

Many of you have noticed the different look of the Prescription Monitoring Program (PMP) site. The new address is *https://pmp-web.rld.state.nm.us/Login.aspx*.

The Board improved the site, effective May 1, 2012. The new site is now compatible with all Internet browsers. Patient requests are now processed automatically 24/7 with reports generated within seconds of the request. Dispensers can upload prescription data through the Web account or by secure file transfer protocol. It is now possible to correct file upload errors on the site.

Remember the changes to the PMP adopted by the Board in April of 2011. These are listed in Rule 19.19.29 on the Board Web site. Briefly, these changes include:

1. All pharmacies, clinics, and dispensing practitioners including veterinarians must submit data to the PMP on all Schedule II through V controlled substances dispensed, including samples of controlled substances.
2. Data must be submitted electronically to the PMP Web site at least once every seven days.
3. The new reporting format will be ASAP Version 4.1. The new PMP manual listing the technical specifications can be found at *www.rld.state.nm.us/boards/Pharmacy_Prescription_Monitoring_Program.aspx*.
4. Dispensers (pharmacies, clinics, practitioners) will be identified by their DEA numbers.

Information about the PMP can be found on the Board Web site in the "Prescription Monitoring Program" tab. Contact information for the PMP administrator is listed on the login screen of the PMP.

Significant Adverse Drug Events

1. An 86-year-old male was prescribed Tylenol® with Codeine #3 but received metformin 500 mg that had been prepared for a different patient. Patient took six doses of metformin. Patient reported no relief of pain but no other injuries. Pharmacist recommends taking the time to check all aspects of medications, even if busy. Do not rush.
2. A resident at a custodial care facility was given hydrocodone/APAP 10/325 mg instead of the prescribed hydrocodone/APAP 7.5/325 mg. Resident did not sleep well and seemed to be in pain. To prevent future incidences, facility will color code narcotics.
3. A resident at a custodial care facility was given the wrong resident's medication. Resident incorrectly received melatonin, Tylenol, and glipizide. Resident's blood glucose was monitored and corrected with snacks. Caregiver was re-educated and instructed not to pre-pour medications.
4. An 85-year-old resident of a nursing home was prescribed imipenem 500 mg but received meropenem 500 mg. Four doses were administered before it was noticed. Resident showed no harmful effects. Pharmacist recommends a second pharmacist verify orders prior to dispensing.
5. A 70-year-old was prescribed fluoxetine 10 mg capsules but received fluoxetine 10 mg tablets. As a result, patient had diarrhea for 24 hours. Pharmacist recommends that staff scan the pharmacy label against the bar code on the stock bottle. Checking pharmacist should verify the National Drug Code (NDC) on the label against the NDC on the bottle. And during counseling, show the patient the medication; the visual check can aid in error prevention.
6. Resident at a custodial care facility was given hydrocodone/APAP 10/325 mg instead of the prescribed hydrocodone/APAP 5/325 mg. The resident suffered no harm.
7. A 29-year-old patient was receiving emergency aid following an accident. The emergency medical services (EMS) personnel inadvertently administered naloxone instead of the prescribed morphine. The patient was in severe pain and received little improvement with the medication administration. The pharmacist recommends that two people double-check on high risk medications such as narcotics and benzodiazepines.
8. A 29-year-old patient was prescribed paroxetine 20 mg but received fluoxetine 20 mg. The patient suffered headache and nausea as a result. This was with a transferred prescription. The pharmacist recommends to read/repeat back information on transfers.
9. A 30-year-old patient was prescribed Klonopin® 1 mg but received clonidine 0.1 mg. As a result, the patient suffered from excessive sleep and slurred speech. Pharmacist recommends that pharmacy technicians double-check work. Then the pharmacist should reevaluate and double-check. This is especially true when dealing with custodial care facility patients who are not available when the medication is dispensed.

This quarter there were several incidences reported regarding residents of a long-term care facility. And there is one report regarding an EMS facility. This is a good opportunity to remind licensees that all facilities must report significant adverse drug events. Generally, reports are submitted by retail pharmacies. Hospital pharmacies, clinics, and anywhere medications are dispensed or administered to patients should report errors.

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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.

Disciplinary Actions

Paul De Santis, IN – License number IN-2825. Respondent's registration as a pharmacy intern revoked by default. Must pay $400 cost of investigation.

Matthew Granillo, PT – License number PT-7015. Respondent's registration as a pharmacy technician revoked by default. Must pay $100 cost of investigation.

Dorothy Loud, PT – License number PT-3582. Respondent voluntarily surrendered her pharmacy technician registration. Must pay costs in the amount of $100.

Jason McCoy, PT Applicant. Default order denying pharmacy technician application. Must pay $200 cost of investigation.

Stephanie Montenegro, PT – License number PT-6974. Respondent's registration as a pharmacy technician revoked by default. Must pay $400 cost of investigation.

Yvonne Mouchette, CS Applicant. Board order granting limited controlled substance registration.

Larry Rustemeyer, PA – License number CS-17746. Respondent voluntarily surrendered his controlled substance registration. Must pay investigative cost of $100.

Sara Wright, PT – License number PT-4072. Respondent voluntarily surrendered her pharmacy technician registration. Must pay Board costs of $100.

From DEA

By Randall L. Bencomo, Diversion Investigator

Did you know an individual practitioner may not legally possess any controlled substance that has been dispensed to an ultimate user (eg, patient) pursuant to a prescription?

The Controlled Substances Act (CSA) and its implementing regulations established a closed system of distribution so that controlled substances are at all times under the legal authority of an entity registered, or specifically exempted from registration. DEA achieves this goal by registering those individuals or businesses that handle controlled substances. Based upon the category of registration, DEA places limitation on the manner in which these registrants handle, document, and secure controlled substances. DEA regulations govern any movement of controlled substances between registered entities, thus the closed system facilitates an accurate accounting of all controlled substances from manufacturing through dispensing to the ultimate users.

A "prescription" is "an order for medication which is dispensed to or for an ultimate user . . . " (21 C.F.R. §1300.01(b)(35)). "The term 'dispense' means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled substance . . . " (21 U.S.C. §802(10)). An "ultimate user" is a "person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household" (21 U.S.C. §802(27)). The CSA exempts ultimate users from the requirement to register pursuant to 21 U.S.C. §822(c)(3).

Once a DEA registrant dispenses a controlled substance to an ultimate user, it is now outside the DEA's closed system of distribution. The CSA does not provide a mechanism for controlled substances to re-enter this closed system of distribution. Because the CSA's definitions for the terms deliver and distribute encompass all methods of delivery and distribution of controlled substances, and because the CSA allows ultimate users to obtain and possess controlled substances solely for the purpose of use, an ultimate user may not, by statute, legally deliver or distribute these controlled substances. As a result, the CSA and its implementing regulations do not authorize practitioners to take possession of controlled substances that have been dispensed to an ultimate user. Thus controlled substances dispensed to an ultimate user cannot be given to a practitioner to be held by that practitioner in a custodial capacity for eventual dispensing to the ultimate user.

Under certain circumstances a DEA-registered pharmacy may provide controlled substances to a DEA-registered individual practitioner for general use in his or her practice if not prohibited by state law or regulation. However, the practitioner may not issue a prescription to obtain controlled substances for supplying the individual practitioner for general dispensing to patients (21 C.F.R. §1306.04(b)). Although a pharmacy may supply a small amount of controlled substances to a practitioner, there are limits to the amount a pharmacy can supply in this fashion in a calendar year, as outlined in 21 C.F.R. §1307.11(a). Alternatively, a DEA-registered practitioner can order controlled substances for general dispensing or administration to his or her patients by ordering the controlled substances from a DEA-registered manufacturer or distributor. A DEA practitioner that dispenses controlled substances must generate and maintain all required records, reports, and inventories outlined in 21 C.F.R. §1304 and §1305.

For additional information regarding DEA's Office of Diversion Control, please visit *www.DEAdiversion.usdoj.gov*. You will also find on this Web site copies of the regulations and statutes listed above along with an electronic copy of DEA's *Practitioner's Manual*. If you have any further questions regarding this matter please contact the Liaison and Policy Section at 202/307-4654.

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.

Bill Harvey, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

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