September 2013

News

New Mexico Board of Pharmacy

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
In-State Only Toll Free: 1-800/565-9102 • *www.rld.state.nm.us/boards/Pharmacy.aspx*

Generic Substitutes for Vicodin, Vicodin ES, or Vicodin HP

All Vicodin® brand products now contain acetaminophen 300 mg per tablet with varying amounts of hydrocodone. Any generic substitution made by a pharmacist for Vicodin brand products must contain the same 300 mg of acetaminophen per tablet. The pharmacist must contact the practitioner for permission to substitute a hydrocodone product containing acetaminophen in any strength other than 300 mg.

Disciplinary Actions

Anastacia Barka, PT – License PT-1727. Respondent voluntarily surrendered her registration as a pharmacy technician (PT). Must pay investigative costs in the amount of $500.

James Gaynor, RPh – License RP-4407. Respondent entered into a stipulated agreement with the New Mexico Board of Pharmacy. Respondent pled no contest to Board allegations that he filled a personal prescription for alprazolam. Must pay investigative and fine costs in the amount of $750.

Daniel Hall, RPh – License RP-6813. Respondent voluntarily surrendered his registration as a pharmacist. Must pay investigative and fine costs in the amount of $1,362.

Madana Harvey, DDS – License CS-216894. Respondent voluntarily surrendered her controlled substance (CS) registration. Must pay investigative costs of $100.

Kelly Kemper, RPh – License RP-5290. The Board found by a preponderance of the evidence that respondent Kelly Kemper unlawfully obtained a CS. Pharmacist license was revoked for a period of three years. May reapply after three years. Within 90 days, must pay investigation and Board costs of $1,121.17.

Lillian Lovato, RPh – License RP-6262. New Mexico Monitored Treatment Program (MTP) reported to the Board that respondent had violated terms of her contract. The Board suspended respondent from the practice of pharmacy until her successful completion of MTP contract.

Robert J. McClellan III, RPh – License RP-4533. Respondent entered into a stipulated agreement with the Board. Respondent pled no contest to Board allegations that he refilled prescriptions without first obtaining prior authorization from the prescribing practitioner. Respondent placed on probation for a one-year period. Must take and pass Multistate Pharmacy Jurisprudence Examination® (MPJE®). Must pay investigative and fine costs in the amount of $3,000.

Cynthia McRae, RPh – License RP-6367. Respondent entered into a stipulated agreement with the Board. Prescription for levothyroxine was incorrectly filled with zolpidem and dispensed to customer. Must pay fine and costs of investigation. Must complete continuing education (CE) on error reduction. On probation for one year.

Srikanth Ponnada, RPh – License RP-7444. Respondent pled no contest to allegation of failing to disclose pending disciplinary action with other state on initial New Mexico pharmacist application. Respondent placed on probation for one year. Must pay $1,100 fine and investigation costs.

Ashley Primrose, PT – License PT-8194. The Board issued an order of summary suspension. Registration as a PT is suspended until further order of the Board. Respondent was ordered to be evaluated within 15 days of February 15, 2013, by the MTP for possible substance abuse. Respondent failed to be evaluated within this time period.

Ramon Ramirez, PT – License PT-7805. On April 19, 2013, the Board issued a Notice of Contemplated Action (NCA) to respondent regarding his noncompliance with the Parental Responsibility Act. Respondent did not request a hearing as required by the NCA. Respondent did not appear at the April 19, 2013 Board meeting. Therefore, on June 20, 2013, the Board issued a default order of revocation.

Cecilio Silva, RPh – License RP-6310. Respondent entered into a stipulated agreement with the Board. Respondent's pharmacist registration suspended for a three-month period. Placed on probation for five years. Must successfully complete a five-year contract with MTP. Must pay administrative and investigative costs in the amount of $250. Must take and pass the MPJE.

Nathan Torres, PT – License PT-3930. On May 23, 2013, the Board received a signed Voluntary Surrender of Pharmacy Technician form from the registrant. The Board accepted the voluntary surrender. Registrant must pay investigative cost of $100.

Wal-Mart Pharmacy #10-0829 (Santa Fe, NM) – License PH-1262. Respondent did not admit or deny allegations described in investigative report regarding violations of the Pharmacy Act, the Controlled Substances Act, and the Board regulations. Respondent must pay a fine and investigative costs. Respondent must provide education to the pharmacist-in-charge regarding return of CS. Respondent must provide to the Board a quarterly report regarding CS returned for a period of two years.

Crucita Zafiro, PT – License PT-8646. Respondent signed a Voluntary Surrender of Pharmacy Technician form. The Board accepted this voluntary surrender. Must pay investigative and

Continued on page 5

Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

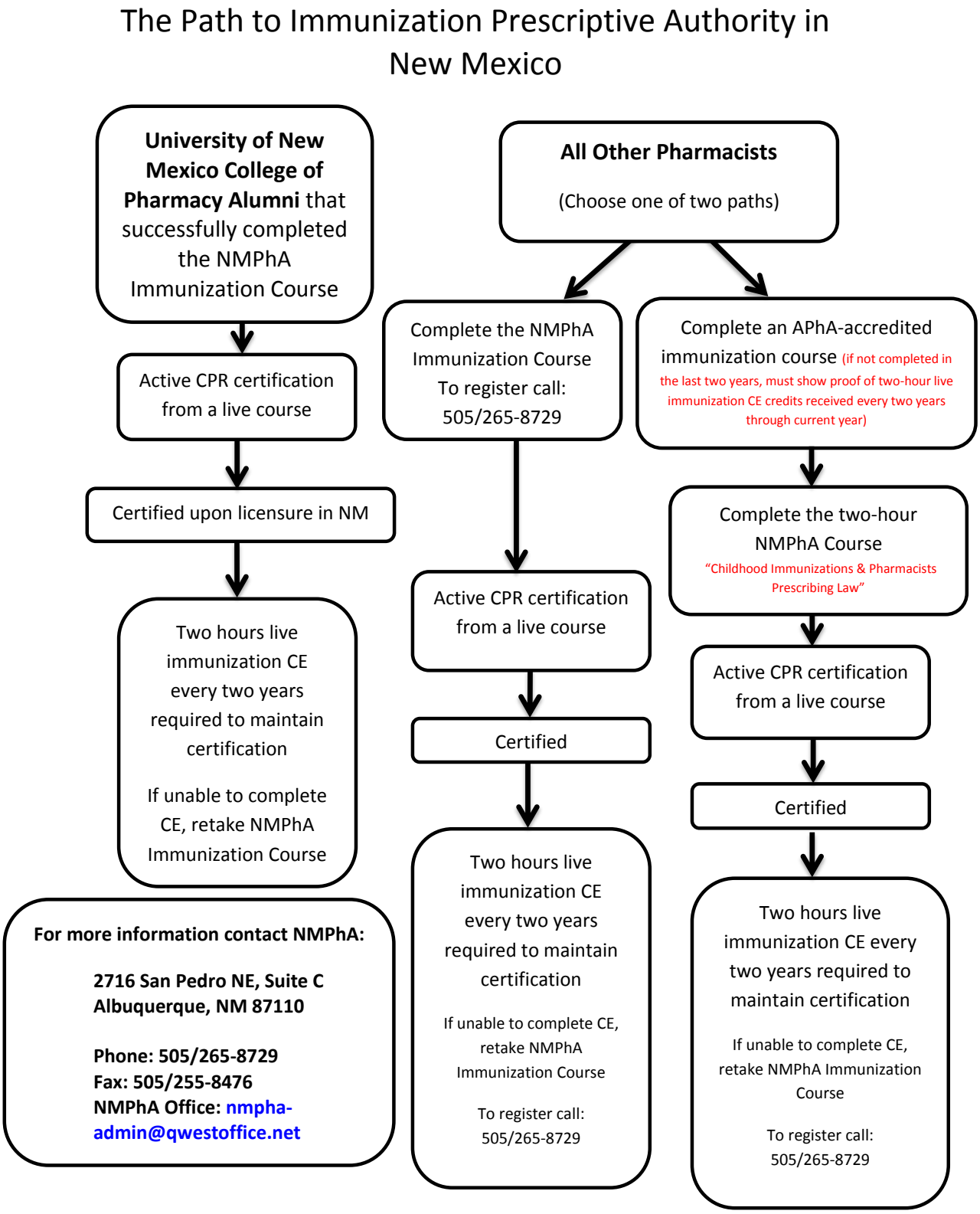
The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

A Path to Immunization Prescriptive Authority in New Mexico

The following is submitted by the New Mexico Pharmacists Association (NMPhA). This is a path to immunization prescriptive authority in New Mexico as suggested by NMPhA. This is not the only path by which a pharmacist may receive prescriptive authority for vaccines. According to Board regulations, Regulation 16.19.26.9.B. NMAC states, "the pharmacist must successfully complete a course of training, accredited by the accreditation council for pharmacy education (ACPE), provided by: a) the centers for disease control and prevention (CDC); or b) a similar health authority or professional body approved by the board." The regulation then goes on to describe what must be in any course that is approved by the Board.



Continued from page 1

fine costs of $1,250. Must be cleared by MTP as a precondition of re-registration eligibility.

Actions taken by the Board are posted online at the Board Web site.

Regulation Changes

During the June 20-21, 2013 Board meeting, three regulations were revised, as follows:

Regulation 16.19.5.8.E. NMAC was revised. This regulation change causes the fee for registration as a pharmacy intern to be raised from $10 to $25.

Regulation 16.19.4.10.A. NMAC was revised. This regulation change allows continuing pharmacy education programs that are approved by other state boards of pharmacy to count toward your New Mexico pharmacist renewal also.

Regulation 16.19.20.53.B. NMAC was revised. This is the regulation regarding exempt pseudoephedrine (PSE) products. Pharmacies are required to submit PSE sales information electronically to the Board or their designated agency in a Board-defined format.

For additional information, please read the regulations online.

Significant Adverse Drug Events

1. A prescription for metoprolol ER 25 mg was incorrectly entered and filled as metoprolol ER 200 mg. The patient took one dose and reported having increased fatigue. Pharmacist recommends repeating the information back to the caller with every verbal order and to write more legibly to allow for correct interpretation of prescription.
2. A prescription written for pantoprazole 40 mg was incorrectly filled with paroxetine 40 mg. The patient reported with suspected serotonin syndrome, which improved moderately after receiving paroxetine taper from physician. Pharmacist recommends the pharmacists double check the National Drug Code (NDC) during final check.
3. A prescription for levothyroxine 50 mcg was incorrectly filled with lisinopril 40 mg. The patient did not report any adverse effects. Pharmacist recommends concentrating on a single task, filling only one prescription at a time, and performing visual inspection of vial contents during the final verification.
4. In a hospital, an order for heparin 40 units/mL was incorrectly filled with heparin 2 units/mL. The patient's cardiovascular shunt clotted off and required replacement. A root cause analysis is being conducted to determine the corrective steps needed.
5. A refill for an old prescription on file for Bactrim® DS was requested and filled even though the patient had a known allergy to sulfa. The patient reported a generalized red rash and itching, which improved with Benadryl®. The pharmacist recommends immediately discontinuing prescriptions not dispensed for patient safety reasons in the system to prevent filling at a later date and be more vigilant for allergy alerts.
6. A prescription for metformin 500 mg was incorrectly entered and filled with metformin 1,000 mg. The patient reported having nausea. Pharmacist recommends slowing down and double checking all facets of prescriptions.
7. A prescription for levetiracetam 100 mg/mL was incorrectly filled with sulfamethoxazole/trimethoprim 200 mg/40 mg/5 mL. The patient was hospitalized due to having multiple seizures in a short time span. Pharmacist recommends restocking product in correct location and checking product image and NDC to ensure the correct product is being dispensed.
8. A prescription for clomiphene 50 mg was incorrectly filled with clonazepam 0.25 mg ODT. The patient took one dose and reported no symptoms. Pharmacist recommends that everyone involved in the filling process should be double checking NDCs.
9. A prescription for prednisolone 5 mg/5 mL was incorrectly filled with prednisolone 15 mg/5 mL. The patient experienced lethargy followed by restlessness. Pharmacist recommends double checking the strength of the medication before dispensing when multiple strengths are available.

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.

Statutory Change

During the 2013 legislative session, the statute 26-1-16.J. NMSA was revised. The revised statute says that a pharmacist may dispense a quantity not to exceed a 90-day supply of a dangerous drug by combining valid fills. The prescription must not state an indication specifically prohibiting a combined fill. And also, the medication cannot be a CS.

Law Update Reminder

In 2013, the Board has been offering two law updates each month in the Albuquerque, NM, area. Both updates are available on the same Friday. One update is offered from 9 AM to 11 AM. The other update is offered from 2 PM to 4 PM. To reserve a space, contact Jessica Chavez-Lance at 505/222-9830 or Jessica .Chavez-Lanc@state.nm.us.

- Law Update Schedule (Albuquerque)
  - ◊ September 13, 2013
  - ◊ October 25, 2013
  - ◊ November 15, 2013
  - ◊ December 20, 2013
- Law Update Schedule (around state)

  These law updates are scheduled for 7 PM to 9 PM.
  - ◊ September 10, 2013 – Clovis, NM
  - ◊ September 17, 2013 – Farmington, NM
  - ◊ September 24, 2013 – Taos, NM
  - ◊ October 29, 2013 – Hobbs, NM
  - ◊ November 19, 2013 – Las Cruces, NM

The New Mexico Society of Health-System Pharmacists (NMSHP) will host a law update on Sunday, October 6, 2013. Please contact NMSHP for information and to reserve a spot.

New Employee! Would You Like to Be One Too?

The Board hired Jessica Chavez-Lance as its new administrative assistant. Jessica is a certified PT. Jessica has worked at Express Scripts Pharmacy and Prime Pharmacy.

The Board currently has an opening for one position. The Board is looking to hire a state drug inspector. If you are interested, please contact Mary James at 505/476-4501 or e-mail at Mary .James2@state.nm.us.

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.

Larry Loring - State News Editor

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

Deborah Zak - Communications Manager