



New Mexico Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Disciplinary Actions

Martin Fritsch, PT – License PT-3097. Respondent voluntarily surrendered registration as a pharmacy technician. Must pay investigative costs in the amount of \$100.

Ashley Reed, RPh – License RP-5907. Respondent entered into a stipulated agreement with the New Mexico Board of Pharmacy.

Vet Pharm and Feed – License WD-0027. Respondent voluntarily surrendered registration as a veterinary drug distributor. Must pay investigative costs in the amount of \$100.

Gail Watters, RPh – License RP-4629. Respondent entered into a stipulated agreement with the Board.

For more information, actions taken by the Board are posted on its Web site.

Regulation Changes

During the August 2012 Board meeting, there were some important regulation changes that have not yet been published. In Regulation 16.19.4. NMAC – Pharmacist, the definition of “practice of pharmacy” was expanded. This expanded definition allows pharmacists to maintain an active license while practicing in different areas previously not recognized as the practice of pharmacy. In addition, active status was revised, stating:

Any pharmacist who maintains competency through the development and maintenance of knowledge, skill and aptitude, to ensure continuing competence as a pharmacy professional, and is able to demonstrate to the Board said competence in the practice of pharmacy shall be issued an active license. Records of continuing education or continuous professional development shall be maintained and available for inspection by the Board or the Board’s agent.

The requirement that you work a minimum of 80 hours per year has been eliminated.

During the January 2013 Board meeting, there was a regulation change. This change also involved Regulation 16.19.4.

NMAC – Pharmacist. The change is regarding continuing pharmacy education. Effective January 1, 2015, the patient safety requirement will change to require that your two contact hours per renewal period be in the area of safe and appropriate use of opioids.

For pharmacist clinicians registered to prescribe Schedule II or Schedule III controlled substances (CS), there will be an additional two contact hours (to total four contact hours per renewal period) in the area of safe and appropriate use of opioids.

Congratulations

Larry Loring has accepted the position of chief drug inspector/executive director of the Board. If you see Larry, please offer him your congratulations.

As a result, the Board is hiring for the position of state drug inspector I. If you are interested, please apply through the State of New Mexico Web site. For more information, please contact Mary James at 505/476-4501 or Rebecca Archuleta at 505/476-4504.

Significant Adverse Drug Events

1. A prescription for tamsulosin 0.4 mg was incorrectly filled with propranolol ER 60 mg. The patient felt lightheaded and continued to experience benign prostatic hypertrophy symptoms. Pharmacist recommends a visual inspection of capsules in the vial and double checking the correct placement of vials when restocking.
2. A caregiver mistakenly administered 0.5 mg of Ativan® instead of 0.25 mg of Xanax®. The patient did not experience any serious side effects, but did sleep for half a day. The caregiver reported having “too many distractions,” which led to the error. No recommendations for improvement were provided.
3. An order for metoclopramide IV was entered. The patient had a known allergy to metoclopramide and experienced agitation and anxiety upon administration. The pharmacist emphasizes the importance of checking a patient’s allergy information when entering new or refilled orders.

Continued on page 4



NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, www.livertox.nih.gov, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to ‘Double Check, Don’t Double Up’ on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition’s “Double Check, Don’t Double Up” message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the KnowYourDose.org Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis



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.

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state’s regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an “unexpected occurrence involving death or serious physical or psychological injury or

risk thereof,” and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves “Why did this happen?” until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask “Why do our systems allow these types of mistakes to happen so easily?” or “What factors set this person up to make this error?”

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer “What normally happens?” (Question 2, in the above table). The difference between “What normally happens?” and “What do the policies and procedures require?” (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. “Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a ‘patient-centered’ manner that best reflects how most patients seek out and understand medication instructions,” as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients



misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- ◆ Emphasizing instructions and other information important to patients
- ◆ Improving readability
- ◆ Giving explicit instructions
- ◆ Including purpose for use
- ◆ Addressing limited English proficiency
- ◆ Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at <http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010>.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law “prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or \$1 million.” According to the Coalition for Patient Safety and Medicine Integrity, “current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips.” By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong

commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards’ collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP’s member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies’ e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from
NABP, ACPE, and ACPE providers that will allow licensees
to track their completed CPE credit electronically.*

4. A prescription for propranolol liquid 20 mg/5 ml to be given 0.5 ml three times a day (TID) was entered incorrectly with directions of 0.5 teaspoonful TID. The six-month-old infant receiving the medication experienced no adverse events as a result of the increased dose. The pharmacist recommends counseling the patient on the dose of medication and having less distraction at the inputting and verification stations.
5. A prescription for morphine sulfate IR 30 mg was mistakenly filled with morphine sulfate 15 mg. The patient noticed the mistake before taking any of the medication. The pharmacist recommends giving more time to fill prescriptions, filling only one prescription at a time, and giving more attention to data entry, National Drug Code (NDC) verification, and drug strength.
6. A prescription written for Adderall XR® 10 mg was incorrectly filled with Adderall XR 30 mg. The patient noticed the error before taking any of the medication. The pharmacist recommends that you complete and verify only one prescription at a time, and that ample time is given to prepare and fill the prescription.
7. A vial correctly labeled for levothyroxine 25 mcg was incorrectly filled with zolpidem 10 mg. As a result, the patient experienced drowsiness, salivation, hallucinations, and was hospitalized after falling and sustaining a concussion, bruises, and scrapes. The pharmacist recommends never rushing through proper procedures established in the pharmacy, even when the pace is hectic and the workload is heavy.
8. A four-year-old was prescribed dexamethasone 1 mg/ml liquid. The pharmacist obtained permission to change the strength from 1 mg/ml to 0.5 mg/5 ml. The change resulted in the patient receiving an “elixir” form of the medication containing a high level of alcohol. The patient was taken to the emergency room with signs of stumbling, mumbling, and confusion. The pharmacist recommends that all liquid formulations for pediatric patients be double checked for their alcohol content.
9. In a senior living facility, a resident was prescribed hydrocodone/APAP 7.5/500 mg. The resident was mistakenly given a dose of hydrocodone/APAP 5/325 mg. The resident did not report any adverse effects. A color coding system has been put into place to help avoid this type of mistake from occurring in the future.
10. A cassette for tramadol 50 mg tablets in an automatic dispensing machine was found to have trazadone 50 mg tablets mixed in. After contacting all patients who had recently received tramadol, it was found that one patient had taken one of the incorrect tablets. The patient experienced insomnia, nausea, and lethargy (the following day). The pharmacist recommends that only a pharmacist be allowed to return medications to stock and to be aware of look-alike, sound-alike drugs.
11. A prescription for progesterone 3% topical gel for patient A and a prescription for progesterone 5%, pregnenolone 5 mg, and DHEA 2.5mg topical gel for patient B were bagged incorrectly and subsequently mailed to the wrong recipients. Patient A reported irregular menses and sleep disturbance. Patient B reported no side effects. The pharmacist recommends that any technician who may bag/package a prescription must initial the package labeling.
12. A prescription written for OxyContin® 20 mg was mistakenly dispensed with OxyContin 60 mg. The patient reported increased drowsiness and dizziness. The pharmacist recommends that pharmacists double check their own work, check the NDC, and minimize interruptions.
13. A patient’s prescription for Isopto® Tears 0.5% was incorrectly filled with Isopto Homatropine 5%. The two-year-old child experienced eye dilation, which improved over 24 hours. The error was attributed to having too many people filling prescriptions during a hectic time. No recommendations for improvement were given.
14. A prescription for amitriptyline 10 mg was entered amitriptyline 100 mg. The patient reported feeling tired and sleepy. The pharmacist recommends that the hard copy should follow the prescription throughout the entire verification process.

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.

Reminder

The Board wishes to remind pharmacists of their duty to counsel. You must offer to counsel on all new prescriptions. Counseling must occur after a prospective drug review. When reviewing the patient’s record, you should have a list of all medications the patient is on. Also, you should have information such as allergies and disease states. There has been a number of prescriptions entered under incorrect patient names. Many times the patient used to enter the prescription information is a child who would not have generally been placed on a particular medication at a particular dose.

Also, if you receive a prescription for a narcotic opioid from a prescriber with whom you are unfamiliar (ie, prescriber is located out of state or prescriber is outside the usual pharmacy geographic prescriber care area), you must receive a prescription monitoring program (PMP) report on the patient prior to filling the prescription. Many forged prescriptions are being filled. These prescriptions are commonly for oxycodone 30 mg #120. The PMP report often shows that the patient has never received a narcotic prescription prior. The phone number on the prescription often is false. Please verify prescriptions with the phone number in your database, not the number on the prescription.

Do You Know – Methotrexate

Many practitioners prescribe methotrexate to be used in rheumatoid arthritis. When the injectable form is used, the dose is typically 0.3 ml per week. Methotrexate is manufactured in multiple sizes. It is also manufactured sometimes containing preservatives, and some dosage forms are preservative-free, but methotrexate is generally manufactured as a single-dose vial. The Board would like to remind pharmacists if a 10 ml vial is dispensed, and the dose is 0.3 ml, then the vial will last the patient 33 weeks. Even if the methotrexate contains a preservative, the vial will last the patient much longer than the United State Pharmacopeia (USP) allowable expiration date for a multi-dose vial. The USP allowable expiration date is 28 days after a multi-dose vial is opened. Please keep this in mind when dispensing methotrexate.

Controlled Substance Ordering System

According to Drug Enforcement Administration (DEA), any registrant who wishes to order any Schedule II CS must have a power of attorney on file. The power of attorney allows a person the authority to purchase the CS. A power of attorney must be on file regardless of whether the electronic Controlled Substance Ordering System or the written DEA Form 222 is used. Multiple individuals at each location may be named as power of attorney. When a new employee is hired, this person may be added as power of attorney. If an individual is no longer authorized to order Schedule II CS, the power of attorney must be revoked.

Way to Go

On the evening of October 10, 2012, New Mexico pharmacist Nicole Gilbert was not only presented with prescriptions to fill in her busy pharmacy, but also with a choking 10-month-old baby. Nicole performed CPR on the infant. By the time emergency medical services personnel arrived on scene, the baby was breathing and doing well.

If you have a similar story, please let us know. We will put it in the *Newsletter* for all to see.

From the DEA

By Randall Bencomo – Albuquerque District Office

Did you know a pharmacist has a responsibility to ensure that a prescription has been issued by an appropriately registered or exempt practitioner? You can validate this on the DEA Web site under the Quick Links menu where you will find the link, **Registration Validation**. Click on this link and it will take you to a screen where you enter your information for the validation of a DEA registration number. It has come to the Board's attention while conducting scheduled and non-scheduled investigations that confirmations for the validity of a prescriber's DEA registration number or authority to prescribe certain CS have not been conducted prior to

the filling of prescriptions. There have been circumstances where CS prescriptions have been filled for providers with retired or expired DEA numbers.

This brings to mind buprenorphine (Suboxone®) prescriptions for addiction treatment that have been filled for unauthorized providers and, in one particular case, for a mid-level practitioner who as of yet, is not authorized to prescribe this product by the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment. The absence of the "X" prefix on the DEA registration number, which is required on a Suboxone prescription (only if for addiction) prior to filling it should tip off the pharmacist. On the other hand, anyone can place an "X" prefix to their DEA number and claim to be a DATA-Waived Practitioner, so a verification of his or her status should be conducted to ensure compliance. A recent update requires both DEA numbers on Suboxone prescriptions for addiction, as in the regular DEA number and the "X" number as well.

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and
2. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in the C.F.R. are met.

The excerpt above was extracted from the DEA online *Pharmacist's Manual*. For more detailed information or if you wish to download the *Pharmacist's Manual* and print it, it can be accessed at the following Web site: www.deadiversion.usdoj.gov/pubs/manuals/.