



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1616 W Adams St, Suite 120 • Phoenix, AZ 85007 • Web site: www.azpharmacy.gov
E-mail: chunter@azpharmacy.gov

2013 Board Meeting Schedule

All Arizona State Board of Pharmacy meetings take place in Board Meeting Room 120, 1616 W Adams St, Phoenix, AZ. AZ law continuing education (CE) will be available.

- ◆ January 24-25
Thursday and Friday
- ◆ March 20-21
Wednesday and Thursday
- ◆ May 8-9
Wednesday and Thursday
- ◆ June 26
Wednesday
- ◆ September 18-19
Wednesday and Thursday
- ◆ November 6-7
Wednesday and Thursday

Prescription Compounding Task Force

The recent tragedy caused by contaminated compounded prescription drugs distributed across the country by a pharmacy in Massachusetts has probably been the “biggest story” in pharmacy in the last decade. Unfortunately, it is not the kind of news that pharmacy as a profession is proud of. Any time a patient suffers a negative outcome is a “failure” both for the professional involved and for the profession as a whole. In this extreme case, there were at least 656 cases where patients were infected by various organisms in the products and 39 deaths in 19 states.

On October 6, NECC [the New England Compounding Center] expanded its recall to include all products in circulation that were distributed from its facility in Framingham, Mass. As part of the ongoing investigation, FDA [Food and Drug Administration] and CDC [Centers for Disease Control and Prevention] have been testing various NECC products for evidence of contamination. Laboratory testing at CDC and FDA has found bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone

solutions distributed and recalled from NECC, as shown in the table below.

Laboratory-Confirmed Organisms from Product Samples Associated With NECC Recalled Lots of Betamethasone, Cardioplegia, and Triamcinolone Solutions		
Medication	Lot Number	Bacterial and Fungal Contamination
Betamethasone 6 mg/mL injectable – 5 mL per vial	08202012@141	<i>Paenibacillus pabuli/amolyticus</i> , <i>Bacillus idriensis</i> , <i>Bacillus flexus</i> , <i>Bacillus simplex</i> , <i>Lysinibacillus sp.</i> , <i>Bacillus niacin</i> , <i>Kocuria rosea</i> , <i>Bacillus lentus</i>
Betamethasone 6 mg/mL injectable – 5 mL per vial	07032012@22	<i>Bacillus niabensis</i> , <i>Bacillus circulans</i>
Betamethasone 12 mg/mL injectable – 5 mL per vial	0730201@22	<i>Bacillus lentus</i> , <i>Bacillus circulans</i> , <i>Bacillus niabensis</i> , <i>Paenibacillus barengoltzii</i> / <i>timonensis</i>
Betamethasone 6 mg/mL injectable – 5 mL per vial	08202012@44	<i>Bacillus lentus</i> , <i>Bacillus firmus</i> , <i>Bacillus pumilus</i>
Betamethasone 6 mg/mL injectable – 5mL per vial	08152012@84	<i>Penicillium sp.</i> , <i>Cladosporium sp.</i>
Triamcinolone* 40 mg/mL – 1 mL vial	06062012@60	<i>Bacillus lentus</i> , <i>Bacillus circulans</i>

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.*

Triamcinolone 40 mg/mL injectable – 2 mL per vial	08172012@60	<i>Aspergillus tubingensis, Penicillium sp.</i>
Triamcinolone 40 mg/mL injectable – 10 mL per vial	08242012@2	<i>Aspergillus fumigatus</i>
Cardioplegia solution 265.5 mL per bag	09242012@55	<i>Bacillus halmapalus/ horikoshii, choshinensis</i>

*Identification of other bacteria for this product is pending.

As a result of the size and scope of the situation depicted above, the Board has determined to form a special compounding task force as soon as practicable (most likely by the January 2013 meeting). The goal of the task force will be to review all rules and statutes in Arizona and elsewhere and form a consensus on what are the best practices for pharmacy compounding. Then Board staff will codify new rules designed to prevent a repeat of any of the negative patient outcomes that occurred as a result of this tragedy. If you feel you can contribute and are able to make the time commitment, which will be substantial, please send a cover letter and a brief résumé to the Board office at PO Box 18520, Phoenix, AZ 85005.

Five-Year Anniversary of the Arizona State Board of Pharmacy Controlled Substances Prescription Monitoring Program

It is hard to believe, but it has been five years since the Board's Controlled Substances Prescription Monitoring Program (CSPMP) started collecting data from dispensers of Schedule II, III, and IV controlled substance prescriptions in October 2008. The CSPMP database has also been available for use by medical practitioners and pharmacists since December 2008. Medical practitioners who are registered with the CSPMP as required by law may request access to the CSPMP database to look up their own patients' prescription information in order to better treat or evaluate their patients. Pharmacists who are licensed may also request access in order to make more informed decisions about whether or not to dispense a particular controlled prescription. Perhaps of equal importance to pharmacists, the CSPMP provides a quick way to comply with the "corresponding liability," or as many prefer, "corresponding responsibility," clause in Drug Enforcement Administration Regulation 1306.05 (f), which can be found in the Code of Federal Regulations.

Until recently, the last few weeks actually, the process for requesting access to the CSPMP required the medical practitioner or pharmacist to complete several paper forms, and one form that also required notarization. After filling out those documents, an applicant had to mail them along with other verifying documents to the CSPMP office at the Board for processing. The Board is very happy and even a little proud to say that on October 22, 2012, the process was changed to an online and paperless process. Now medical practitioners and pharmacists can utilize an online application to request access to the CSPMP.

It is important to acknowledge the budgetary (dollars, money) assistance from the Arizona Department of Health Services, and their Director Will Humble and his staff, without which the Board could not have implemented the majority of the enhancements this year.

The link to request access to the CSPMP online is <http://azpharmacy.gov/pmp/access.asp>. Medical practitioners and pharmacists will still need to successfully complete the CSPMP's online training course provided by careermap.net. When the applicant completes the training course (which takes about 15 to 20 minutes), the medical practitioner or pharmacist will receive two e-mails from the CSPMP's technical staff at hidinc.com. The first e-mail contains his or her username and database Web link (URL), and the second e-mail lists his or her personal identification number (PIN), temporary password, login instructions, and an 866 telephone number for the help desk.

Medical practitioners and pharmacists who are not licensed in Arizona can also request access online, but they must print out the online forms, have the forms notarized, and mail the forms to the CSPMP office along with a copy of their current state license (and for medical practitioners, their DEA registration) and driver's license. Once all documents are received and verified, the out-of-state licensed medical practitioner or pharmacist will receive an e-mail from the online training course at careermap.net, and when the course is completed, the out-of-state licensed medical practitioner or pharmacist will receive the two e-mails from the CSPMP's tech staff at hidinc.com with their user name and the database Web link, and their PIN, temporary password, login instructions, and 866 telephone number to the help desk, just the same as the in-state applicants did.

Questions can be directed to CSPMP Director Dean Wright at 602/771-2744 or via e-mail at dwright@azpharmacy.gov or to CSPMP Manager Richard Cieslinski at 602/771-2732 or via e-mail at rcieslinski@azpharmacy.gov.

Disciplinary Actions

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Pharmacists

Alnoah, Fahad (S015734) – Placed on probation for two years; fined \$2,000. Required to retake Multistate Pharmacy Jurisprudence Examination®. Effective September 21, 2012.

Boel, Eric (S018886) – Probation terminated. Effective November 14, 2012.

Coppola, Thomas (S017161) – License revoked. Effective September 21, 2012.

Hannibal, Jeffrey (S011674) – Probation terminated. Effective September 19, 2012.

Hodges, James (S009569) – Fined \$500 and required to complete six additional hours of CE within 90 days. Effective September 27, 2012.

Hunter, Lisa (S013072) – License reinstated; no additional conditions. Effective September 19, 2012.

Makai, Gerwyn (S016844) – Board agreed at November 14, 2012 meeting to terminate Pharmacists Assisting Pharmacists of Arizona (PAPA) contract. **Effective upon signing of revised consent.**

Martinez, David (S015190) – Probation terminated. Effective November 14, 2012.

Merkel, D. Steven (S009366) – License reinstated with five years of probation. Effective September 27, 2012.

Oxford, Sherri (S009874) – Suspended for a minimum of six months, followed by five years of probation and a five-year PAPA contract.

Tobin, Robert (S016952) – Placed on probation for one year, fined \$6,000, both due within 90 days. Effective September 27, 2012.

Intern

Desai, Hitesh (I007035) – Request to renew intern license denied. Effective September 19, 2012 (Mr Desai's pharmacy technician trainee license, T007991, is open and is in good standing).

Technicians

Arvizo, Michael (No No. Issued) – Application for pharmacy technician trainee denied. Effective November 14, 2012.

Eversole, Shawna (T017431) – Revoked. Effective November 15, 2012.

Ganster, Donald (T017909) – Revoked. Effective November 15, 2012.

Schrey, Michael (T001807) – Revoked. Effective September 27, 2012.

Skousen, James (T018726) – Revoked. Effective September 27, 2012.

Permits

Avondale Pharmacy (Y004448) – Request to terminate probation denied. Effective September 19, 2012.

Holiday Rx (Y005095) – Revoked. Effective September 27, 2012.

Disciplinary Updates and Actions – Other Boards

Arizona Board of Medicine (MDs)

Fernando, Norman (MD 15894) – *Interim Consent Agreement for Practice Limitation* – Physician's practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective November 1, 2012.

Hovey, Charlotte (MD 28361) – Non-disciplinary – *Consent Agreement for Practice Limitation* – Practice limitation terminated due to cancellation of license. Effective September 14, 2012.

Jones, Michael F. E. (MD 13267) – License surrendered to the Board. Effective October 4, 2012.

Petrone, Thomas J. (MD 23585) – License surrendered to the Board. Effective October 4, 2012.

Win, Tin T. (MD 28212) – *Interim Findings of Fact, Conclusions of Law, and Order for Summary Suspension of License* – Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Effective October 26, 2012.

Arizona Board of Osteopathic Examiners (DOs)

Collins, Joseph (D 3858) – *Interim Consent Agreement for Practice Restriction* – Respondent is placed on a practice restriction that prohibits him from prescribing any controlled substances. In addition, respondent shall not execute written certifications or recommendations for medical marijuana. Further, any health care practitioner who is supervised, employed by, or contracted with respondent is prohibited from prescribing any of these medications. Effective November 26, 2012.

Hunsaker, Colleen (D 2843) – *Interim Consent Agreement for Practice Restriction* – Respondent is restricted from prescribing amphetamines and opioids until the Board continues its investigative hearing and issues a final decision or order in the investigative hearing with respondent. Effective October 3, 2012.

Michel, Lucinda (D 4314) – *Interim Consent Agreement for Practice Restriction* – Respondent is restricted from practicing osteopathic medicine until the Board continues the investigative hearing with respondent at its regularly scheduled meeting in May 2013. Effective October 4, 2012.

Arizona Regulatory Board of Physician Assistants (PAs)

Borgesen, Paul (PA 2389) – *Request for License Inactivation with Cause* – License held by respondent is inactive with cause. Effective September 14, 2012.

Parrett, Karin L. (PA 2392) – *Interim Consent Agreement for Practice Limitation* – Respondent's practice is limited in that she shall not perform health care tasks in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until respondent applies to the Board and receives permission to do so. Effective October 12, 2012.