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News

Wyoming State Board of Pharmacy

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Compounding Update

At its December 2012 meeting, the Wyoming State Board of Pharmacy had an extensive discussion about sterile and non-sterile compounding due to the recent deaths in other states from fungal meningitis caused by contaminated products from the New England Compounding Center. Richard Johnson, RPh, from Pharmaceutical Compounding Specialists of Wyoming discussed his policies and procedures and testing protocols. Dave Pestotnik, RPh, from Pharmacy Solutions, Inc, described his sterile compounding for home infusions. His pharmacy is also registered through Food and Drug Administration (FDA) as a "re-labeler" with unique National Drug Code (NDC) numbers on products. Leith Culver, RPh, from Care Trust IV in Casper, WY, also described compounding that is certified to medium-risk sterile products as defined in Chapter 17 of the Board's rules and in United States Pharmacopeia (USP) Chapter 797. The Board members had many questions and appreciated the expertise of the pharmacists.

The Board directed agency staff to send a letter to each pharmacy in Wyoming to determine what type(s) of compounding is being done, whether or not products are shipped out of state, if the pharmacies or personnel have been accredited or certified, and to ask for copies of the pharmacy's policies/procedures so compliance officers can review them before the 2013 inspections. Mary Walker, RPh, executive director, attended a meeting in December at FDA along with all other state boards to discuss compounding. Chapter 13 of the Board's Rules is being reviewed against USP Chapter 795 for possible revisions.

Medical Foods

By Bernadine Bunt, PharmD Candidate

According to FDA, a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." Medical foods are not the same as prescription drugs or dietary supplements. FDA does not regulate medical foods as it does prescription drugs, although some medical foods require a prescription. Medical foods do not have to undergo premarket review or approval by FDA and they do not have to be registered with FDA.

Medical foods may look like prescription drugs, have an NDC number, include a package insert, and may say "Rx only"; however, medical foods are not legend drugs. Also, medical foods are not simply food as the name may imply; they must meet specific criteria. FDA uses a criterion to define a medical food.

Unlike supplements, a medical food can be promoted to manage a specific disease. For example, glucosamine (a supplement) may be labeled for "joint health," but not "for osteoarthritis," whereas a medical food could be labeled "for osteoarthritis." An example of a medical food is Axona®, a powder that is administered once daily after breakfast or lunch and "offers a novel approach to managing Alzheimer's disease by providing an alternative energy source for brain cells that safely improves cognitive function and memory." Since Axona is a medical food, the manufacturer may state "Alzheimer's disease" rather than just "for memory improvement," which would be required if it were a supplement. Many medical foods stretch the limit of their definition and often contain vitamins, minerals, or plant extracts just like dietary supplements.

Manufacturers are trusted to follow the "honor system" to ensure the safety of their medical foods and their claims of efficacy are accurate. However, medical foods must comply with the requirements for the manufacture of foods and the ingredients must be Generally Recognized as Safe, be approved food additives, or a food additive that is the subject of an exemption for investigational use. FDA has a specific compliance program for medical foods to assist in monitoring their safety.

Due to the lack of research and evidence supporting many medical foods, strong consideration is necessary to determine if a medical food should be added to a patient's regimen or replace standard therapy for his or her illness. Currently, medical foods are not addressed in Wyoming pharmacy laws or in the federal Title 21: Food and Drugs, Part 1306 – Prescriptions.

Wyoming Recognized for E-Prescribing Achievement

In December 2012, the Office of the National Coordinator for Health Information Technology announced Wyoming is one of five states to achieve a significant milestone in electronic prescribing ("e-prescribing"). Ninety-seven percent of Wyoming pharmacies are able to receive prescriptions electronically.

Wyoming e-Health Partnership (Partnership) is the non-profit organization leading Health Information Exchange activities in Wyoming and has been monitoring Wyoming e-prescribing rates.

The Partnership's chief executive officer Heather Roe Day commented, "This is great news for Wyoming. The decision by most Wyoming pharmacies to receive e-prescriptions sets the

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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.

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stage for encouraging more providers to send prescriptions electronically. E-prescribing makes it more convenient for patients to obtain their prescription medications and is a central part of exchanging health information in Wyoming."

Disciplinary Actions

Note: All fines are payable to the county treasurer where the action occurred for the credit of the public school fund in that county pursuant to Wyoming Statute §33-24-113(f).

C.W. Pharmacy Technician License #2088T. Administrative penalty in the amount of $500 for performing compounding without a pharmacy technician license. Required to complete two additional hours of continuing education (CE).

K.L. Pharmacist License #2028. Admonition for dispensing a prescription different than prescribed. Required to complete five additional hours of CE on the topic of medication error prevention and provide a written personal plan of action to prevent future medication errors.

Retail Pharmacy License #52-03283. Administrative penalty of $500 for allowing a person who is not licensed by the Board to perform duties as a pharmacy technician and $500 for authorizing a pharmacy technician-in-training to perform compounding. Required to provide a written policy regarding licensure of technicians.

Institutional Pharmacy License #52-01164-IP. Administrative penalty of $2,000 for allowing a person who is not licensed by the Board to perform duties as a pharmacy technician and $4,000 for allowing two pharmacy technicians-in-training to perform pharmacy functions at a pharmacy location not specified on their permit. Also required to provide a written policy regarding licensure of technicians.

License Renewals

By David Wills

A record number of pharmacists (1,071) and pharmacy technicians (504) renewed their 2013 licenses using the online process. One of the most common problems in the online process occurs when a person has had a name change that was not reported to the Board office. Renewal notices are mailed to the address of record on November 1, each year. If the address has changed and you do not receive the notice, you may be facing a late fee or reinstatement process. A "snapshot" of the Board's database is taken just before renewals and if the information does not match, the person will have to contact the Board for a paper renewal. Always notify the Board in writing (including by e-mail or fax) if your name, address, or employer has changed. All pharmacist and pharmacy technician licenses expire on December 31, each year. Thank you for continuing to use the online process, which saves time, paper, and postage. Agency staff are available to help with questions and to walk you through the process.

Kay McManus Retires from the Board

Pharmacist Kay McManus, RPh, completed her 12th year as a Board member on February 28, 2013. Originally appointed in 2001 by Governor Jim Geringer, she twice served two-year terms as president. Kay was a leader in the efforts toward collaborative practice, the prescription drug monitoring program, telepharmacy, e-prescribing, and many other projects. The Board wishes Kay well; she will be missed.

Focus of Inspections in 2013

By Richard Burton and Hank York, Compliance Officers

Policies and procedures will be a major focus during 2013 for both sterile and nonsterile compounding including documentation of competency. Refrigerator temperature logs, immunization records, emergency box permits, and other pharmacist-in-charge responsibilities will be reviewed. The Pharmacy Self-Inspection Report will be sent out around April 1, and should be completed with the assistance of your pharmacy staff. The compliance officers will be observing for work flow, clutter, congestion, counseling, and if security measures are in place.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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