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Wyoming State Board of Pharmacy News

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New Board of Pharmacy Staff Member

Beverly Fontaine is the new office assistant at the Wyoming State Board of Pharmacy.

Beverly has extensive experience working in health care as well as other professional office settings. She enjoys making stained glass art, traveling, and music. Beverly and her husband are parents of three daughters.

Rules Revisions

On July 6, 2011, Governor Matt Mead signed the rules revisions that had been approved by the Wyoming State Board of Pharmacy. The home page of the Board's Web site has the changes in each chapter listed in a red box *(http://pharmacyboard.state.wy.us)*. The "Laws" tab has the revised chapters incorporated.

Wyoming Controlled Substances Act Rules Chapters 3, 4, 6, and 8 were revised for grammar and format and content changes are summarized:

- Chapter 3 changes the controlled substance registration for practitioners from annual to every two years with a late fee in effect on July 1, in the year of renewal.
- Chapter 4 deletes the controlled substances inventory on the anniversary of the date of the initial inventory (annual inventory in the first week of May is still required).
- Chapter 4 Section 4 describes the documentation of sales of methamphetamine precursors in the electronic or written logbook and lists forms of ID to be used (matches federal Combat Methamphetamine Epidemic Act of 2005).
- Chapter 6 provides definitions and processes for electronic prescriptions for controlled substances. **Note: no prescriber or dispenser has yet to become accredited for electronic prescriptions for controlled drugs.**
- Chapter 6 Section 5 adds quantity check-off boxes and refill indicators to security paper.
- Chapter 8 clarifies elements to be reported to the Wyoming Prescription Drug Monitoring Program and the procedure to request a waiver from reporting.
- Chapter 8 Section 3 describes the process for obtaining prescription drug monitoring program reports with a written consent of the person.

Wyoming Pharmacy Act Rules Chapter 5 (Poisons) and Chapter 7 (Computer Regulations) were **repealed** because they are no longer relevant. Chapters 2, 3, and 14 were revised for grammar and format and content changes are summarized:

- Chapter 2 Section 4 added definitions for electronic prescriptions, defined "pharmacy intern," and revised the definition of "pharmaceutical care." "Readily retrievable" means that records must be produced for review within 48 hours of the request.
- Chapter 2 Section 10 describes transfers of prescriptions by a pharmacy intern to a pharmacist. Controlled substance transfers are between two licensed pharmacists.
- Chapter 2 Section 19 states that a signature on a non-controlled substance prescription can be digital or electronic as a "recognizable signature of the practitioner."
- Chapter 2 Section 29 describes electronic prescriptions for controlled substances and the requirement for accreditation by a third party for prescribers, transmission, and dispensers. **At publication date no software has been approved by Drug Enforcement Administration for electronic controlled substance prescriptions.**
- Chapter 3 Section 4 allows pharmacy interns to provide pharmaceutical care and administer immunizations under the direct supervision of a licensed pharmacist.
- Chapter 3 Section 5 provides definitions for preceptors.
- Chapter 14 allows controlled substances to be stocked and dispensed from telepharmacies and updates temperature guidelines in telepharmacies.

Rules Revisions That Were Not Approved

At the public rules hearing on April 15, 2011, the Board did not approve a section in Chapter 2 proposed for pharmacists to provide Clinical Laboratory Improvement Amendments-waived testing without a collaborative practice agreement. Governor Mead did not approve Chapter 2 Section 35 of the proposed rules revisions entitled "Pharmacist Work Conditions" listing processes to use for a pharmacist mandatory meal break. The governor cited that W.S. 16-3-103(d)(ii) Section 35 "does not appear to be within the scope of the legislative purpose of the statutory authority, W.S. 33-24-101 through 33-24-301."

Pharmacists Receive 50-Year Certificates

Originally licensed in Wyoming in 1960, these pharmacists have held an active license for 50 years: Sally Vandenberg, John Hickman, Donald Griss, James Shawver, Barry Horn, and Iris Harnagel. Golden certificates were presented at the Wyoming Pharmacy Association convention in June. Richard Wilder was given a plaque commemorating his 60th year of active pharmacist license #1230 since June 20, 1950. Mr Wilder told the convention audience of the many changes in pharmacy and his wife Marjorie also spoke about their early days in the family pharmacy in Cody, WY.

Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts and to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning on Benzocaine Use

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. FDA also stresses that benzocaine products should not be used on children less than two (2) years of age, except under the advise of a health care provider. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov*.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 60 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov*.

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).

W.M. Pharmacist License #2093. Failure to complete controlled substance reconciliation, failure to have readily retrievable invoices and records for controlled substances. Letter of admonition. Order: submit a plan for correction, $2,000 administrative penalty, additional three hours of continuing education on pharmacy law.

J.W. Pharmacist License #1967. Failure to disclose on renewal application that there was a pending action in another state. Order: five hours continuing education on ethics, conditional license for two years.

S.L. Technician-in-Training #1715. Permit revoked for conviction of larceny by bailee, a felony. Court order for restitution.

K.M. Pharmacist License #2051. Failed continuing education audit. $300 administrative penalty plus complete an additional 10 hours of continuing education.

Retail Pharmacy License #R10037. Failure to prevent unprofessional conduct. Administrative penalty of $2,000. Submit a plan for improvement in training current and future staff.

Retail Pharmacy Licenses #52-02089, 52-02166, 52-02267, 52-03334, 52-01885, 52-03803, 52-01998, 52-01809, and 52-03699. Failure to report tramadol prescriptions to the Wyoming Prescription Drug Monitoring Program. $2,000 administrative penalty (each) plus a plan for compliance.

Emergency Preparedness in Wyoming

By Donna Artery, PharmD, RPh, Office of Pharmacy Services, Wyoming Department of Health

The Centers for Disease Control and Prevention (CDC) in Atlanta, GA, try to prepare our country for emergencies should they arise. After the disaster in Japan and a perceived threat of nuclear radiation was possible, Wyoming was contacted. The CDC asked the Department of Health to evaluate the amount of potassium iodide (KI) on pharmacy shelves and available for consumers in Wyoming should it be needed. They do not do this flippantly or on a whim, as the last time the Department of Health was asked for pharmaceutical information was in 2009 when a pandemic flu situation was possibly coming to Wyoming. In 2009, the Department of Health was asked to determine the amount of Tamiflu® (both tablets and suspension) and Relenza® available in Wyoming pharmacies.

The Department of Health is not in a competition with pharmacies and agrees that consumers should first use the products available by retail from pharmacies. However, if it is determined there is a shortage on the shelves, the Department of Health may be ordered to purchase medication at a state level and distribute. So stated again, the Department of Health is **really** helping pharmacies out by asking Wyoming citizens to purchase from their pharmacies if at all possible (generating pharmacy income) and, **only** if pharmacies have inadequate stock, will the Department of Health step in and purchase the medication for its people.

I am not certain about the legal aspect of ignoring a request from your Department of Health, but I am very concerned about the disrespect shown to Wyoming citizens and their welfare when these infrequent and reasonable requests are made, yet go unanswered by pharmacists and pharmacies around the state.

The inquiry made by blast fax concerning influenza medications in 2009 resulted in a 51% response rate. The inquiry in March 2011 concerning KI resulted in a 38% response. Thank you to the pharmacies and pharmacists that completed the questionnaire. As a field of respected professionals, I would hope that we pharmacists take the subject of public safety more seriously than indicated by these rates. I would encourage you to answer these important requests promptly and completely in the future. Thank you.

When A Prescriber Dies

Rules, Chapter 2 Section 14, Doctor-Patient Relationship as Affecting Prescriptions states "(a) Upon learning that a patient/practitioner relationship has been terminated for reasons other than discharge of the patient by the practitioner, a pharmacist utilizing his/her professional judgment may honor patients' request for remaining medication refills, for a period not exceeding twelve (12) months." The key words are **utilizing professional judgment** so that maintenance medications are covered until a new practitioner can be found but unreasonable requests are not automatically allowed. Patient safety must be considered over convenience.

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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