March 2014

Wyoming State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
http://pharmacyboard.state.wy.us

Changes in Pharmacy: Immunizations

By Tracey Le, 2014 PharmD Candidate, University of Wyoming School of Pharmacy

On January 16, 2014, Governor Matt Mead signed rule revisions in Chapter 16, Immunization Regulations, of the State of Wyoming Pharmacy Act Rules and Regulations, which provides the right for pharmacists to prescribe and administer influenza shots for children as young as seven years old under Wyoming Statute (W.S.) 33-24-157, which was revised by the legislature in 2013 (House Bill 0094). A parent or legal guardian must provide consent and be present during the administration of the immunization for minors, which includes ages seven through 17. An adult is now considered 18 years or older. Pharmacists who choose to immunize children must successfully complete training specific to administering vaccines for children. W.S. 33-24-157 does not require any pharmacist to administer immunizations to patients younger than 13 years of age and employers shall not discriminate against a pharmacist on the basis that the pharmacist determines not to administer to individuals less than 13 years old.

When communicating with children, it is important to help the child remain calm by not making sudden movements and by speaking in a soft and calm voice. It also helps to have the parent or legal guardian hold the child to prevent the child from swinging his or her arms when the injection is administered. Distractions, such as toys, squeeze balls, lollipops in each hand, stuffed animals, and even conversation about school or his or her favorite thing to do for fun, can help the child feel more comfortable. Older children can also be very curious, and pharmacists should answer any questions they may have to explain the process. When communicating with adolescents, it is important to remember that they can be unpredictable and their attitude or behavior may be concealing their fear or anxiety. They also highly value privacy and it is important to respect their desires. Provide accurate and user-friendly information for the parent and realize he or she may have a fear of the adverse reactions or things he or she hears from media. It is okay to ask the parent to put away a cell phone and to focus on the child. Additionally, it is okay to tell the parent that you are uncomfortable administering a vaccine if the child is upset to the point of screaming or thrashing and ask them to return another time.

When administering immunizations for a child, use a 5/8-inch or 1-inch needle and two to three finger-widths below the acromion process, depending on the size of the child. Furthermore, children should only receive 0.25 mL of the vaccine.

Chapter 16 also states that all patients receiving immunizations must be seated with back support. Furthermore, a pharmacy intern who administers immunizations must be registered and be under direct supervision of a pharmacist who is registered to administer immunizations. Private spaces have been defined as 48 square feet and partitions must be at least six feet high. Curtains are not allowed and private space will be necessary by July 20, 2014.

For record keeping, pharmacists must recommend that the patient send one copy of a completed Immunization Questionnaire and Consent Form to his or her medical provider and that the patient keep one for his or her own records. The consent form shall include documentation that the pharmacist has discussed the possible side effects of the vaccination and a recommendation that the patient stays within the vicinity for 15 minutes after the injection. If the patient chooses not to remain in the vicinity, the pharmacist must provide information about how he or she can seek care if an event occurs. All immunizations provided to adults and minors must be recorded into the Wyoming Immunization Registry (WyIR), which is free, and additional information can be found in the December 2013 edition of the *Wyoming State Board of Pharmacy Newsletter,* or call the help desk at 800/599-9754, WyIR Project Coordinator John Anderson, MS, at 307/777-5773, or visit *https://wyir.health.wyo.gov/.*

In Chapter 16, Section 11, there are regulations added for immunizations administered away from the pharmacy. It states that vaccines may be administered off-site if the proper storage, transportation, and disposal of vaccines and supplies are utilized. Records for off-site vaccinations must also be maintained by the sponsoring organization for at least six years.

The 2011 National Immunization Survey, published by the Centers for Disease Control and Prevention (CDC), estimated the final state-level influenza coverage and found:

- Among children aged five to 12 years, the estimated national coverage was 54.7%;
- Among children aged 13 to 17 years, the estimated national coverage was 34.5%;
- Among adults aged 18 to 49 years, the estimated national coverage was only 30.5%;
- Among adults 50 to 64 years, the estimated national coverage was 44.5%;
- Among older adults (greater than 65 years), the estimated national coverage was 66.6%; and

continued on page 4

Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

WYOMING STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

- In Wyoming, only 41.6% of people six months or older were vaccinated for influenza.

It is also important to educate patients about receiving the influenza vaccination during the right time of year. Many pharmacies are receiving early shipments of influenza vaccines, some as early as July and August. This may be too early for patients to receive influenza shots since the efficacy wanes, especially after three months. Based on reported facts by CDC, there remains a large role for pharmacists to advocate for influenza immunization through all age groups in Wyoming.

Compliance Corner

By Richard Burton, RPh, and Hank York, RPh

The focus of inspections of pharmacies in 2014 will include the following:

- Sterile compounding policies and procedures for cleaning and disinfecting the primary and secondary engineering controls, aseptic technique, safety, quality assurance, and personnel practices.
- Sterile and nonsterile compounding training and competency documentation and reconciliation of all ingredients utilized.
- Emergency drug box policy and procedures for pharmacies supplying such.
- Immunization practices and private space compliance with revised rules.
- Proper maintenance of all required pharmacy records.
- Counseling.

Goodbye and Thank You to Stephanie McAntee, CPhT

Stephanie was appointed to the Wyoming State Board of Pharmacy in 2009, and reappointed by Governor Mead in 2013. She has been a pharmacy technician in Virginia and Wyoming and practiced at Albertsons in Laramie, WY, for many years before joining Meds by Mail under the United States Department of Veterans Affairs Health Administration Center. She has recently transferred within Veterans Affairs to Topeka, KS. The Board thanks her for her dedication and commitment. She was a voting delegate for the National Association of Boards of Pharmacy® (NABP®) Annual Meeting and participated in committee work for NABP. Stephanie was the second pharmacy technician to serve on the Wyoming Board.

Wyoming Pharmacy Act Rules and Regulations Revisions January 2014

All chapters were reviewed and revisions to Chapters 1, 3, 4, 6, 9, 12, 13, 15, and 16 include corrections for spelling, numbering, and formatting. Reductions in length, complexity, and total number of rules were promulgated whenever possible at the request of Governor Mead.

Rules have been updated on the Board website at *http://pharmacyboard.state.wy.us,* and the changes are listed on the website in the red-lined versions under the Laws tab and in Items of Interest. A summary of changes is also listed under Items of Interest. The Board "tabled" revisions to Chapter 10, Pharmacy Technician Regulations, and to Chapter 2, General Practice Of Pharmacy Regulations, so that the public comments could be further reviewed.

Wyoming Controlled Substances Act Rules and Regulations Revisions January 2014

All chapters were reviewed and revisions were promulgated to Chapters 1, 2, 3, 5, 6, and 8. The Board held a public comment period and hearing, and followed the 33-step process for rule revisions required in Wyoming. The revised chapters, summaries, and red-lined versions can be found at the Board website under the Laws tab and in Items of Interest.

Schedule of Board Meetings for 2014

- **June 25-26, 2014,** in Casper, WY
- **September 10-11, 2014,** location to be determined
- **December 3-4, 2014,** in Casper

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.

Mary K. Walker, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager