January 2014

News

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

Compliance Officer Resigns for Career Opportunity in the State of Washington

Rich Cieslinski, the Arizona State Board of Pharmacy Controlled Substances Prescription Monitoring Program (CSPMP) manager/compliance officer, has resigned effective December 17, 2013. Mr Cieslinski was presented a plaque that recognizes his 10 years of service as well as his many achievements, teamwork, and dedication. Rich has worn many hats at the Board offices (he has worked at and moved furniture for three of them) including compliance officer, inventory manager, Board meeting "disk jockey" (audio/visual technician), as well as his most recent activities as manager of the CSPMP for the last year. He also has received commendations from the Arizona Department of Racing for his expert advice during an investigation there, and served as an evaluator of the state employee insurance plan when it was out for bid. Last but not least, Rich was the official "picture hanger" for the Board and is solely responsible for the fact that all of the pictures in the Board office are hung straight and spaced evenly. Rich will be missed and everyone at the Board wishes him well in his new endeavors.

New Drug Enforcement Administration Number (Only for Department of Defense Service Providers)

Effective immediately, Drug Enforcement Administration (DEA) officials have notified the industry and other stakeholders that a new DEA registration "number" that begins with the letter "G" will be reserved for and issued for the United States Department of Defense (DOD). The new number will rarely be seen outside of the mail-order environment or at military bases both at home and abroad. The new numbers will follow the existing number format (two letters and seven numbers) and the verification formula used for years.

The "G" series designator applies to the DOD personal service contractors **only** and does not apply to any other federal agency. The DOD's active duty and civil service employees will continue to use their A/B/F series DEA registration numbers.

Pharmacy Board Audit – First Office of the Auditor General Audit Since 1983

The Board staff was kept busy and on their toes the past few months while undergoing a comprehensive audit by the Office of the Auditor General. This is only the second such audit since 1903, the previous one occurring in 1983. It was a two-part audit, consisting of both financial and procedural processes review. For most of the audit, there were three auditors in the office and they had keys to come in after hours as well. The results of the audit (#13-07) can be found at the link *www.azauditor.gov/PADDate.htm.*

The auditors were very thorough and did not forget to review anything. All audit recommendations have been agreed to and the new processes should be in place by their follow-up visit in March 2014. On December 10, 2013, the joint Committee of Reference (COR) voted to extend the life of the Board of Pharmacy for eight more years. Thanks to the auditors for the opportunity they provided to improve operations and to the legislators who served on the COR for renewing the agency as part of their sunset review.

Loss or Theft and Records of Controlled Substances

Cheryl Frush, deputy director for the Board, reports less than satisfactory compliance with the following rule.

Arizona Administrative Code R4-23-1003(A)

2. A loss of a controlled substance shall be reported:
   a. Within 10 days of discovery;
   b. On a DEA form 106;
   c. By the pharmacist-in-charge of a pharmacy or a manufacturer;
   d. By the permittee or designated representative of a full-service wholesaler; and
   e. To the federal Drug Enforcement Administration (DEA), the Narcotic Division of the Department of Public Safety (DPS), and to the Board of Pharmacy. A copy of the DEA form 106 shall be kept on file by the pharmacy permittee. The DEA form 106 shall state whether the police investigated the loss.

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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*.

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3. Every person manufacturing any controlled substance, including repackaging or relabeling, shall record and retain for not less than three years the manufacturing, repackaging, or relabeling date for each controlled substance.
4. Every person receiving, selling, delivering, or disposing of any controlled substance shall record and retain for not less than three years the following information:
   a. The name, strength, dosage form, and quantity of each controlled substance received, sold, delivered, or disposed;
   b. The name, address, and DEA registration number of the person from whom each controlled substance is received;
   c. The name, address, and DEA registration number of the person to whom each controlled substance is sold or delivered or who disposes of each controlled substance; and
   d. The date of each transaction.
5. A full-service drug wholesale permittee or the designated representative shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or designated representative shall conduct this inventory:
   a. On May 1 of each year or as directed by the Board; and
   b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a designated representative.
6. A drug manufacturer permittee or the pharmacist-in-charge shall complete an inventory of all controlled substances in the manner prescribed in subsection (A)(1). The permittee or pharmacist-in-charge shall conduct this inventory:
   a. On May 1 of each year or as directed by the Board; and
   b. If there is a change of ownership, or discontinuance of business, or within 10 days of a change of a pharmacist-in-charge.

Disciplinary Actions and Updates

Pharmacists

Bueno, Lisa (S009676) – Probation terminated. Effective November 6, 2013.

Oxford, Sherri (S009874) – Suspension terminated. Probation imposed. Effective September 18, 2013.

Tobin, Robert (S016952) – Probation terminated. Effective November 6, 2013.

Pharmacies

KVP (Y005701) – Withdrew application for nonresident permit. Effective November 6, 2013 (located in California).

Steven's Pharmacy (Y005444) – Probation on nonresident permit terminated. Effective September 18, 2013 (located in California).

Disciplinary Actions and Updates – Other Health Boards

Arizona Board of Dental Examiners (DDSs, DMDs)

Mendenhall, Wade A. (DDS D05259) – License is fully restored. Effective December 8, 2013.

Arizona Board of Medicine (MDs)

Gomez, Rick J. (MD 33677) – *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 and he is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications or injections of any kind. Effective November 8, 2013.

Harris, Michael J. (MD 46808) – *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 14, 2013.

Kassenbrock, John (MD 17245) – *Letter of Reprimand and Consent Agreement for Practice Restriction* – Respondent issued a letter of reprimand. Respondent's practice is restricted in that he shall be prohibited from injecting local anesthetic agents during the performance of inguinal or femoral hernia repair for a period of five years. Effective October 3, 2013.

Laurel, Edgardo R. (MD 21887) – Non-Disciplinary – *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 October 25, 2013.

Mondschein, Robert J. (MD 32344) – *Interim Consent Agreement for Practice Restriction* – Respondent'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 respondent applies to the Board and receives permission to do so. Effective November 19, 2013.

Arizona Regulatory Board of Physician Assistants (PAs)

Sakakihara-Chavarria, Arthur R. (PA 4404) – License surrendered to the Board. Effective August 29, 2013.

The *Arizona State Board of Pharmacy News* is published by the Arizona 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.

Hal Wand, MBA, RPh - State News Editor
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