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Virginia Board of Pharmacy News

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Board Officer Elections Results and Member Appointments

Elections for the offices of the Virginia Board of Pharmacy chairman and vice chairman for the period of July 1, 2014 through June 30, 2015, were held during the full Board meeting on June 4, 2014. The Board voted unanimously to elect Ellen B. Shinaberry to the position of Board chairman and Empsy Munden to the position of vice chairman. The Board extends appreciation to Jody H. Allen and Ellen B. Shinaberry for their leadership during this past year while serving as chairman and vice chairman, respectively. Also, the Board welcomes new Board member Ryan K. Logan, who replaced David Kozera who completed two full terms on the Board.

Dispensing of Tramadol Must Be Reported to the PMP

Effective July 1, 2014, §54.1-3456.1 of the Drug Control Act adds "drugs of concern" as covered substances that must be reported to the Virginia Prescription Monitoring Program (PMP) when dispensed. The supporting legislation, House Bill (HB) 874, specifically states that "drugs of concern" shall include any material, compound, mixture, or preparation that contains any quantity of the substance **tramadol.** The legislation further authorizes the Board to promulgate regulations to designate other specific drugs and substances as "drugs of concern" if warranted.

Please note that the legislation did not place **tramadol** into a different drug schedule. Tramadol remains a Schedule VI controlled substance in Virginia and is subject to all requirements associated with a Schedule VI drug. The only change in requirements is that the dispensing of tramadol must be reported to the PMP beginning July 1, 2014.

Please contact your pharmacy software application vendor for instructions on actions you may need to take to start reporting the dispensing of **tramadol** prescriptions as of July 1, 2014. HB 874 may be accessed at *http://leg1.state.va.us/cgi-bin/legp504.exe?141+ful+CHAP0664.*

Pharmacists May Authorize Delegates to Access PMP

Pharmacists in Virginia will be able to authorize delegates to make requests for prescription histories to the PMP on their behalf beginning July 1, 2014. In addition to any prescriber, effective July 1, 2014, HB 539 authorizes any dispenser who is authorized to access the PMP to delegate his or her authority to health care professionals who are (i) licensed, registered, or certified by a health regulatory board within the Virginia Department of Health Professions or in another jurisdiction and (ii) employed at the same facility and under the direct supervision of the dispenser.

Pharmacists who wish to authorize a delegate to access the PMP, such as a registered pharmacy technician, may do so by using the form found on the PMP website at *www.dhp.virginia.gov/dhp_programs/pmp/pmp_forms.asp* and submitting it to the PMP for review and approval. The delegate will receive his or her own username and password to access the PMP, and pharmacists will be able to view reports requested by their delegates.

HB 539 may be accessed at *http://leg1.state.va.us/cgi-bin/legp504.exe?141+ful+CHAP0072.*

For more information, please visit *www.dhp.virginia.gov,* e-mail the PMP at pmp@dhp.virginia.gov, or call 804/367-4566.

Prescriptions Written for 'Office Use Only'

A pharmacy may provide prescription drugs to a physician for office use in accordance with §54.1-3435.02 of the Drug Control Act, which states that

> A permitted pharmacy may engage in wholesale distributions of small quantities of prescription

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

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> drugs without being licensed as a wholesale distributor when such wholesale distributions are in compliance with federal law as follows: such wholesale distributions of controlled substances do not exceed five percent of the gross annual sales of prescription drugs by the relevant permitted pharmacy or such wholesale distributions of Schedules II through V controlled substances do not exceed five percent of the total dosage units of the Schedule II through V controlled substances dispensed annually by the pharmacy.

Occasionally, a physician will request prescription drugs by providing the pharmacy with a prescription indicating "For Office Use Only" in the name field. This does not constitute a valid prescription because it is not issued in the name of a specific patient for a specific drug that resulted from a bona fide practitioner-patient relationship. Pharmacists must not dispense prescriptions written "For Office Use Only." To properly transfer the requested drugs, the pharmacist must create an invoice containing the following information: the date of transfer, the name and address of the physician to whom the drugs are to be transferred, the name and address of the pharmacy from where the drugs were transferred, and the kind and quantity of drugs transferred. The transferring pharmacy maintains the original invoice for two years from the date of transfer and provides a copy to the receiving physician or pharmacy. Once received, the physician must indicate the date of receipt on the invoice and maintain the invoice for two years from the date of receipt. If the requested drug is classified as Schedule II, the physician wishing to obtain the drug must execute a Drug Enforcement Administration (DEA) Form 222 as the "purchaser" and provide this form to the transferring pharmacy. The transferring pharmacy would then complete DEA Form 222 acting as the "supplier" in this instance. Copies of DEA Form 222 must then be properly forwarded as required by federal law.

If maintaining a separate record of the distribution electronically in the pharmacy's computer, pharmacists must ensure that the information is not transmitted to the PMP with other dispensing records. Assigning a "prescription" number to the transaction may result in the distribution information being uploaded to the PMP.

Changes to Guidance Document 110-9

Significant changes were made to Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide* at the December 12, 2013, full Board meeting. Changes include:

- Increasing the number of minor deficiencies that result in a consent order and monetary penalty from three to five;
- Addition of Minor Deficiency 43 to be cited rather than Major 6 for the **first** offense where the pharmacist-to-pharmacy technician ratio is exceeded;
- Addition of Minor Deficiency 44 to be cited rather than Major Deficiency 9a when the alarm system does not fully protect the prescription department or is not capable of sending a signal to the monitoring entity when the communication line is not operational, provided there was no loss of drug during the period of non-compliance;
- Addition of Minor Deficiency 45 to be cited rather than Major Deficiency 11 for an insufficient enclosure or locking device, provided there has been no loss of drug;
- Addition of Minor Deficiency 46 to be cited rather than Major Deficiency 12a when Schedule II drugs are not properly stored, provided there has been no loss of drug;
- If the biennial inventory and change of pharmacist-in-charge inventory do not include the expired drugs, Minor Deficiency 13 will now be cited in lieu of Major Deficiency 13;
- The threshold associated with Major Deficiency 15 has changed such that 10 different Schedule II drugs for a six-month period will be reviewed to determine compliance rather than 25 drugs for a three-month period;
- Addition of Major Deficiency 21a to be cited when a pharmacist compounds sterile drug products outside of a United States Pharmacopeia-National Formulary (USP-NF) compliant cleanroom;
- Major Deficiency 34 regarding compliance with requirements for continuous quality improvement was eliminated and combined into Minor Deficiency 42;
- Elimination of Minor Deficiency 3 regarding decreased hours of operation without providing the required notice to the public and Board; and
- Addition of Minor Deficiency 47 to be cited if particle counts, environmental sampling, and smoke pattern testing are not performed under dynamic conditions.

Media-Fill Testing

Depending upon the risk level, media-fill testing must be performed either annually or semi-annually. In Guidance Document 110-36, the Board defined the terms "annually" and "semi-annually" as used in USP Chapters <795> and <797> to mean every 12 months and every six months, respectively. At the December 12, 2013 meeting, the Board amended Guidance Document 110-9 to include the following conditions.

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- Major Deficiency 25a – Media-fill testing for persons performing high-risk level sterile compounding must be performed no later than the last day of the sixth month from the previous certification.
- Major Deficiency 26 – Media-fill testing for persons performing low- and medium-risk level sterile compounding must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated.

Gloved Fingertip Sampling

During inspections it has been observed that gloved fingertip sampling is not always being performed. The requirement in USP Chapter <797> is that

> All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero [colony-forming units]) no less than three times before initially being allowed to compound [compounded sterile products (CSPs)] for human use. After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low and medium-risk level CSPs and semi-annually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use.

Please note, documentation of completion of gloved fingertip sampling must be available for each individual who engages in the preparation of compounded sterile drug products.

Frequently Cited Deficiencies

The deficiencies referenced below may be reviewed in Guidance Document 110-9, found at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm*.

Perpetual inventory (Major Deficiency 15) continues to be the most frequently cited major inspection deficiency. Board Regulation 18VAC110-20-240 states that each pharmacy shall maintain a perpetual inventory of **all** Schedule II drugs received and dispensed, with reconciliation at least monthly. This includes slow moving and expired drugs. During the inspection, you will be asked to provide the inspector with documentation of compliance for 10 different drugs over a six-month period. The perpetual inventory record must accurately indicate the physical count of **each** Schedule II drug "on-hand" at the time of performing the inventory. To comply with the requirement to perform the required "reconciliation" of the perpetual inventory, an explanation for any difference between the physical count and the theoretical count must be noted (refer to Guidance Document 110-16).

The second-most frequently cited minor deficiency (Minor Deficiency 13) is when a required inventory is taken on time but does not include the required components, such as not being signed and dated by the person taking the inventory; failing to indicate whether the inventory was taken prior to the opening of business or after close of business; and not listing drugs in Schedule II separately from drugs in Schedules III, IV, and V. Additionally, it is cited when pharmacies are open 24/7 and fail to clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

Guidance Documents

Board Guidance Documents are available at *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm*. The following Guidance Documents have been added or amended since December 2013:

- **110-9:** Pharmacy Inspection Deficiency Monetary Penalty Guide
- **110-17:** Instructions for Graduates of Foreign Schools of Pharmacy
- **110-23:** Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide
- **110-22:** Use of Dispensing Records to Identify Pharmacist Responsible for Dispensing Error
- **110-27:** Pharmacist-in-charge Responsibilities
- **110-36:** Compliance with USP Standards for Compounding
- **110-38:** Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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