August 2013

Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233
Phone: 804/367-4456 • *www.dhp.virginia.gov/pharmacy*

Board Officer Election Results and Member Appointments

Elections for the offices of the Virginia Board of Pharmacy chairman and vice chairman for the period of July 1, 2013 through June 30, 2014, were held during the full Board meeting on June 18, 2013. The Board voted unanimously to elect Jody H. Allen to the position of Board chairman and Ellen B. Shinaberry to the position of vice chairman. The Board extends appreciation to David Kozera and Jody Allen for their leadership during this past year while serving as chairman and vice chairman. The Board would like to extend its gratitude to Dave Kozera for his dedication, leadership, and professionalism during his eight-year tenure on the Board. For a complete list of current Board members, please visit *www.dhp.virginia.gov/Pharmacy/pharmacy_board.htm.*

Guidance Documents

Board guidance documents referred to in this *Newsletter* are available at *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.*

Domperidone

Domperidone is not a Food and Drug Administration (FDA)-approved drug, and it is not legally marketed in the United States. In June 2004, FDA warned compounding pharmacies, as well as firms that supply domperidone for use in compounding that it is illegal to compound domperidone. In addition, FDA put into place an import alert permitting FDA personnel to detain domperidone shipments of bulk ingredients and shipments of finished drug products offered for importation without an active investigational new drug application. These actions resulted from FDA's concern about the potential health risks associated with the use of domperidone in lactating women. These risks include cardiac arrhythmias, cardiac death, and sudden death.

Although domperidone is not FDA approved, FDA recognizes there are some patients with severe gastrointestinal motility disorders that are refractory to standard therapy who may benefit from the use of domperidone and for whom the benefits of the drug may outweigh its risks. Domperidone is available to these patients through an Expanded Access to Investigational Drugs for Treatment Use program. Under this program, domperidone may be obtained only from certain specified suppliers and authorization must be obtained prior to the importation, interstate shipment, and administration of the drug. It is the Board's understanding that as of July 1, 2013, there are currently no pharmacies in Virginia with FDA approval to possess domperidone.

Obtaining or compounding domperidone not in compliance with FDA requirements may result in an investigation by the Board and FDA. Deficiencies that may be cited during an inspection include Major Deficiency 27 and/or Major Deficiency 25 as listed in Guidance Document 110-9.

Questions regarding FDA's standards for domperidone may be directed to FDA Division of Drug Information at *www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082585.htm,* 855/543-3784, 301/796-3400, or druginfo@fda.hss.gov.

Declining to Fill a Prescription

Virginia law does not compel a pharmacist to fill a prescription. When a pharmacist declines to fill a prescription for any reason, other than for unavailability of the drug prescribed, Board Regulation 18VAC110-20-270 (D) requires that the pharmacist record the following information on the back of the prescription before returning it to the patient: the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist. Please note that the regulation does not require the pharmacist to record an explanation for declining to fill the prescription.

If the pharmacist determines that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it in accordance with Board Regulation 18VAC110-20-270 (E). The forged prescription may be given to a law enforcement official investigating the forgery, or it shall be retained for a minimum of 30 days before destroying it in the event it is needed for an investigation or other legitimate purpose.

Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

Nurse Practitioner Prescriptive Authority Number

Emergency regulations of the joint Virginia Boards of Medicine and Nursing, effective May 8, 2013 through May 7, 2014, revised the disclosure requirement of 18VAC90-49-110 regarding prescriptive authority. Nurse practitioners who are authorized by a practice agreement to prescribe Schedule II through VI drugs are not required to include on the prescription the prescriptive authority number issued to them by the Boards of Nursing and Medicine if their Drug Enforcement Administration (DEA) registration number is included on the prescription. Nurse practitioners who are authorized by a practice agreement to only prescribe Schedule VI drugs and therefore do not possess a DEA registration number must include on the prescription the prescriptive authority number issued to them by the Boards of Nursing and Medicine. Guidance on Virginia prescription requirements is available in Board Guidance Document 110-35.

Purchase of Drugs

Board Regulation 18VAC110-20-395 states that except for an emergency purchase from another pharmacy, a pharmacist may only purchase Schedule II through VI drugs from a wholesale distributor or warehouser licensed or registered by the Board. Major Deficiency 35, found in Guidance Document 110-9, will be cited if it is identified during an inspection that drugs are purchased not in compliance with the regulation. Pharmacists can verify if a wholesale distributor or warehouser holds a current license or registration issued by the Board by using License Lookup on the Board's Web page at *https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi.*

Compliance With USP-NF Standards for Compounding

At the June 18, 2013 full Board meeting, the Board adopted revisions to Guidance Document 110-36, *Compliance With USP Standards for Compounding*. Guidance Document 110-36 addresses deficiencies that are frequently cited during inspections as well as commonly asked questions about sterile and nonsterile compounding. The following is a continuation of frequently asked questions from the May 2013 Board electronic *Newsletter.* Pharmacists are encouraged to review Guidance Document 110-36 in its entirety.

1. **How may a hospital pharmacy "batch producing" a limited quantity of compounded sterile preparations (CSPs) for *in-house* use extend the beyond-use date (BUD) past the default dating in United States Pharmacopeia (USP) Chapter <797>?**

   Each batch must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797>, and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

2. **Do batches less than 25 require sterility testing to be performed?**

   No, however, the batches may not be assigned a BUD that exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP Chapter <71> before CSPs are dispensed or administered for:

   - high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (eg, ampuls, bags, syringes, vials),
   - multiple-dose vials for administration to multiple patients, or
   - CSPs that are exposed longer than 12 hours at 2°C to 8°C and longer than six hours at warmer than 8°C before they are sterilized.

3. **Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?**

   Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

4. **Because batches less than 25 do not require sterility testing to be performed, may the CSP, which may have been autoclaved, be assigned an extended BUD based on stability data?**

   Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The Board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

5. **Does the United States Pharmacopeia–National Formulary (USP-NF) address how long a CSP may hang for infusion?**

   No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

6. **May a pharmacist repackage Avastin® for office administration not pursuant to a patient-specific prescription?**

   No. While pharmacists may repackage a drug product when dispensing a drug pursuant to a patient-specific prescription, a pharmacist may not repackage a drug for another entity. The Board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Virginia Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US FDA. The allowance in Virginia Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does

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not constitute compounding as it does not involve the mixing of two or more substances.

7. **May a pharmacist repackage Avastin pursuant to a patient-specific prescription?**
   Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

Frequently Cited Deficiencies During Routine Pharmacy Inspections

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

Perpetual Inventory (Major Deficiency 15): Failure to maintain the perpetual inventory as required is the most frequently cited deficiency. Board Regulation 18VAC110-20-240 states 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. The perpetual inventory record must accurately indicate the physical count of each Schedule II drug "on hand" at the time of performing the inventory. Furthermore, 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).

Partial Filling (Minor Deficiency 19): For **each** partial filling or dispensing, a dispensing record must exist that includes the dates of filling, quantities of drug dispensed, and the initials of the dispensing pharmacist(s). If the pharmacy uses an alternative record as described in Board regulation 18VAC110-20-255, such as a combination of an electronic and manual record, to record the dispensing or partial filling, the pharmacy must maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted (refer to Guidance Document 110-22).

Labeling of Prescriptions (Minor Deficiency 24): Although a requirement for many years, inspectors continue to identify prescriptions that do not include the generic name on the label when a drug product possessing a single active ingredient is dispensed. Additionally, prescription labels are often found that do not contain the phrase "generic for" followed by the brand name of the drug prescribed when a generic drug is dispensed for a prescription written for a brand-name drug. Terms such as "sub for" or "substitute for" are not compliant with the Board regulation.

Requirement for Nonresident Pharmacy to Submit Current Inspection Report

Effective July 1, 2013, §54.1-3434.1 of the Virginia Drug Control Act requires a nonresident pharmacy applying for registration or renewing a registration with the Board to submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of the Virginia Drug Control Act, including compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding. The inspection report shall be deemed current if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required time period, the Board will accept an inspection report from the National Association of Boards of Pharmacy® that satisfies the inspection report requirements of §54.1-3434.1. Refer to Guidance Document 110-38 for additional information.

Prescription Monitoring Program

Method of Payment Reporting: The "99" code for payment method corresponds to "other," meaning the method of payment does not fit one of the predefined methods of payment such as private pay, Medicare, Medicaid, commercial insurance, Veterans Benefits Administration, workers' compensation, or Indian nations. Private pay includes cash, credit, check, debit, etc. Three percent of prescriptions reported in May 2013, had Code 99 for the method of payment.

When may a dispenser request a prescription monitoring program (PMP) report? The code stipulates that the director has discretion to provide:

> Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with §54.1-3303 when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.

Dispensers may not request a PMP report for any other purpose. Inappropriate use of the PMP may result in disciplinary action being taken by the Board or criminal prosecution.

The *Virginia Board of Pharmacy News* is published by the Virginia 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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