



Virginia Board of Pharmacy

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Board Appointments and Officer Election Results

The following individuals were recently appointed by Governor Bob McDonnell to the Virginia Board of Pharmacy: Robert M. Rhodes, Winchester, VA; Ellen B. Shinaberry, Harrisonburg, VA; Jody H. Allen, Midlothian, VA; and Pratt P. Stelly, Richmond, VA. These individuals join six other current members of the Board of Pharmacy in carrying out the specific duties and powers of the Board, which includes regulating the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, and disposal of drugs and devices. Additionally, Brandon Yi, Great Falls, VA, and John Beckner, Richmond, VA, were recently elected to the positions of Board chairman and vice chairman, respectively, for the period of July 1, 2010 through June 30, 2011. For a complete list of the names of the current Board members, visit www.dhp.virginia.gov/Pharmacy/pharmacy_board.htm.

Pharmacists and Pharmacy Technicians to Renew Licenses

Renewal notification letters were mailed in mid-November. This letter stated that pharmacists and pharmacy technicians may now renew their licenses via the online renewal process on the Board's Web site using a personal identification number (PIN). Either an established log in ID and password from a previous renewal cycle may be used to gain access or licensees may use the license number and PIN provided in the renewal letter. As always, licensees are encouraged to renew online. However, instructions for obtaining a paper renewal form that may be mailed to the Board are included in the notification letter. Renewal fees are as follows: pharmacist active license – \$90; pharmacist inactive license – \$45; and pharmacy technician registration – \$25.

In addition to submitting the renewal fee, each pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2010 calendar year. Each year pharmacists are required to obtain 15 hours per calendar year and pharmacy technicians must obtain five hours per calendar year. Individuals that have not obtained the appropriate amount of CE during 2010 may request a one-time extension for no cause shown. Any subsequent extension requests will be granted for good cause only. Such requests must be made in writing and **prior** to renewing the license. Any individual who requests an extension will have his or her CE audited the following year and be required to submit the original CE documents as proof of compliance. Refer to guidance documents 110-4 and 110-42 at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm for more information related to CE.

Frequently Cited Deficiencies in Community Pharmacies

The new process for performing routine inspections of pharmacies and handling of associated disciplinary matters was piloted in community pharmacies between January and June 2010 and went "live" in July 2010. The following is a description of the most frequently cited deficiencies found in community pharmacies since June 2010. References to "major" or "minor" refer to the major or minor deficiencies as listed on Guidance Document 110-9 found at www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.

Inventories

During an inspection, the inspector will look for three types of inventories. Since inspections are not announced and may be conducted when the pharmacist-in-charge (PIC) is not available, it is strongly recommended that staff, other than the PIC, be familiar with the location of inventories.

- ♦ A **perpetual inventory** (major 15) of all Schedule II drugs received and dispensed shall be performed with reconciliation at least monthly. The inspector will verify that the inventory has been completed in each calendar month and includes all Schedule II drugs, including those not dispensed during that month.
- ♦ A **biennial inventory** (major 13 and minor 12) shall be taken on any date which is within two years of the previous biennial inventory. The inventory is a **physical count**, not an estimate, of all Schedule I through V drugs the pharmacy possesses on the day the inventory is taken, including expired drugs.
Note: At the March, 9, 2011 meeting, the Board clarified in Guidance Document 110-16 found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm the requirement for physically counting drugs in Schedule II and estimating drugs in Schedules III, IV, and V when performing an inventory. Please see the July 2011 *Newsletter* for additional information on this topic.
- ♦ Whenever there is a change in PIC (major 14 and minor 13), a complete **incoming PIC inventory** shall be made of all Schedule I through V drugs on hand. The inventory shall be completed as of the date the individual becomes PIC and prior to opening for business on that date. Please recall that Regulation 18VAC110-20-110 was amended in 2009 to no longer require an outgoing PIC inventory, however, it does require that the pharmacist shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he or she ceases to be the PIC, unless the owner submits written notice to the Board showing good cause as to why this opportunity should not be allowed.

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for

those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.

Safeguards to Implement with 'High Alert' Medications



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 a FDA Med-Watch 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.

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. 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 that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag



check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- ◆ Is this the prescribed drug?
- ◆ Is this the prescribed dose/strength/rate and route of administration?
- ◆ Is this the right patient (use two patient identifiers)?
- ◆ Is this the prescribed frequency?

Additional cognitive checks:

- ◆ Does the drug's indication correspond to the patient's diagnosis?
- ◆ Is this the right drug formulation?
- ◆ Are dose calculations correct?
- ◆ Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- ◆ Is the prescribed dose/frequency/timing appropriate for this patient?
- ◆ Is the route of administration safe and proper for this patient?
- ◆ Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- ◆ A thorough explanation of all expanded access programs available
- ◆ Links to key references and resources that are relevant to the slide content
- ◆ Selected virtual meeting presentations from ASCO Annual Meetings
- ◆ Helpful resources to use with patients

The program is available at <http://university.asco.org/ExpandedAccess> and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admis-

sions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at www.samhsa.gov/newsroom/advisories/1007140544.aspx.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at <http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d>.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- ◆ Recommendations: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm.
- ◆ Response Letter: AMA Scope of Practice Data Series: Pharmacists, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149.
- ◆ Scope of Contemporary Pharmacy Practice, www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150.

The biennial and incoming/outgoing pharmacist-in-charge inventories shall comply with the following requirements:

1. Drugs listed in Schedules I and II shall be maintained separately from drugs in Schedules III, IV, and V.
2. Inventory shall be signed and dated by the person taking the inventory.
3. Inventory shall contain indication whether the inventory was performed prior to the opening of business or after close of business.
4. A 24-hour pharmacy with no opening or closing of business shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.
5. Inventories of Schedule II through V drugs shall be maintained at the same address as the stock of drugs to which the records pertain.
6. Inventory shall be maintained for two years from the date the inventory was taken.

Partial Filling of Prescriptions

When a pharmacist partial fills a prescription, a record shall be made of each partial filling. For each partial filling the record must include the date of filling, quantity of drug dispensed, and the initials of the dispensing pharmacist (minor 19).

Automated Counting Devices

When an automated counting device is used, a bin filling record shall be maintained for one year from the date of filling. The record can be manual or computerized and shall include the following information (minor 27):

1. Drug name and strength, if any;
2. Name of the manufacturer or distributor;
3. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;
4. Any assigned lot number;
5. An expiration date determined according to United States Pharmacopeia guidelines for repackaging;
6. The date of filling; and
7. The pharmacist's initials verifying the accuracy of the process.

If a pharmacy technician fills the bin, be sure the pharmacist who is verifying the accuracy of the process records his or her initials on the bin filling record (major 20).

Labeling Prescriptions

When a drug product is dispensed possessing a single active ingredient, the generic name of the drug is to be included on the label. If a generic drug is dispensed when a prescription is written for a brand name drug, the label is to contain the generic name followed by the words "generic for" followed by the brand name of the drug prescribed, and the label shall also contain the generic's brand name or the manufacturer or distributor of the drug dispensed (minor 24).

Security System

Effective September 2009, Board Regulations require that the security system be capable of sending an alarm signal to the monitoring entity when breached if the primary communication line is not operational (major 9). Pharmacists need to be able to demonstrate or justify to the inspector that the alarm system is capable of meeting this requirement.

Emergency Key

The PIC or a pharmacist on-duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. In lieu of the pharmacist's signature across a seal, the executive director for the Board may approve other methods of securing the emergency access to the prescription department. When approved, it is strongly recommended that the pharmacy maintain this

letter of approval to provide as documentation to the inspector during inspections. A pharmacy using another method for securing the emergency access to the prescription department that was not approved by the Board executive director prior to implementation shall be cited a deficiency (minor 8).

Storage of Drugs

Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs. The inspector will use his or her calibrated thermometer to ensure drugs are stored at the proper temperature within the refrigerator and freezer. A refrigerator is a cold place in which temperature is maintained thermostatically between 2°C and 8°C (36°F and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20°C and -10°C (-4°F and 14°F). A deficiency shall be cited if the pharmacy's refrigerator or freezer is not monitored by a thermometer or the temperature varies from that required by regulation (major 8 and minor 5). Drugs, including dispensed prescriptions awaiting pickup by the patient, that are improperly stored may be embargoed by the inspector.

Update from the Virginia Prescription Monitoring Program

Approximately 1,900 resident pharmacies, nonresident pharmacies, and dispensing physicians submit over one million prescription records each month to the Virginia Prescription Monitoring Program (VPMP). The program database currently maintains over 55 million prescription records; prescribers and pharmacists submit approximately 2,000 requests per day for patient-specific dispensing information, which they use to assist them in making treatment and dispensing decisions. On October 1, 2009, the VPMP turned on 24/7 access with auto-response software. The response to this new capability has been remarkable with the number of pharmacists registered to use the program more than doubling during this period. Additionally, requests received for patient-specific dispensing information have increased from 75,000 in all of 2009, to over 364,000 in 2010 thus far, with prescribers and pharmacists accounting for 98% of all requests to the program.

The VPMP Web site, www.dhp.virginia.gov/dhp_programs/pmp, is the gateway to the VPMP Data Center where pharmacists can apply for registration and submit requests to assist in making dispensing decisions. Other features of the main Web page include an online pain course; laws and regulations; data collection manual; presentations from conferences; registration and other forms; program statistics; reports; and other information of interest.

The VPMP offers an online pain management course developed by the Virginia Commonwealth University School of Medicine, which pharmacists (licensed in Virginia) may complete free of charge and receive up to 6.5 hours of CE credit as approved by the Virginia Board of Pharmacy. The course is case study driven, has a pre and post test, and has several resources that the pharmacist may refer back to again and again as needed. The course is reviewed annually for legislative and regulatory changes and new practice standards. During this past year, a module on pediatric pain management was added to the CE course.