



Virginia Board of Pharmacy

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Nonresident Pharmacies: Statutory Change to Requirement for Submission of Current Inspection Report

As a prerequisite to obtaining registration as a non-resident pharmacy or renewing a nonresident pharmacy registration, the nonresident pharmacy shall 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 United States Pharmacopeia-National Formulary (USP-NF) standards for pharmacies performing sterile and nonsterile compounding. Effective July 1, 2013, §54.1-3434.1 states 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 to the Virginia Board of Pharmacy for registration as a non-resident pharmacy or (ii) no more than two years prior to the date of submission of an application for renewal of a nonresident pharmacy registration with the Board. If the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is located within the required time period, the Board will accept an inspection report from the National Association of Boards of Pharmacy® (NABP®) that otherwise satisfies the inspection report requirements of §54.1-3434.1. Requests for obtaining an inspection from NABP through the Verified Pharmacy Program™ can be sent to vpp@nabp.net or by visiting www.nabp.net/programs/licensure/verified-pharmacy-program.

An application submitted for registration or renewal without an inspection report indicating compliance with the requirements of the Virginia Drug Control Act, including compliance with USP-NF standards for pharmacies performing sterile and nonsterile compounding, will be deemed incomplete and a registration will

not be issued or renewed until such time as a report or other acceptable documentation is produced. Please note that all nonresident pharmacy registrations expire annually at midnight on April 30, unless properly renewed. Additional information may be accessed in Guidance Document 110-38 at www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.

Pharmacist and Pharmacy Technician Renewal

Current pharmacist licenses and pharmacy technician registrations expire at midnight on December 31, 2013. Please note that practicing on a lapsed license or registration is unlawful and constitutes grounds for disciplinary action by the Board. Renewal notification letters will be mailed in early November to your address of record. If your address of record has changed since the last renewal, please update the address either online utilizing “Update Your Information” at www.dhp.virginia.gov/Pharmacy/ or by e-mailing a request to change your address to pharmbd@dhp.virginia.gov.

After the renewal notification letters have been mailed, pharmacists and pharmacy technicians may renew their license or registration via the online renewal process on the Board’s Web page using a personal identification number (PIN). Either an established login 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. Licensees are encouraged to renew online. If you are unable to renew online, the notification letter will include instructions for obtaining a paper renewal form that may be mailed to the Board. Fees for renewals received by the Board by December 31, 2013, are as follows: pharmacist current active license – \$90; pharmacist current inactive license – \$45; and pharmacy technician registration – \$25. You are encouraged to renew early as an additional late fee of \$30 for current active pharmacist licenses, \$15 for cur-

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.

¹Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

²Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

³Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

⁴American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.



FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from
NABP, ACPE, and ACPE providers that will allow licensees
to track their completed CPE credit electronically.*

rent inactive pharmacist licenses, and \$10 for pharmacy technicians must be submitted for renewals received by the Board after December 31, 2013.

In addition to submitting the renewal fee, each current active pharmacist or pharmacy technician must attest to having successfully obtained all necessary continuing education (CE) hours during the 2013 calendar year. Each year pharmacists are required to obtain 15 hours of CE per calendar year and pharmacy technicians must obtain five hours of CE per calendar year. Individuals that have not obtained the appropriate amount of CE during 2013 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 that 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.

When a Pharmacist May Administer Drugs

A pharmacist may administer a drug to a person of any age pursuant to a valid order or prescription that authorizes the pharmacist to dispense and administer the drug. This allowance is supported through the definitions of “practice of pharmacy” in §54.1-3300, “administer” and “practitioner” in §54.1-3401, and the requirement in §54.1-3307(A)(1) for the Board to adopt regulations that include criteria for maintenance of the quality, quantity, integrity, safety, and efficacy of drugs distributed, dispensed, or **administered**.

Pharmacists may also, pursuant to §54.1-3408(W), administer influenza vaccine to minors without a prescription, when acting in accordance with guidelines developed by the Virginia Department of Health. These guidelines may be accessed at www.vdh.state.va.us/epidemiology/flu/Vaccine.htm. Additionally, pharmacists may administer any type of immunization to adults without a prescription, via a protocol authorized by a prescriber and approved by the Virginia Board of Nursing as indicated by §54.1-3408, Subsection I.

Inspection Thresholds

Guidance Document 110-9 “Pharmacy Inspection Deficiency Monetary Penalty Guide,” includes conditions or thresholds that the Board has provided as guidance to the inspector. For example, Major Deficiency 14 states, “No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V.” The Virginia Drug Control Act in §54.1-3434 states, “The succeeding pharmacist-in-charge shall cause an inventory to

be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the **date he becomes pharmacist-in-charge** and prior to opening for business on that date.” While the law requires the incoming pharmacist-in-charge (PIC) inventory to be performed on the date the individual becomes PIC, current Board guidance to inspectors is to not cite a deficiency if the inventory is taken within five days of that date. Since the Board can change guidance provided to inspectors, the expectation is that licensees comply with the requirements of the law or regulation, not the threshold or condition on Guidance Document 110-9.

To review Board guidance documents, visit www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.

Medical Equipment Supplier

Effective July 1, 2013, a permitted medical equipment supplier may distribute sterile water or saline for irrigation to the ultimate consumer. Other items that may be distributed by a medical equipment supplier, pursuant to the lawful order of a practitioner, include hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, solutions for peritoneal dialysis, and those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment.

Pharmacy Technician Registration

Inspectors continue to identify individuals performing pharmacy technician duties that are not properly registered by the Board or enrolled in a Board-approved pharmacy technician training program. The duties restricted to a pharmacy technician in §54.1-3321 of the Code of Virginia may only be performed by an individual registered by the Board as a pharmacy technician or an individual currently enrolled in a Board-approved pharmacy technician training program. The individual enrolled in a Board-approved pharmacy technician training program may perform the duties restricted to a pharmacy technician for no more than nine **consecutive** months from the initial date of enrollment in the technician training program regardless of whether the trainee successfully completed the program or enrolled in a different training program during those nine months. Individuals with current Pharmacy Technician Certification Board (PTCB) certification may not perform pharmacy technician duties unless registered by the Board or enrolled in a Board-approved pharmacy technician training program. Applying for PTCB certification is not considered to be enrollment in a Board-approved training program.

Documentation that a pharmacy technician trainee is enrolled in a Board-approved training program, including the name of the program and date of enrollment, must be available for review by an inspector. Major

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Deficiency 3 will be cited for each individual performing pharmacy technician duties who is not registered as a pharmacy technician or enrolled in a Board-approved pharmacy technician training program.

For individuals that intend to apply for registration based upon completion of a Board-approved pharmacy technician training program and the passing of the Virginia Pharmacy Technician Exam or the Exam for the Certification of Pharmacy Technicians, it is recommended that you verify the program is Board approved. The list of Board-approved programs is available at www.dhp.virginia.gov/Pharmacy/ptprograms.asp.

Applications for registration as a pharmacy technician are accepted online at www.dhp.virginia.gov/Pharmacy/pharmacy_forms.htm#Technician. When applying for registration, you will be required to send the Board a copy of the certificate of completion provided by the Board-approved pharmacy technician training program or supply a current PTCB certification number. Additional information may be read in Guidance Document 110-20 found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

Recent Changes to Board Regulations

Effective August 2, 2013, Regulation 18VAC110-20-355 was amended to remove the requirement in Section C that the counting device be run dry every 60 days; clarify action to be taken in the event of a drug recall; and require the counting device to be cleaned and maintained in accordance with recommended manufacturer guidelines and specifications. Also, effective September 25, 2013, and resulting from a statutory amendment of §54.1-3408 (B) of the Virginia Drug Control Act, Regulation 18VAC110-20-500 was amended to recognize emergency medical service personnel administering drugs pursuant to standing protocols and eliminate the need for the administration record to be signed by the prescriber. The administration record, however, must still accompany the drug kit when it is returned to the pharmacy for exchange.

Lastly, resulting from Governor Bob McDonnell's Regulatory Reform Initiative to reform regulations that are unnecessarily burdensome, the following regulations were amended effective September 26, 2013: 18VAC110-20-20; 18VAC110-20-40; 18VAC110-20-105; 18VAC110-20-270; 18VAC110-20-420; 18VAC110-20-425; and 18VAC110-20-710. The amend-

ments (i) facilitate electronic renewal of licenses; (ii) accommodate verification of practical experience for pharmacy interns coming from other states; (iii) eliminate the requirement for pharmacy technicians to submit documentation of CE to renew registration; (iv) allow for more than one pharmacist to be involved in verifying the accuracy of a prescription and clarifying documentation for each involvement; (v) modify the requirement for labeling in unit-dose dispensing systems to protect patient privacy; (vi) allow for current technology that uses compliance packaging instead of a unit-dose dispensing system in hospitals or long-term care facilities; and (vii) eliminate the requirement for an alarm system for teaching institutions that only stock Schedule VI drugs.

The current revision of the *Regulations Governing the Practice of Pharmacy*, effective September 26, 2013, may be accessed at www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm.

Certification of Hoods and Cleanrooms

Certifying companies must comply with guidelines published by the Controlled Environment Testing Association (CETA). In Guidance Document 110-36, the Board indicates pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with CETA guidelines. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO Standard for each primary and secondary engineering control and not simply indicate "passed."

Additional guidance for complying with USP-NF compounding standards may be accessed in Guidance Document 110-36, found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

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