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Virginia Board of Pharmacy News

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Regulations for Continuous Quality Improvement

Final regulations promulgated pursuant to §54.1-3434.03 of the Code of Virginia for continuous quality improvement (CQI) became effective on December 31, 2014. This law requires each pharmacy to implement a program for CQI in compliance with Virginia Board of Pharmacy regulations or to actively report to a patient safety organization (PSO) that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). To provide sufficient time for pharmacies to come into compliance, the Board will not cite a deficiency during a routine inspection for the first six months from the date the regulations became effective. Thus, through June 30, 2015, if the pharmacy is not in compliance with CQI requirements, the inspector will simply note this as a comment on the inspection report rather than citing a deficiency. As of July 1, 2015, the inspector will cite a minor deficiency for noncompliance.

In a pharmacy that chooses to comply with CQI requirements by actively reporting to a PSO, the inspector will look for a record indicating the date a report was submitted to the PSO. If no dispensing errors occurred within the past 30 days, the record must indicate a "zero report" with date. The record is to be maintained for 12 months from the date of reporting. In a pharmacy that chooses to implement its own CQI program in compliance with Board regulations, the inspector will look for a record that includes the following general information: (1) dates the analysis was initiated and completed; (2) names of the participants in the analysis; and (3) general description of remedial action taken to prevent or reduce future errors. A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. The record is to be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors. The report is not intended to be punitive by revealing patient-specific information associated with dispensing errors, but is intended to demonstrate to the inspector the pharmacy's compliance with CQI requirements. For more information, review §54.1-3434.03 found in *The Pharmacy Act and The Drug Control Act with related statutes* as well as Regulations 18VAC110-20-10 and 18VAC110-20-418 found in the *Regulations Governing the Practice of Pharmacy,* which are both available at *www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm#reg.*

Clarification on Opioid Use or Abuse Continuing Education Requirement in 2015

Board staff has received a number of inquiries regarding the recent decision to require pharmacists to obtain at least one hour of continuing education (CE) in the subject of "opioid use or abuse" during the calendar year of 2015. Please note that the requirement does not specify particular objectives that must be included in the program, nor does it identify a list of approved programs. The general requirement is of a broad nature in order to allow pharmacists the flexibility in choosing an appropriate CE program that focuses on the use or abuse of opioids. The CE must be obtained between January 1 and December 31, 2015.

Background. Pursuant to §54.1-3314.1(J), and to address concerns with prescription drug abuse, the Board is requiring all pharmacists to obtain at least one hour of CE in the subject of "opioid use or abuse" during the calendar year of 2015. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2015, and not in addition to the required 15 hours. This is a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years. This requirement applies only to pharmacists, not pharmacy technicians.

DEA Diversion Awareness Conference

Drug Enforcement Administration (DEA) will be hosting a regional one-day Pharmacy Diversion Awareness Conference (PDAC) on Saturday, May 30, 2015. A second offering of the conference will be held on Sunday, May 31, 2015. Both conferences will be held at the Sheraton Norfolk

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

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, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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Waterside Hotel, 777 Waterside Dr, Norfolk, VA 23510. The PDAC is designed to assist pharmacy personnel in identifying and preventing diversion activity. Each one-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss prevention personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in the state of Virginia. Upon completion of the one-day conference, pharmacists and pharmacy technicians will be eligible to earn up to seven hours of Accreditation Council for Pharmacy Education-approved CE credits. While there is no registration fee, interested pharmacy personnel must register to attend by visiting *www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.* Questions regarding the conference should be directed to ODLL@usdoj.gov.

Safety Recommendation From the NTSB

The National Transportation Safety Board (NTSB) has recently adopted a safety study about the risk of impairment in transportation accidents. As a result, it has made several recommendations, including publication and dissemination of a reminder to all prescribers and pharmacists of the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation. To read an excerpt from the study, please visit the Board's website at *www.dhp.virginia.gov/pharmacy* and click on the link provided in the yellow box.

Pharmacy Security Systems

As a clarification of the notice sent to pharmacists in December 2014 with regard to cellular technology, please note that not all carriers will require an upgrade of your pharmacy's alarm equipment. The alarm company should be contacted to determine which technology is currently being utilized and if an upgrade will be necessary. The amount of work necessary to upgrade the security system will depend on the security system in place, and could involve only a minor modification, but may require a significant modification or possibly a replacement of the security system. Per Board guidance, if the upgrade requires only a change to the circuit board, then a remodel application will not need to be submitted to the Board office. However, if the upgrade involves any other type of action, to include replacement of the alarm panel, then a remodel application must be submitted to the Board office along with the appropriate fee, as the modified or new alarm system must be reinspected. Additionally, the Board advises that documentation should be maintained at the pharmacy that indicates what type of technology is currently being used, if and when an upgrade was performed, and what action was necessary to upgrade the security system. This documentation should be readily available for review by an inspector. At all times, the security system must comply with Regulation 18VAC110-20-180.

Emergency Medical Services

In 2014, Regulation 18VAC110-20-500 was amended to conform to statutory changes in §54.1-3408 of the Drug Control Act to allow emergency medical services (EMS) personnel to administer drugs and devices pursuant to an oral or written order or **standing protocol.** Currently, Board regulation continues to require that the record of administration must accompany the opened kit when presented to the pharmacy for exchange. Additionally, the regulation continues to require that the record of the administration shall continue to be maintained as part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years. In the past, the regulation required the record of administration to be signed by a prescriber who assumed responsibility for the drugs administered to the specific patient. This signed administration record served as the signed order for the administration of the drugs. Because the law now authorizes EMS personnel to also administer drugs pursuant to a standing protocol, the regulation no longer requires that the record of administration be signed by a prescriber if a copy of the standing protocol(s) signed by the EMS operational medical director is maintained by the pharmacy. If drugs are administered pursuant to an oral order, then a signed order is still required for the authorization of these drugs to be administered. In this situation, the record of administration signed by the prescriber could serve as the signed order.

While the state law and Board regulation authorize the administration of drugs by EMS personnel pursuant to a standing protocol, the Board cannot advise as to whether this complies with federal requirements for the administration of drugs in Schedules II-V. Please note that nothing in state law or Board regulation prohibits a hospital pharmacy from requiring EMS personnel to obtain a prescriber signature on the records of administration or provide the pharmacy with a patient-specific order signed by a prescriber for the administration of drugs in Schedules II-V by EMS personnel.

Recently Amended Guidance

Guidance Document 110-9 – Routine Pharmacy Inspection Deficiencies

The Board, at the December 9, 2014 full Board meeting, amended Major Deficiency 25A and Major Deficiency 26 within Guidance Document 110-9 to include the United States Pharmacopeia (USP)-required "gloved fingertip testing" be performed annually (12 months) for persons performing low- and medium-risk level compounding of sterile preparations, and semiannually (six months) for persons performing high-risk level compounding of sterile preparations. The gloved fingertip testing is in addition to the requirements for media fill testing.

Guidance Document 110-36 – Compliance With USP Standards for Compounding

On December 9, 2014, the Board approved several changes to Guidance Document 110-36 relating to the United States Pharmacopeia–National Formulary (USP–NF) standards for compounding. The changes are as follows.

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3. Are there specific educational and training requirements regarding personnel?

Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and [appropriately] don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also [successfully] complete a site-specific training program as required in Regulation 18VAC110-20-111.

4. What [beyond-use date (BUD)] must be assigned to a single dose vial used in preparing a compounded sterile product?

- ♦ If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;
- ♦ If the single dose vial is [punctured] within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;
- ♦ A [punctured] single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center[s] for Disease Control [and Prevention] (CDC) and USP Appendix);

6. How may stability information be taken into consideration when assigning a BUD?

Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional [judgment] of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

7. What concepts, at a minimum, should be taken into consideration when determining drug stability?

Pharmacists should use professional judgment to determine appropriate references of chemical stability information and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:

- ♦ Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
- ♦ Stability of the drug is not concentration-dependent; and,
- ♦ The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

8. What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?

[The Board added the statement that] information regarding skip lot testing may be accessed at *http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm*

25. How often must air and surface sampling be performed?

[The Board added the recommendation that] air and surface sampling should be performed at least quarterly.

To review Guidance Document 110-36 in its entirety, as well as other guidance documents, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.*

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