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Virginia Board of Pharmacy News

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

Executive Director

The Department of Health Professions (DHP) has named Caroline Juran executive director of the Virginia Board of Pharmacy. Ms Juran has been acting executive director of the Board of Pharmacy since the August 2010 retirement of Elizabeth Scott (Scotti) Russell. Caroline Juran joined the Board of Pharmacy in 2005 as deputy executive director. A graduate of the School of Pharmacy at Virginia Commonwealth University (VCU), following studies at the College of William and Mary, Ms Juran worked in both community and long-term care pharmacies, where she held certification as a geriatric pharmacist and served as a preceptor for the School of Pharmacy at VCU.

Inventories

At the March 9, 2011 meeting, the Board clarified the requirement for taking an inventory of drugs in Schedules I-V. As indicated in Guidance Document 110-16, found at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm*, those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and they are unable to determine the exact kind and quantity of the drug loss. Otherwise they may perform the inventory in a manner consistent with federal allowances, which require a physical count of drugs in Schedule I and II, and allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules. Nothing shall prohibit those persons from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

New Inspection Process Update

In July 2010, the Board went live with the new inspection process for "community" pharmacies and began piloting the new process for hospitals and other institutional pharmacies. The Board intends to end the pilot inspections and go live with the new inspection process for all pharmacies beginning in July 2011. Consistent with the past, routine inspections will be unannounced. Inspections resulting in cited deficiencies as identified in Guidance Document 110-9 may lead to the inspector leaving a pre-hearing consent order at the conclusion of the inspection, which may involve a monetary penalty. Many of the deficiencies listed in the guidance document are not written identically to the actual requirement in law or regulation, but instead are written to reflect the threshold at which an inspector will cite a deficiency. For example, Major Deficiency 13 indicates that a biennial inventory taken more than 30 days late is a deficiency. The actual law requires the biennial inventory to be taken on any date which is within two years of the previous biennial inventory; however, the Board has established guidance indicating that a deficiency will not be cited if the biennial inventory is taken within 30 days of the date it should have been taken. Additionally, the guidance document indicates the monetary penalty that is associated with a deficiency. The citing of a major deficiency automatically results in a monetary penalty being imposed. The citing of an individual minor deficiency will not result in a monetary penalty, however, a monetary penalty of $250 will be imposed when three minor deficiencies are cited during a routine inspection. An additional $100 monetary penalty will be added for each additional minor deficiency cited.

The Board amends Guidance Document 110-9 as necessary to improve the inspection process and address new issues. At the June 8, 2011 meeting, the Board approved changes to the following deficiencies: Major Deficiencies 9a, 12a, 16, 17, 23, and 24; and Minor Deficiencies 1, 9, 16, 17, 24, 26, and 38. Pharmacists and pharmacy technicians are encouraged to review the current guidance document and perform a self-inspection to proactively identify and correct any potential deficiencies. Information regarding the new inspection process may be accessed in the yellow box on the homepage at *www.dhp.virginia.gov/Pharmacy/default.htm*.

Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

- Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
- Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
- Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
- Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
- Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts. Further, ISMP calls on FDA to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

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 is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning: Benzocaine Use and Rare, But Serious Condition

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov*.

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 60 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov*.

Frequently Cited Inspection Deficiencies

The major and minor deficiencies listed below reference deficiencies found in Guidance Document 110-9, which may be accessed at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Partial Filling of Prescriptions

The most frequently cited inspection deficiency is the failure to document the partial filling of a prescription (Minor 19). 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. **Inspection tip:** Pharmacists must be prepared to show the inspector how they document the partial filling of a prescription.

Perpetual Inventory

The second most frequently cited inspection deficiency is failure to perform a perpetual inventory of all Schedule II drugs (Major 15). Board Regulation 18VAC110-20-490 requires that each pharmacy shall maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly. Electronic monitoring at the pharmacy or by another entity that provides alerts for discrepancies between drugs received and drugs dispensed is acceptable provided such alerts are reviewed at least monthly. It should be noted that the Board softened the parameters for citing this deficiency during the March 2011 meeting when it created a more liberal window for when the inventory may be performed. Currently, the monthly perpetual inventory may be performed as early as seven days prior to the applicable calendar month and taken as late as seven days after the applicable calendar month. For example, the July perpetual inventory may be performed as early as June 24, and as late as August 7. In general, a deficiency will be cited when a perpetual inventory is performed more than seven days prior or more than seven days after the designated calendar month for which an inventory is required. **Inspection tip:** Be prepared to provide the inspector with documentation clearly indicating on which date the perpetual inventory and reconciliation was performed. Be sure to inventory all Schedule II drugs, to include slow moving drugs not dispensed during the month and expired Schedule II drugs.

Inventories

Other issues involving inventories contribute to the next most frequently cited group of deficiencies. The Drug Control Act states that a biennial inventory shall be taken on any date which is within two years of the previous biennial inventory. Additionally, it states that whenever there is a change in pharmacist-in-charge (PIC), a complete incoming PIC inventory shall be made of all drugs on hand in Schedules I-V and that the inventory shall be completed as of the date the individual becomes PIC and prior to opening for business on that date. Major Deficiency 13 and Minor Deficiency 13 indicate the level of non-compliance at which a deficiency will be cited for these requirements. Inspection tip: Be sure the inventories are taken on time and comply with the following requirements:

1. drugs listed in Schedules I and II are maintained separately from drugs in Schedules III, IV, and V;
2. the inventory is signed and dated by the person taking the inventory;
3. the inventory indicates whether it was performed prior to the opening of business or after close of business;
4. for a 24-hour pharmacy with no opening or closing of business, documentation clearly indicating whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken; and
5. the inventory includes expired drugs on hand.

Storage of Drugs in a Refrigerator or Freezer

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 (Major 8 and Minor 5). The inspector will use a calibrated thermometer to ensure drugs are stored at the proper temperature within the refrigerator and freezer. A deficiency will be cited if the pharmacy's refrigerator or freezer is not monitored by a thermometer or the temperature meets the level of noncompliance as identified in the guidance document. **Inspection tip:** Be sure there is a functioning thermometer in each refrigerator or freezer where drugs are stored or awaiting pick-up by the patient and that the proper storage temperature is maintained. Do not overcrowd drugs within the refrigerator or freezer as this may prohibit proper airflow which may adversely affect the drug storage temperature. Ensure that vaccines or other drugs required to be stored at specific temperatures are stored properly. Improperly stored drugs may be embargoed by the inspector.

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. 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 or storing the key or alarm code for emergency access in an envelope or other container which is not sealed or bearing the pharmacist's signature across

continued on page 5

continued from page 4

the seal shall be cited a deficiency (Minor 8). **Inspection tip:** If using an envelope or other container, be sure it is sealed in a manner to prevent removal of the key and alarm code and that the pharmacist's signature is placed across the seal. If using a "see through" envelope or container, be sure the alarm code cannot be read through the container. If using another method approved by the executive director, it is recommended that the pharmacy maintain the letter of approval to provide as documentation to the inspector during an inspection.

Electronic Prescriptions for Controlled Substances

On June 1, 2010, the Drug Enforcement Administration (DEA) Interim Final Rule on "Electronic Prescriptions for Controlled Substances" became effective. Prescribers may not electronically transmit prescriptions for drugs in Schedules II-V and pharmacies may not dispense these electronically received prescriptions until the applications used by both the prescribers and the pharmacies to process prescriptions comply with the requirements of the DEA rule. While it is thought that application systems may soon be capable of meeting DEA requirements, a pharmacy may not dispense an electronically transmitted prescription for drugs in Schedules II-V until the application provider provides the pharmacy with an auditor or credentialing body's report indicating that the application complies with DEA requirements. Prior to receiving such report, if a pharmacist receives an electronically transmitted prescription for a drug in Schedules III, IV, or V, the pharmacist may only dispense the prescription after calling the prescriber's office to **verify** the prescription and treating it as a verbal order. Note that an electronically generated prescription for drugs in Schedules II, III, IV, or V that is printed out and given to the patient or is faxed to the pharmacy must be manually signed by the prescriber even if it bears an electronic signature. Information about the DEA rule is available at *www.deadiversion.usdoj.gov/ecomm/e_rx/index.html.*

Legislative Changes Regarding Proof of Identity

The 2011 General Assembly passed HB 2256, which amends §54.1-3420.1 of the Drug Control Act regarding proof of identity when filling prescriptions. The amendments are scheduled to become effective July 1, 2011. The bill amends the statute to allow an agent of the pharmacist to perform certain acts, describe information to be collected by the pharmacist or his agent, and reduce the documentation retention period from one year to one month. The bill is written that a pharmacist, or his agent, shall require proof of identity at the time of delivery from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. If the person seeking to take delivery of the Schedule II drug is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID, but no documentation is required.

More information regarding proof of identity may be read in the subsequently amended Guidance Document 110-11, found at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.*

Automated Devices for Dispensing and Administration of Drugs in Hospitals

Please be aware that effective March 17, 2011, Regulation 18VAC110-20-490 was amended to remove the requirement to obtain a nurse or other person's signature on the delivery record for Schedule II through V drugs at the time drugs are loaded into the automated dispensing device.

September 2011 Full Board Meeting Rescheduled

Please note that the September full Board meeting has been rescheduled to September 22, 2011, at 9 AM.

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.

Caroline Juran, Executive Director - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
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