

July 2012

News



# Virginia Board of Pharmacy

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Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233

Phone: 804/367-4456 • [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy)

## **Board Officer Elections Results and Member Appointments**

Elections for the offices of the Virginia Board of Pharmacy chairperson and vice chairperson for the period of July 1, 2012 through June 30, 2013, were held during the full Board meeting on June 12, 2012. The Board voted unanimously to elect David C. Kozera to the position of Board chairperson and Jody H. Allen to the position of vice chairperson. The Board extends appreciation to Gill Abernathy and David Kozera for their leadership during this past year while serving as chairperson and vice chairperson. Also, Dinny Li was appointed by Governor Bob McDonnell as a citizen member to the Virginia Board of Pharmacy.

## **Virginia Medical Reserve Corps**

The Board would like to increase the awareness of pharmacists and pharmacy technicians of the Virginia Medical Reserve Corps (MRC) and the current need for pharmacists and pharmacy technicians to receive necessary training to assist local MRC during emergency situations. According to the Department of Health, while a significant number of pharmacists and pharmacy technicians have provided emergency contact information when renewing their pharmacist licenses and pharmacy technician registrations indicating that they would be willing to assist their communities during an emergency, most of these individuals have not received the necessary training offered by the MRC to ensure they will be able to operate and apply their skills under emergency situations and conditions. As a result, many local MRC units have people without a pharmacy background who will supervise the dispensing at places of dispensing (POD). Because pharmacists and pharmacy technicians possess specialized training and experiences critical for accurately and efficiently dispensing drugs, pharmacists and pharmacy technicians can greatly assist their local MRC units by getting involved and receiving necessary training. In addition to significantly contributing to the dispensing process during emergencies, local MRCs need volunteers with pharmacy knowledge and experience to help develop their training programs to ensure best practices are taught for meeting the community needs during emergencies.

The Virginia MRC is a force of dedicated volunteers who stand ready to support the community in the event of a public health emergency. The mission of the MRC is to engage vol-

unteers to strengthen public health, emergency response, and community resiliency. MRC units are community-based and function as a way to locally organize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies and promote healthy living throughout the year. MRC volunteers supplement existing emergency and public health resources.

MRC volunteers include medical and public health professionals such as physicians, nurses, pharmacists, dentists, veterinarians, and epidemiologists. Many community members – interpreters, chaplains, office workers, legal advisors, and others – can fill key support positions. Each of the 31 local MRC units is composed of teams of medical and public health professionals who, along with interested community members, volunteer their skills, expertise, and time to support ongoing public health initiatives and assist during emergencies throughout Virginia.

The Virginia MRC local units have many needs for pharmacists and pharmacy technicians. These needs are both general and specific in nature. The specific needs include pharmacy services at medical shelters. Many patients will arrive without their medications, and knowledgeable staff will be required to assist in determining which medications are needed. One of the largest and most vital needs will be if mass dispensing or immunizations are required. PODs will open where the population will go for their medications. These PODs will be staffed by lay volunteers. It is ideal that the lay volunteers be trained and supervised by pharmacists or pharmacy technicians. The minimum needs are four pharmacists or pharmacy technicians per POD. To staff the PODs across the state will require approximately 1,500 pharmacists and pharmacy technicians.

During emergencies, the conditions, procedures, and facilities used to dispense drugs may be significantly different from typical pharmacy practice. One of the goals of the local MRC units is to prepare people to provide services under emergency conditions. Because each community has different needs, the MRC units throughout Virginia vary in structure and activities. To learn more about a Virginia MRC unit near you and to apply to become a volunteer visit [www.vamrc.org](http://www.vamrc.org). You can also “like” the Virginia Medical Reserve Corps on Facebook.

*continued on page 4*



## **FDA Warned Medical Practices About Counterfeits in US and Risks to Patients**

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm), may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm).

### **Rethink the Vial**



*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](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid pre-

scriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request Parents' Guide to Understanding Prescription Drug Abuse brochures for distribution to your patients, visit [www.SafeguardMyMeds.org](http://www.SafeguardMyMeds.org).

### **Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports**

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at [www.abbott.com/vicodin-consumer-alert.htm](http://www.abbott.com/vicodin-consumer-alert.htm). Abbott advises that anyone who has the counterfeit ver-

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sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at [www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm](http://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

## **PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits**

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at [www.safemedicines.org/resources-for-healthcare-professionals.html](http://www.safemedicines.org/resources-for-healthcare-professionals.html). Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

## **FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches**

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm). Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at [www.fda.gov/Drugs/DrugSafety/ucm300747.htm](http://www.fda.gov/Drugs/DrugSafety/ucm300747.htm). Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWARE<sub>x</sub>E<sup>®</sup> Web site at [www.awarerx.org/informedSiteMap.php](http://www.awarerx.org/informedSiteMap.php).

## **Providers Asked to Advise Patients of Acetaminophen Safe Use Steps**

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWARE<sub>x</sub>E Web site at [www.awarerx.org/OTCMedUse.php](http://www.awarerx.org/OTCMedUse.php). The AWARE<sub>x</sub>E consumer protection program and the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) are part of the Acetaminophen Awareness Coalition.



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continued from page 1

The content of this article was contributed by Chuck Baker, pharmacy consultant for Emergency Preparedness and Response, Virginia Department of Health. Mr Baker can be contacted at [charles.baker@vdh.virginia.gov](mailto:charles.baker@vdh.virginia.gov).

## **Prescription Monitoring Program 2012 Legislation Update**

The following changes to Chapter 25.2 of the Code of Virginia became effective on July 1, 2012:

- ◆ Method of payment for a controlled substance prescription was added as a required element for reporting to the Prescription Monitoring Program (PMP); see ASAP Version 4.1, DSP 16 for information on how to report this information.
- ◆ Removed the restriction on how many licensed health care professionals a prescriber could designate to serve as a delegate.
- ◆ Expanded access to all federal law enforcement with drug diversion investigatory authority and the existence of a specific open investigation related to a specific person, prescriber, or dispenser.
- ◆ Expanded the authority of the PMP to allow the sending of unsolicited reports on patients who meet or exceed certain criteria to the Drug Diversion Unit of the Virginia State Police.

### **Frequently Asked Question of the PMP**

**Q:** When reporting the dispensing of a prescription for a buprenorphine product, is the “X” number of the prescriber required to be reported in PRE02 of the ASAP Version 4.1 reporting format?

**A:** No. The Drug Enforcement Administration (DEA) number of the prescriber (eg, BA1234567) is required to be entered in PRE02 for all prescriptions reported to the program.

### **Compliance with USP Standards for Compounding**

Media-fill testing is required when performing low, medium, and high-risk level compounding of compounded sterile preparations (CSPs). USP35-NF30 states:

Media-Fill Test Procedure – This test or an equivalent test is performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level CSPs. Once begun, this test is completed without interruption. Quality assurance procedures for medium-risk level CSPs include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually or more frequently. In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs.

On June 12, 2012, the Board approved changes to Guidance Document 110-36. The terms “annually” and “semiannually” as used in United States Pharmacopeia (USP) Chapters 795 and 797 are defined to mean every 12 months and every six months, respectively. Records associated with annual and semiannual requirements shall be maintained for two years from the date performed. Such records may be maintained in off-site storage

or as an electronic image that provides an exact image of the document that is clearly legible provided such off-site or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the Board or an authorized agent. Board of Pharmacy guidance documents are available at [www.dhp.virginia.gov/Pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm).

### **Prescriptions from Out-of-State Prescribers and Patients**

Both the Board and DEA are receiving an increasing number of calls from Virginia pharmacists seeking guidance on filling prescriptions from out-of-state prescribers for patients who do not reside in Virginia. For example a patient from Ohio presents a prescription from a prescriber in Florida at a pharmacy located in Richmond, VA. Code of Virginia §54.1-3303 does allow a Virginia pharmacy to dispense a controlled substance pursuant to a prescription issued by an out-of-state prescriber if the prescription complies with Virginia’s requirements. However, while the Board cannot advise a pharmacist to fill or decline a prescription, there are several “red flags” the pharmacist may consider when determining if the prescription should be filled. Examples of red flags may include:

- ◆ patients who reside in another state are routinely returning to the Virginia pharmacy presenting prescriptions for multiple controlled substances, such as oxycodone and benzodiazepines, written by out-of-state prescribers;
- ◆ upon return to the Virginia pharmacy, the patient is accompanied by an increasing number of friends with prescriptions; multiple patients all present identical or similar prescriptions from the same out-of-state prescriber;
- ◆ the patients pay for the prescription using cash or credit card – there is no third-party billing; and
- ◆ the patient who resides in another state may simply justify having the prescriptions dispensed in Virginia because it is cheaper than in his or her home state.

Pharmacists must exercise professional judgment when determining a prescription’s validity. Contacting the out of state prescriber may or may not necessarily alleviate a pharmacist’s concern and the pharmacist is encouraged to consider other relevant factors before dispensing the medication. The law does not require a pharmacist to dispense a prescription; however, if the pharmacist declines a prescription for any reason other than the unavailability of the drug prescribed, the following information shall be recorded on the back of the prescription: the word “declined”; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist. When warranted, a pharmacist may also contact the Virginia State Police and the local DEA field office for possible investigation.

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Page 4 – July 2012

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