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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 Announces Retirement

Elizabeth Scott "Scotti" Russell, executive director of the Virginia Board of Pharmacy, announced at the June 2, 2010 full Board meeting that she will retire from the state effective August 1, 2010, having worked in public service for over 32 years. Ms Russell began her career as a staff pharmacist at Hiram Davis Pharmacy, then worked as an inspector for the Department of Health Professions for nine years prior to assuming the role as executive director of the Virginia Board of Pharmacy in 1991. During her 19 years as executive director, she has been instrumental in developing legislation and Board regulations and has provided the Board with strong leadership as it served the public to ensure safe and competent patient care. The Board would like to extend its appreciation and gratitude to Ms Russell for her many years of dedicated service and wishes her well in her future endeavors.

CPAP and BiPAP Devices Sold by a Medical Equipment Supplier

A facility licensed as a medical equipment supplier may dispense continuous positive airway pressure (CPAP) machines and bilevel positive airway pressure (BiPAP) machines pursuant to a prescription. These devices, commonly used to treat sleep apnea, deliver a stream of compressed air at a prescribed pressure rate via a hose often attached to a nose mask or full-face mask. Recently, there was question as to whether the fitting of such masks and manipulation of the device's pressure rate were tasks that only a respiratory care therapist may perform.

On October 6, 2009, the Advisory Board on Respiratory Care within the Board of Medicine reviewed this issue and determined that the setting of pressures on CPAP and BIPAP machines is a task that could clearly be performed by trained personnel of a durable medical equipment company. Additionally, it acknowledged that there was no law or regulation that specifically stated that the task of fitting masks was clearly defined as the practice of respiratory care and that it appeared that the task of fitting a mask could be safely accomplished by a properly trained individual with any subsequent compliance issues being referred to the prescribing physician. To read the full minutes from the October 6, 2009 meeting of the Advisory Board on Respiratory Care visit *www.dhp.virginia.gov/medicine/medicine_minutes_archive.htm#RESPIRATORYCARE.*

New Legislation Effective July 1, 2010

Proof of Identity

The 2010 General Assembly passed HB 964 which amends §54.1-3420.1 of the Drug Control Act by adding several requirements regarding proof of identity when filling prescriptions. The law now allows a pharmacist to require proof of identity prior to dispensing or refilling prescriptions written for drugs in Schedules III through V. Additionally, it is written that a pharmacist shall require proof of identity from any person seeking to take delivery of any Schedule II drug before dispensing such drug, unless such person is known to the pharmacist. "Proof of identity" is defined to mean a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address. When proof of identity is required, the pharmacist shall make a photocopy or electronic copy of the identification, or an electronic record documenting that proof of identity was provided. There is confusion, however, regarding the pharmacist's record keeping requirements, because the law provides an option to maintain an electronic record yet requires the maintenance of copies of identification. Therefore, the Board interpreted at the June 2, 2010 full Board meeting that a pharmacist may make a photocopy or electronic copy of the identification, or an electronic record documenting that proof of identity was provided, and that whichever type of record is used, it must be maintained for at least one year.

Additionally, if the person seeking to take delivery of the Schedule II drug is not the patient for whom the drug is prescribed, then the pharmacist shall record the full name and address of such person, regardless of whether this person seeking to take delivery of the drug is known to the pharmacist. This record of names and addresses shall be maintained by the pharmacist for a period of at least one year. While the law does not directly address where the names and addresses shall be recorded, it is reasonable to construe that this information may be captured in the pharmacy's automated data processing system, a logbook, or on the prescription.

Lastly, the statute requires that when a pharmacy delivers a Schedule II drug by mail, common carrier, or delivery service to a Virginia address, that the method of delivery employed shall require the signature of the recipient as confirmation of receipt. To read §54-1-3420.1 in its entirety, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm* and open the document entitled *The Pharmacy Act and The Drug Control Act with related statutes.*

Prevention of Communicable Disease

HB 286 was also passed by the 2010 General Assembly and amends §54.1-3303 of the Code of Virginia by authorizing a health care practitioner to prescribe Schedule VI antibiotics and antiviral agents to a person in close contact with a diagnosed patient of the practitioner without first conducting a physical examination of the person when

continued on page 4

FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.*

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA 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.*

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see *www.ismp.org/Tools/confuseddrugnames.pdf* for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when Norvasc® is entered into the computer, a formulary note screen appears, alerting the pharmacist that Norvasc often looks like Navane® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at *www.fda.gov/AboutFDA/WhatWeDo/track/default.htm*. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm*, Center FDA-TRACK Program Areas available at *www.fda.gov/*

AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor® (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin® which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5 % to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at *http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml*.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

continued from page 1

the practitioner has a bona fide practitioner-patient relationship with the diagnosed patient, the practitioner meets all requirements for a bona fide practitioner-patient relationship with the person in close contact with the diagnosed patient other than the requirement for a physical examination, the practitioner believes that there is urgency to begin treatment to prevent transmission of a communicable disease, and emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. Examples of communicable diseases for which this may apply include meningococcal meningitis, H. influenzae meningitis, pertussis, pandemic flu (worse than H1N1 influenza virus), and anthrax. To review §54.1-3303 in its entirety, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm* and open the document entitled *The Pharmacy Act and The Drug Control Act with related statutes.*

New Inspection Process Update

The Board has been piloting its new inspection process for performing routine inspections of "community" or "retail" pharmacies since January 2010. During this piloting phase, no pre-hearing consent orders involving monetary penalties have been issued. However, the Board intends to cease the piloting phase for community or retail pharmacies and go live with the new process in July 2010. Therefore, pharmacists working in these environments and pharmacy owners should be aware that an inspection 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. Until September 1, 2010, pharmacy inspectors will continue to call pharmacies alerting them to the fact that a routine inspection will be performed of the facility at some point within a two-week period. After September 1, 2010, inspections will resume an unannounced schedule.

During the June 2, 2010 full Board meeting, the Board determined it is now ready to begin piloting this new inspection process in hospital and other institutional pharmacies. Consistent with the Board's procedures for piloting the process in community pharmacies, pharmacy inspectors will schedule or announce the performing of a pilot inspection in hospital or institutional pharmacies; the inspection will not result in the issuance of a monetary penalty during this piloting phase.

Background information regarding the new inspection process may be accessed in the yellow box on the homepage at *www.dhp.virginia.gov/Pharmacy/default.htm.*

Amended Guidance Documents

Please note that Guidance Document 110-27 regarding pharmacist-in-charge responsibilities was recently amended to clarify storage and record keeping requirements and includes language regarding the new inspection process. Additionally, Guidance Document 110-35 was recently amended to address Drug Enforcement Administration's Interim Final Rule for e-prescribing. Both guidance documents may be accessed by visiting *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.*

Perpetual Inventory of Schedule II Drugs

Based on recent calls to the Board office, there appears to be confusion regarding the requirement for a pharmacy to maintain a perpetual inventory of all Schedule II drugs received and dispensed, with reconciliation at least monthly as indicated in Regulation 18VAC110-20-240. Please note that the pharmacy's documentation must indicate that a reconciliation was performed on **every** Schedule II drug in stock at least once per calendar month, eg, January, February, March. If a particular drug was not dispensed that month, it must still be reconciled. Additionally, the reconciliation process of all Schedule II drugs is not required to be performed on a single day, ie, the reconciliation process may occur over multiple days as long as each drug is reconciled at least once per calendar month.

Regulation 18VAC110-20-240 may be accessed online at *www.dhp.virginia.gov/Pharmacy/leg/PharmacyRegs_03172010.doc#_Toc256065633.* The definition of "perpetual inventory" may be found in Regulation 18VAC110-20-10.

Use of the Virginia Prescription Monitoring Program

It has come to the attention of the Virginia Prescription Monitoring Program (VPMP) that some employers would like to obtain dispensing history information for employment purposes. Please note that this is not permitted as it is a violation of Virginia law to request information from the VPMP for this reason. Pharmacists who are registered users of the VPMP, however, may request the dispensing history of drugs in Schedules II-IV for the purpose of establishing a prescription history to assist the pharmacist in determining the validity of a presented prescription in accordance with §54.1-3303. Additionally, a pharmacist may make a request on behalf of a prescriber if the pharmacist is serving as an authorized delegate of the prescriber as indicated in Regulation 18VAC76-20-60.

Once the pharmacist has received the dispensing history report, he or she may discuss the contents of the report with the patient, another health care provider treating the patient, or a dispenser who has dispensed or will dispense medications to the patient. Additionally, a pharmacist may enter a comment in the prescription record to document the use of the VPMP in the dispensing decision process. However, the report must not be maintained in the prescription files or given to anyone, including the patient. The report is the requesting pharmacist's property, and Virginia law firmly prohibits further distribution of VPMP reports. As indicated in §54.1-2525 of the Code of Virginia, any person who obtains dispensing history reports from VPMP for an unauthorized use or discloses confidential VPMP information in violation of the Code shall be guilty of a Class 1 misdemeanor upon conviction. Such conviction shall also serve as grounds for disciplinary action by the relevant health regulatory board. Should a patient over the age of 18 request a copy of his or her dispensing history report from a pharmacist, the pharmacist must advise the patient to submit his or her own request for this information directly to the VPMP.

To become a registered user, access VPMP online at *https://www.pmp.dhp.virginia.gov/VAPMPWebCenter/login.aspx* and click on "Not a user? Register to become a user." Fill out the form completely and click "Submit." Additionally, print the form, sign and date it, and fax it to 804/527-4470. Once the request for registration is verified and approved, a username, temporary password, and directions for using the program will be provided to the pharmacist via e-mail.

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Elizabeth Scott Russell, RPh, Executive Director - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
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