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Virginia Board of Pharmacy

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

Published to promote voluntary compliance of pharmacy and drug law.

Date for Compliance with USP Chapter 797 Revised; Monetary Penalty May be Enforced

§54.1-3410.2 requires pharmacies performing sterile or nonsterile compounding to comply with United States Pharmacopeia (USP) standards. Specifically, requirements regarding sterile compounding are addressed in USP Chapter 797, "Pharmaceutical Compounding – Sterile Preparations." This chapter was recently revised, and the final revision was published in December 2007 with an effective date of June 1, 2008. As a result of the changes to USP Chapter 797, the Virginia Board of Pharmacy decided to allow a one-time extension until October 31, 2008, for pharmacies to comply with the physical standards provisions. Pharmacies that are currently noncompliant with the physical standards are not required to contact the Board, but are expected to meet full compliance with USP Chapter 797 by October 31, 2008. After this date, the Board will begin enforcing the physical standards provisions, and noncompliance may result in a monetary penalty of not more than $5,000 per violation. Each sterile preparation that is compounded under conditions not in conformity with §54.1-3410.2, and by reference USP Chapter 797, may constitute a single violation. This recent decision is noted in the last paragraph of guidance document 110-36, which may be accessed at *www.dhp.virginia.gov/Pharmacy/guidelines/110-36%20Compliance%20with%20USP%20Chapter%20797-June%202008.doc*.

Expiration Date for Pharmacy Permits Anticipated to Change

Currently, all licenses issued by the Board, approximately 25,000, expire on January 1 annually. In an effort to more evenly distribute workload, legislation was sought to remove the statutory requirements that certain licenses expire on January 1 annually, and to allow the Board to set an annual expiration date by regulation. The 2008 General Assembly approved the statutory changes, and the Board is currently in the process of amending regulations on the subject. At the June full Board meeting, the Board approved draft emergency amendments to the regulations that would allow pharmacy permits and nonresident pharmacy registrations to expire on April 30 annually, and all other facility permits, licenses, or registrations, eg, medical equipment supplier permits, wholesale distributor registrations, manufacturer registrations, controlled substances registration certificates, to expire on February 28 annually.

As with all regulatory changes, an administrative review of the Board-approved draft emergency amendments must occur prior to the regulations becoming final. The Board anticipates the regulatory changes to be approved and to become final this fall; therefore, the current expiration date for all facility permits will be extended accordingly. Thus, a pharmacy with a permit currently indicating an expiration date of December 31, 2008, will in effect be changed to an expiration date of April 30, 2009. Therefore, the renewal period for renewing a pharmacy permit will not begin until mid-March. Notification letters will be sent this fall to all facilities informing them of the extension of the expiration date for their facility permits and alerting them that their facility permits may not be renewed until mid-March 2009. A second notification letter will be sent in early March 2009 announcing the beginning of the renewal cycle for pharmacy permits and nonresident pharmacy registrations and instructing facilities on how to complete the renewal process. The actual renewal process will remain the same as previous years, only the dates surrounding the renewal cycle will change.

Please note that the Board-approved draft emergency regulatory amendments will not affect licenses and registrations issued to individuals, ie, pharmacists and pharmacy technicians. All pharmacist licenses and pharmacy technician registrations will continue to expire on December 31 annually. Therefore, renewal notification letters will be mailed in early November, as done in the past, alerting pharmacists and pharmacy technicians that it is now time to renew their license/registration. This letter will provide instructions on how to complete the renewal process. As always, individuals are strongly encouraged to renew online. Additionally, the requirements for obtaining continuing education will remain the same, ie, pharmacists must annually obtain 15 contact hours consistent with Board regulation 18VAC110-20-90, pharmacy technicians must annually obtain five contact hours consistent with 18VAC110-20-106 prior to renewing, no later than December 31, and both must attest to completing the required continuing education requirements for that year.

In summary, if the Board-approved draft emergency regulations become final this fall, then the expiration associated with

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A Community Pharmacy Technician's Role in Medication Reduction Strategies

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at *www.fda.gov/cder/guidance/6911fnl.pdf*) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- Drugs with potential safety concerns
- Drugs that lack evidence of effectiveness
- Fraudulent drugs
- Drugs with formulation changes made as a pretext to avoid enforcement
- Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs
Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: *www.fda.gov/cder/drug/unapproved_drugs/*.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at *www.rxpatrol.com/videos.asp* and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

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facility permits will be extended. More information on this subject will be forthcoming. Questions regarding upcoming renewals should be directed to the Board office.

Board Officer Election Results

Elections for the offices of Board of Pharmacy chairman and vice chairman for the period of July 1, 2008 through June 30, 2009, were held during the last full Board meeting on June 4, 2008. The Board voted unanimously to elect David C. Kozera to the office of chairman. Additionally, the Board voted unanimously to elect Michael E. Stredler to the office of vice chairman. The Board looks forward to working under the leadership of these two individuals and, also, wishes to extend its appreciation to Bobby Ison and David C. Kozera for their many contributions during the past year as Board chairman and vice chairman, respectively.

Correct Pharmacy Data Crucial to Prescription Monitoring Program

Pharmacies licensed by the Virginia Board of Pharmacy report almost one million Schedule II through IV prescription records dispensed to the citizens of Virginia each month. These records, when accessed by authorized prescribers and pharmacists, assist in making informed treatment decisions and help pharmacists determine the validity of prescriptions. Recently, the prescription monitoring program (PMP) has received several calls resulting from information provided on requested program reports. The inquiries have involved records that contain incorrect prescriber information. The reported prescribers who state that they have never seen the patient in question have expressed concern that perhaps someone is abusing the system by fraudulently using the prescriber's information. However, in most cases, the incorrect prescriber information has simply been entered erroneously by the dispensing pharmacy. As a result, the Board is reminding pharmacists and pharmacy technicians that the entering of prescription information into the data entry system must be performed accurately including proper identification of the prescriber. Also, it is important to ensure that the Drug Enforcement Administration number is being reported accurately in the format of two alphabetical characters followed by a seven-digit number.

The program has also experienced problems related to the formatting of the reported National Drug Code (NDC) number that is used to identify the drug product in the PMP program software. The ASAP R.5/95 format requires that the NDC number be reported as an 11-digit number in the format of five digits followed by four digits followed by two digits (5-4-2 format). If a number does not contain 11 digits, then leading zeros may be added to create an 11-digit number. The PMP software cannot convert the number to the correct drug name and strength if it is not reported in the appropriate format. NDC numbers reported in an incorrect format result in a blank spot on a requested program report.

Another area of concern involves missing records that have not been reported to the PMP program. This is generally the result of the drug being listed incorrectly in the pharmacy's data entry system. For example, a Schedule III drug that is not properly coded in the pharmacy's data entry system as a Schedule III drug may not be properly captured for reporting to the PMP program.

Last, requested program reports containing records for a compounded prescription occasionally do not reflect accurate information. This erroneous information results from improperly entering the compounded prescription into the pharmacy's data entry system. Prescriptions compounded by the pharmacist containing a Schedule II, III, or IV drug must be reported to the program. Consistent with the reporting manual for the PMP program, dated May 2006, the NDC number of the Schedule II, III, or IV ingredient in the compounded product must appear in the NDC field and the actual metric quantity of the Schedule II, III, or IV substance used in the compounding must be reported in the quantity field. If **more than one** Schedule II, III, or IV drug is used in a compounded prescription, the amounts of each covered ingredient are added and the total must be reported as the quantity. The NDC number must be reported as an 11-digit number with the number 9 repeated 11 times (99999999999).

Additional information regarding reporting requirements to the PMP program and the use of the ASAP R.5/95 format may be found in the reporting manual at *www.dhp.virginia.gov/dhp_programs/pmp/default.asp* under "Contractor Information."

New Requirements for Nonresident Pharmacies: Virginia-licensed PIC, VIPPS Accreditation

The Virginia General Assembly passed a law, effective July 1, 2008, resulting in two significant changes that may affect nonresident pharmacies. The first change is a new requirement for nonresident pharmacies to designate to the Board the name and license number of a Virginia-licensed pharmacist-in-charge (PIC) who will be responsible for the nonresident pharmacy's compliance with Virginia laws. This requirement will not apply to those nonresident pharmacies providing services as pharmacy benefits administrators. Nonresident pharmacies, other than pharmacy benefits managers, will be required to first report information pertaining to the designated Virginia-licensed PIC at the time of the next renewal (anticipated to be April 30, 2009) and annually thereafter, or within 30 days of any change in PIC. Pharmacists licensed in other states, in most cases, may obtain a Virginia license by using the National Association of Boards of Pharmacy® (NABP®) licensure transfer process found at *www.nabp.net*, and passing the Virginia Federal and State Drug Law Exam.

The second statutory change requires a nonresident pharmacy to be accredited by NABP through the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program, or certified by a substantially similar program approved by the Board, if the pharmacy dispenses more than 50% of its total prescription volume pursuant to prescriptions received as a result of solicitation on the Internet to include solicitation by e-mail. Information regarding the VIPPS accreditation program offered through NABP may be accessed at *www.nabp.net*.

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