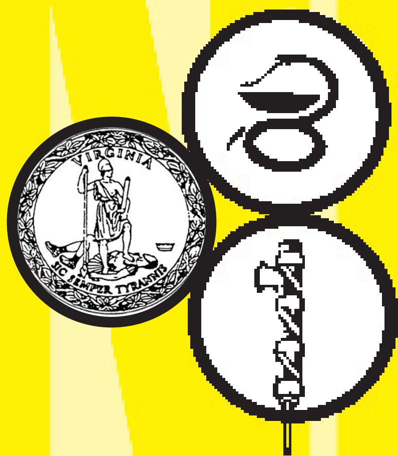
NEWS

May 2009



Virginia Board of Pharmacy

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www.dhp.virginia.gov/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Changes to a Schedule II Prescription

In March 2009, the Virginia Board of Pharmacy approved its new Guidance Document 110-41 that addresses allowable changes that a pharmacist may make to a prescription written for a Schedule II controlled substance after consultation with the prescriber. Previous guidance on this issue was provided by the US Drug Enforcement Administration (DEA) on its Web site. However, when DEA published the final rule, *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921), the preamble to this rule conflicted with its previous guidance regarding allowable changes. Therefore, DEA removed the previous guidance from the Web site, and replaced it with a statement that it would resolve this issue through future rulemaking, and that in the interim, pharmacists should adhere to state regulations or policy for allowable changes to a Schedule II prescription. For this reason, the Board adopted Guidance Document 110-41 to establish such state policy. The guidance document, which is consistent with DEA's previous guidance, may be found at *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm*.

New Process for Enforcing CE Requirements

The Virginia Board of Pharmacy continually strives to make processes more efficient, timely, and convenient for licensees and the public, and strives to reduce or hold down costs in an effort to prevent or delay the need for licensing or renewal fee increases. A significant part of the Board's expenses are related to costs associated with the Board's processes for enforcing its laws and regulations. For this reason, the Board is testing some new processes to streamline the handling of certain types of noncompliance with laws and regulations that are relatively straightforward, such as compliance with continuing education (CE) requirements. In this vein, the Board approved Guidance Document 110-42, creating a new process for enforcing CE requirements. With CE, there is little room for interpretation as to whether the licensee complied or not (ie, he or she either obtained the required CE or he or she did not). Additionally, there are very few circumstances that should impact a decision about noncompliance, because the licensee has the opportunity to request an extension or exemption for CE requirements prior to renewal.

Consistent with past Board policy, the new guidance document states that the Board may audit the following persons for CE compliance: persons checking "no" to the CE attestation on the annual license renewal form, persons who requested a continuance for obtaining CE on the previous year's renewal, and persons selected for random audit. When audited, a licensee will receive a letter stating that he or she must submit to the Board office the original certificates for the required CE during the previous two years (ie, pharmacists must submit certificates for 15 hours of CE gained in each calendar year, totaling 30 hours for the previous two-year audit period and pharmacy technicians must submit certificates for five hours of CE gained in each calendar year, totaling 10 hours for the previous two-year audit period).

If a licensee's response to the audit does not show compliance with CE requirements, Board staff will send a letter to the licensee offering resolution of the matter by consent, payment of an established monetary penalty, and proof of late compliance with CE requirements. The letter will also offer an additional opportunity for the licensee to furnish proof that CE requirements were actually met during the specified time period. If the letter is signed and returned to the Board by the licensee, the letter will constitute an order of the Board and the licensee's consent to the imposition of a monetary penalty and an agreement to the submission of documentation of late CE compliance.

The monetary penalty offered in the letter shall be $250 for each year a pharmacist does not meet CE requirements. Because the maximum audit period is two years, the maximum penalty would be $500. The monetary penalty offered for each year that a pharmacy technician does not meet CE requirements will be $50, for a maximum penalty of $100.

In addition to lowering Board costs, the new process may benefit the pharmacist or pharmacy technician by eliminating travel expenses and absences from work associated with attending an informal conference before a committee of the Board to resolve the matter. However, a pharmacist or pharmacy technician who does not want to use this new consent process may always request an

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NABP Seeking Pharmacists in All Practice Areas to Take Survey

The expertise of pharmacists in all areas of pharmacy practice is needed for an online survey NABP is conducting as part of a full pharmacy practice analysis. The survey, which is available at *www.zoomerang.com/Survey/?p=WEB2297C9ZRC3F,* will run from April 1 to June 30, 2009. Survey results will furnish data necessary to update and validate the current North American Pharmacist Licensure Examination® (NAPLEX®) competency statements, which are scheduled to be revised and implemented into the 2010 blueprint.

NABP conducts a pharmacy practice analysis at least every five years in accordance with standard testing industry examination development and revision guidelines. The analysis allows NABP to ensure that the NAPLEX competencies are in line with the existing pharmacy practice standards and that they accurately reflect the current knowledge, skills, and abilities of entry-level pharmacists seeking licensure. Questions may be directed to custserv@nabp.net or 847/391-4406.

Teen Abuse of Prescription Medications: Curtailing a Growing and Dangerous Trend

Teen-targeted, antidrug campaigns have shifted focus to tackle the current culprit in teen drug abuse: prescription medications. The nonprofit Partnership for a Drug-Free America (Partnership), and government agencies such as the Office of National Drug Control Policy (ONDCP) are using Web sites and televised public service announcements to educate parents and teens about the dangers of prescription drug abuse as well as prevention strategies. In support of such efforts, the National Association of Boards of Pharmacy® (NABP®) is taking steps to raise awareness among pharmacy stakeholders about the urgency of the issue, the benefits of prevention counseling for parents and teens, and support of local medication disposal programs.

A Trend with Deadly Consequences

The teen prescription drug abuse trend demands an assertive approach, as the Centers for Disease Control and Prevention (CDC) indicates that unintentional drug poisoning from misuse of prescription drugs is now the second leading cause of accidental death in the United States. Further, according to the Drug Abuse Warning Network, emergency room visits for prescription medication abuse and "street drugs" are almost equal. Substance Abuse and Mental Health Services Administration (SAMHSA) studies reveal that more teens are trying prescription medications in order to "get high" than marijuana.

To complicate matters, a study done by the Partnership suggests that prescription drugs are not just replacing illicit drugs but instead appear to be an intermediate step in drug use. As one survey participant stated, "[T]aking pills made me much more open to taking x [ecstasy]. At a certain point, it just became another pill."

Prescription Drugs of Choice for Teens

Pain relievers such as Vicodin® and OxyContin®, stimulants such as Adderall® and Ritalin®, and tranquilizers such as Xanax® and Valium® are the prescription medications most frequently abused by teenagers, the Partnership finds.

Putting the problem in perspective, SAMHSA studies from 2007 show that 2.1 million adolescents age 12 or older tried prescription medications for nonmedical uses – the same number that tried marijuana. Tranquilizers (1.2 million teens), cocaine (0.9 million teens), ecstasy (0.8 million teens), inhalants (0.8 million teens), and stimulants (0.6 million teens) were the next drugs most frequently chosen by teens for first time use. SAMHSA reports that, every day, 2,500 youths (age 12 to 17) abuse a prescription pain reliever for the first time. Among teens who have abused painkillers, nearly one-fifth (18%) used them at least weekly in the past year.

Teens are also abusing over-the-counter products such as cough/cold medications. According to a SAMHSA study, 3.1 million people aged 12 to 25 had tried cough or cold medications to get high in their lifetime, and almost 1 million had done so in 2005.

Why Teens Choose Prescription Medications

In surveys conducted by the Partnership, teens reported that they used prescription drugs to help them deal with problems, manage their lives, lower stress, and enhance performance, as well as to get high.

According to ONDCP's 2008 report, *Prescription for Danger: A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens*, teens think that using prescription medications to manage stress or get high is safer than using street drugs. Further, prescription medications are more easily available to teens than illicit drugs such as cocaine or ecstasy. Teens obtain medications from the medicine cabinet at home, through friends, or at friends' homes.

While prescription drugs may be more readily accessible for teens, large numbers are combining these medications with alcohol and/or illicit drugs. For example, 49% of teens who abused painkillers reported using two or more other drugs, including alcohol (81%) and marijuana (58%), ONDCP reports. Further, the report notes, poisonings as a result of combining prescription and over-the-counter drugs have risen drastically.

Stemming the Growth of Prescription Drug Abuse

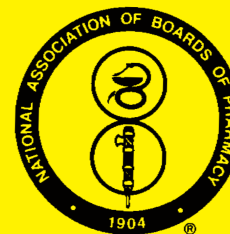
In response to this growing problem, organizations and government agencies recommend educating both parents and teens about the dangers of prescription drug abuse, and modifying and encouraging the use of prescription medication disposal programs.

At its 104th Annual Meeting in May 2008, NABP passed a resolution that stipulates use of its newsletter programs to keep pharmacists and other constituents informed about the urgent issue of teen prescription drug abuse, so that they in turn can help to provide parents and teens with current prevention information. Such educational efforts are vital, as the Partnership reports that most parents do not realize that teens are intentionally abusing medications to get high, and that they think their teens are not vulnerable to prescription drug abuse. Further, the Partnership finds that, like many teens, parents tend to think that teen abuse of prescription medications is safer than teen abuse of street drugs.

Organizations such as the Partnership aim to educate parents and teens directly, informing them about the abuse trend, and emphasizing the necessity of using prescription medications appropriately.

Knowledge of this information is important to pharmacists since they are in an excellent position to counsel parents on teen drug abuse when dispensing prescriptions with high abuse potential.

Phil Bauer of the Partnership stated in his presentation at the NABP 104th Annual Meeting: "We need to reach out and empower parents, give them the information they need. Parents talking to kids reduces drug use by 50%." Similar to past drug prevention programs that



focused on illicit drugs, Bauer and the Partnership encourage parents to communicate with their kids about prescription drug abuse and its dangers. Likewise, ONDCP reports that when parents express strong disapproval of drug abuse, teens are much less likely to adopt this dangerous behavior.

Another immediate step parents can take, the Partnership advises, is safeguarding the medications kept in their homes. Safeguarding involves properly disposing of unused and expired medications, and taking an inventory of all current medications. Further, parents can keep medications stored in an area that is not readily accessible to teens or their friends.

To raise awareness among families and the public, the Partnership, along with ONDCP, launched a media campaign using their Web sites as well as televised public service announcements aired during the 2008 Super Bowl. The Partnership Web site provides a list of facts parents can stress to teens. The Web site states: "The Partnership is urging parents, both through this new campaign and through our online resources and information to learn about this serious problem, share the information with their teens, and take action to prevent teens from accessing these medications at home."

More information and resources are available on the Partnership Web site at *www.drugfree.org*.

Health Care Consumers: Essential Partners in Safe Medication Use

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 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 Food and Drug Administration (FDA) MedWatch partner. Call 1-800-FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program (MERP) 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.*

A study in the September 10, 2007 *Archives of Internal Medicine* found that a significant percentage of American consumers may not be using their medications safely.

Between 1998 and 2005 alone, there was a 360% increase in deaths attributed to consumers using medications incorrectly at home (not involving alcohol or street drugs).

Proactive communication between pharmacists and patients is a major way to reduce the risk of medication errors.

However, there are barriers to patients communicating with pharmacists about the drugs they are taking, including limited time for speaking with patients and lack of appropriate written materials. Pharmacists should explore ways to make suitable written materials on medications readily available. Be sure to seek feedback from patients (eg, through focus groups and targeted satisfaction survey questions) to ensure that written materials effectively communicate the most important information.

Management support for widespread education is essential to ensure effective use of electronic resources as well as dedicated time to talk with patients.

Many pharmacists assume that their patients can read, understand, and act on instructions on medication labels and in medication information pamphlets. But although 90 million Americans read below the 5th grade level, 98% of the medication information sheets accompanying dispensed prescriptions are written at a 9th to 12th grade level or higher.

Poor health literacy can lead to consumers misusing and making mistakes with their medications. Adults with low health literacy:

- Are less likely to adhere to prescribed treatment and self-care regimens
- Make more medication or treatment errors

Children are particularly vulnerable to medication misuse. One study has demonstrated that parents give their children an incorrect dose of over-the-counter fever medicine 47% of the time. Other recent studies have shown that educating parents on how to measure and administer the correct dose of medication for their children can prevent serious errors.

When dispensing pediatric medication, involve the child's parents and demonstrate correct measurement and administration techniques when possible. Emphasize the importance of using an appropriate measuring device (the original product dropper or dosing cup, or proper type of syringe), not a household spoon.

The Internet has opened a whole new avenue for consumers to obtain information on how to use their medications. Americans spend a large portion of time online searching for advice about health and safety. According to the 2007 *Preventing Medication Errors*, the percentage of adults who have sought health information online grew from 27% (54 million) in 1998 to 53% (117 million) in 2005.

But the report found that while there is an abundance of Internet-based health information, the quality of that information is variable.

ISMP maintains links to leading patient safety entities and information on its Web site, *www.ismp.org*, and recently launched a consumer-focused Web site that provides even more specific medication safety information. Visit the new site at *www.ConsumerMedSafety.org*. ISMP allows and encourages all state board Web sites to link to this new consumer patient safety Web site.

FDA Expands Warning to Consumers about Tainted Weight Loss Pills

On January 8, 2009, FDA expanded its nationwide alert to consumers about tainted weight loss pills that contain undeclared, active pharmaceutical ingredients. On December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products that may put consumers' health at risk. The complete list of drugs is available on the FDA Web site.

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informal conference before a committee of the Board. Persons who prefer to have an informal conference will certainly not be penalized for making such a request, but the outcome from an informal conference will most likely not vary from the standard sanctions unless the committee finds facts or circumstances that warrant either an increase or decrease in the standard penalty. Persons who fail to respond to the consent letter will automatically be scheduled for an informal conference. To read Guidance Document 110-42 in its entirety, please visit *www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm*.

Related CE note

Please be advised that effective January 1, 2009, new Accreditation Council for Pharmacy Education (ACPE) standards require a CE provider to identify the target audience for CE programs. CE providers are required to identify the target audience, either pharmacists or pharmacy technicians or both, in any advertising or promotional materials for the program. The certificates issued to a pharmacist will have the letter "P" as the last character in the program identification number. Certificates issued to pharmacy technicians will have a "T" as the last character in the program identification number. Pharmacists will not be given credit if the CE certificate has a "T" designation, and likewise, pharmacy technicians will not be given credit for certificates with the "P" designation. Complete information about CE standards can be found on the ACPE Web site at *www.acpe-accredit.org/pdf/CPE_Standards_Final.pdf*.

Diversion Alert

The following article was provided by the Virginia State Police, Drug Diversion Unit. To access an enrollment form for the Diversion Alert Fax System, visit www.vsp.state.va.us/BCI_SSD_DrugDiversion.shtm.

The Department of State Police has in existence a Diversion Alert Fax System (DAFS), which is designed to provide the pharmaceutical community with critical information needed to aid in the prevention of diversion activities.

If a practitioner discovers a prescription pad stolen, alterations to his or her prescriptions, and/or the illegal use of a name or DEA number in order to obtain false telephone prescriptions, the practitioner should contact the Virginia State Police, Drug Diversion Unit. Pharmacists can also provide similar information which will be verified before its inclusion in the system. The Drug Diversion Unit, through DAFS, will send a single page computer-generated alert containing the critical information to all fax-equipped pharmacies within the practitioner's county or city and surrounding jurisdictions.

DAFS is an additional tool that we can all utilize to help eliminate the unnecessary diversion of pharmaceutical drugs into our communities. The system will only be successful if you provide the appropriate information to the Virginia State Police for dissemination. The contact person is Drug Diversion Analyst Euniqueca Reed. She may be contacted at 804/674-2779 between 8 AM and 4:30 PM, Monday through Friday. During other times, please call the Virginia Drug Hot Line 1-800/553-DOPE (3673) and tell them this is a DAFS request.

Inspection Tips

Posting of Licenses within a Pharmacy

Please remember that the pharmacy permit and pharmacists' licenses must be posted in a conspicuous place in the pharmacy. This means the public must be able to easily read the information on the licenses. Please inspect the current location of the pharmacy permit and licenses to ensure compliance with this statutory requirement.

Record of Dispensing

Inspection reports reveal that pharmacists are occasionally failing to properly sign the printouts or log book maintained as the official record of dispensing for each day's dispensing data. Either the pharmacist is initialing the record and not signing his or her name as indicated on the pharmacist license or he or she is simply failing to sign the record altogether. Regulation 18VAC110-20-250 requires the individual pharmacist using a computer to dispense prescriptions to provide documentation of the fact that the information entered into the computer is correct. This documentation may either be in the form of a daily printout, bound log book, or separate file.

If a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated, and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his or her name appears on the pharmacist license (eg, J.H. Smith or John H. Smith). If a bound log book or separate file is maintained rather than a printout, then the pharmacist must ensure that he or she signs this record and that the record contains a statement attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him or her and is correct as shown.

Agent's Full Name

Inspectors continue to cite deficiencies for oral prescriptions that do not contain the first and last name of the authorized agent calling in the prescription. Writing just the first name of the agent does not meet compliance. As a reminder, an authorized agent of a prescriber, as stated in §54.1-3408.01, shall be an employee of the prescriber who is under the prescriber's immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs (eg, a nurse, physician assistant, or another pharmacist) and who is specifically directed by the prescriber.

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 voluntary 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.

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