



Virginia Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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General Assembly – HB 2312

HB 2312, sponsored by Delegate Chris Jones and passed during the 2013 General Assembly session, amends several sections of law affecting pharmacy. In addition to clarifying the definition of “compounding” in §54.1-3401, the bill requires the pharmacist-in-charge (PIC) or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding to notify the Virginia Board of Pharmacy of its intention to dispense or otherwise deliver a sterile compounded drug product into the commonwealth. Notification may be accomplished by providing a written statement from the PIC or owner to the Board office. Additionally, following the directions provided on the annual renewal form, pharmacies will be required to inform the Board if it will continue dispensing or delivering sterile compounded drug products into Virginia, and the Board will be required to maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies. While HB 2312 did not amend the current allowance for a pharmacist to provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, the bill does add the following language to §54.1-3410.2 H:

Pharmacists shall not engage in the following: . . . 3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

HB 2312 further amends §54.1-3434.1 to require pharmacies, upon submission of an application for registration as a nonresident pharmacy, to submit an inspection report from an inspection that occurred no more than six months prior to the date of submission of the application. Also, upon renewal of the registration, the nonresident pharmacy must submit an inspection report from an inspection that occurred no more than two years prior to the date of application for

renewal. The bill further clarifies that the inspection report must indicate compliance with the Drug Control Act, including United States Pharmacopeia-National Formulary (USP-NF) standards for sterile and nonsterile compounding. If the pharmacy has not been inspected within the required time frame by the regulatory or licensing agency in the jurisdiction where the pharmacy is located, then the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection. Lastly, HB 2312 clarifies the Board’s ability to summarily suspend or restrict a pharmacy permit.

HB 2312 becomes effective July 1, 2013, and may be read in its entirety at <http://leg1.state.va.us/cgi-bin/legp504.exe?131+ful+CHAP0765>.

Sterile Compounding FAQs

Pursuant to Virginia Code §54.1-3410.2 and Regulation 18VAC110-20-321, both sterile and nonsterile compounding must be performed in compliance with USP-NF standards. The following frequently asked questions (FAQs) and answers are provided to assist pharmacists and pharmacy technicians in their understanding of requirements regarding sterile compounding. Guidance documents referred to in these FAQs are available at www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.

1. Where may information regarding USP-NF standards for compounding be located?

A subscription to the current version of *USP on Compounding: A Guide for the Compounding Practitioner* may be purchased at www.usp.org/store/products-services/usp-compounding. This guide provides access to all compounding-related general chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36-NF 31, published on November 1, 2012, becomes official May 1, 2013.

continued on page 4



FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- ◆ Ambien[®], Edluar[™], and Zolpimist[®]: 5 mg for women, 5 mg or 10 mg for men
- ◆ Ambien CR[®]: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo[®], a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at www.fda.gov/Drugs/DrugSafety/ucm334033.htm.

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

 *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 an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at www.ismp.org. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good

reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (www.nccmerp.org), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- ◆ Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- ◆ Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- ◆ Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- ◆ Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at <http://verp.ismp.org/>.



Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- ◆ Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- ◆ Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- ◆ Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- ◆ Ensure the correct strength is ordered.
- ◆ Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- ◆ Order 5% as “vinegar,” which reduces the potential for confusion with glacial acetic acid.
- ◆ Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at www.ismp.org/NAN/files/20130121.pdf.

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as “acet” or “APAP.” Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that “state boards of pharmacy

prohibit the use of the abbreviation ‘APAP’ on prescription labels, and require that ‘acetaminophen’ be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity.” The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist’s role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers “estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation” of the recommendation to use the complete spelling of acetaminophen on prescription labels. “This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines,” states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at www.ncdpd.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf, developed for pharmacists that summarizes some of NCPDP’s key recommendations regarding acetaminophen. In addition, the white paper, available for download at www.ncdpd.org/ind_WP.aspx, includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at www.ncdpd.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.

Pharmacists Rated High for Honesty and Ethical Standards in Gallup’s 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx.



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CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

2. Does the law require compliance only with Chapter 797?

No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters <1> *Injections*, <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Testing*, <85> *Bacterial Endotoxin Testing*, and <797> *Pharmaceutical Compounding—Sterile Preparations*.

3. In the absence of sterility testing, what beyond use dates (BUDs) must be used?

When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is ensured for 90 days?

No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

5. What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?

Skip lot testing is a process that only tests a fraction of the drugs compounded. It is **not** appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm.

6. How often must the primary engineering control, eg, laminar airflow workbench, and secondary engineering control, eg, ante and buffer rooms, be certified?

Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than **the last day of the sixth month**, following the previous certification.

Note: This guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9, which was amended at the March 2013 full Board meeting.

7. How often must media-fill testing be performed?

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low- and medium-risk compounding, and semiannually for high-risk level compounding.

Note: The terms “annually” and “semi-annually” are defined within Guidance Document 110-36.

8. If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low-, medium-, or high-risk) prior to retraining and receipt of a passing media-fill test.

Note: This guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9, which was amended at the March 2013 full Board meeting.

Regulations for Continuous Quality Improvement Programs

On October 1, 2012, emergency regulations for continuous quality improvement (CQI) programs became effective. As emergency regulations, the regulations will remain in effect for one year until replaced with permanent regulations. A review of the CQI requirements was provided in the February 2013 Board *Newsletter* and is available at www.dhp.virginia.gov/Pharmacy/pharmacy_newsletters.htm.

Inspections performed since the regulation became effective have identified that approximately 60% of pharmacies inspected are not compliant with the regulation. Currently, the Board has instructed inspectors to note a comment on the inspection report when there is noncompliance with this relatively new requirement and to not impose a monetary penalty at the conclusion of the routine pharmacy inspection. The Board, however, agreed to revisit this issue at a later time to determine if noncompliance with this requirement should result in a monetary penalty. Pharmacists are advised to evaluate the pharmacy’s operations to determine if it complies with the CQI regulations.

During an inspection, the inspector will look for records indicating the following:

If the pharmacy reports to a Patient Safety Organization (PSO):

1. The name of the PSO and documentation that it is credentialed by the Agency for Healthcare Research and Quality (AHRQ);
2. The date a report was submitted to the PSO; and
3. A zero report on the record if no dispensing errors have occurred within the past 30 days.

If the pharmacy does not report to a PSO, the record shall include:

1. Dates the analysis of dispensing errors were initiated and completed;
2. Names of participants in the analysis;
3. A general description of remedial action taken to prevent or reduce future errors; and
4. A zero report on the record if no dispensing errors have occurred within the past 30 days.

The records described above must be available to the inspector even if the corporate office reports dispensing errors on behalf of the pharmacy and they shall be maintained for 12 months.

The emergency CQI regulations may be read at www.dhp.virginia.gov/Pharmacy/leg/EmergencyRegs_QualityImprovementPrograms.doc.

Statistics from the Virginia Prescription Drug Monitoring Program

Top 10 Controlled Substances Dispensed in Virginia Between January 1, 2012 and December 31, 2012 by Number of Prescriptions

2012 Most Prescribed Drugs	Number of Prescriptions	Doses	Doses/Rx
Hydrocodone/APAP	2,785,447	152,987,584	55
Alprazolam	1,274,219	79,162,390	62
Oxycodone/APAP	1,213,277	67,163,427	55
Zolpidem Tartrate	1,070,909	35,775,026	33
Clonazepam	785,821	47,386,834	60
Lorazepam	755,607	40,850,542	54
Diazepam	459,071	22,309,058	49
Amphetamine Salts	457,246	27,367,680	60
Oxycodone HCL	409,962	45,535,136	111
Methylphenidate HCL	374,322	18,783,111	50

Total number of all prescriptions in 2012: 13,853,426

Total number of doses in 2012: 787,780,324

In 2012, pharmacists made 8% of all requests to the Virginia Prescription Monitoring Program (PMP). For the first quarter of 2013, pharmacists made 11% of all requests. Pharmacists are encouraged to use the PMP when making dispensing decisions. You may register at the [Virginia Prescription Monitoring Program Web site](#).

PMP Hint: When reviewing a PMP report, carefully review the Date Written field. Photocopied prescriptions fraudulently presented for the same patient will have different fill dates, but the written date will be the same.

New AHRQ Tool Assesses Patient Safety Culture in Pharmacies

The AHRQ has released the *Pharmacy Survey on Patient Safety Culture* and a free toolkit of materials that helps community pharmacies assess their culture of patient safety. It is the latest survey in AHRQ's suite of patient safety culture surveys now being used by hospitals, nursing homes, and medical offices. The new survey, designed for pharmacy staff, including clerks, pharmacy technicians, and pharmacists, includes 36 survey items that measure 11 areas of patient safety culture such as physical space and environment, patient counseling, communication about prescriptions across shifts, and teamwork. The survey also includes items about the frequency of documenting mistakes and an overall rating on patient safety. Toolkit materials include the survey form, a document identifying items by composite, a *Survey User's Guide*, and results from 55 pharmacies that participated in the 2012 pilot study. To download the survey, visit www.ahrq.gov/qual/patientsafetyculture/pharmsurvindex.htm.

Page 5 – May 2013

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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