



Virginia Board of Pharmacy

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Compounding Sterile Preparations

Virginia Board of Pharmacy Regulation 18VAC110-20-321 states compounding of both sterile and nonsterile drug products shall be performed in accordance with United States Pharmacopeia-National Formulary (USP-NF) compounding standards and §54.1-3410.2 of the Code of Virginia. While pharmacists often associate sterile compounding requirements with USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*, it is important not to overlook the requirements in USP Chapters <1> *Injections*, <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, and <85> *Bacterial Endotoxin Testing*.

At the December 12, 2012 Board meeting, the Board addressed several issues in Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*, related to compliance with USP-NF standards regarding the compounding of sterile preparations. Modifications, including changes for when an inspector should cite a deficiency, were made to Major Deficiencies 20, 21, 22, 24, 25, 26, and 33, and Minor Deficiencies 30, 31, and 32. To access Guidance Document 110-9, visit www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm.

Deficiencies Associated With Compounding Sterile Preparations

Certification of the direct compounding area, buffer or clean room, and ante room is to be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed (refer to Major Deficiencies 22 and 23). Every six months is interpreted to be six months from the date of the last certification. For example, a direct compounding area certified as ISO Class 5 on January 17, 2013, requires certification on or before July 17, 2013. The inspector will ask for documentation of at least the two most recent certifications to ensure that the areas comply with the appropriate ISO class.

Individuals preparing compounded sterile preparations (CSP) must complete media-fill testing annually when preparing low and medium-risk CSPs and semiannually when preparing high-risk level CSPs (refer to Major Deficiencies 25a and 26). The terms “annually” and “semiannually” as used in USP Chapter <797> are defined to mean every 12 months and every six months, respectively. In the event an individual fails a media-fill test, that individual may not perform high-risk level compounding prior to retraining and receipt of a passing media-fill test (refer to Major Deficiency 25c). Individuals preparing low or medium-risk level CSPs must provide documentation of passing the media-fill test within 45 days of the failed test (refer to Major Deficiency 26a). Records associated

with annual and semiannual requirements shall be maintained in accordance with USP standards. The records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection. The inspector will ask for documentation that each individual who prepares CSPs has completed the required media-fill testing and retesting if required.

Compounded sterile preparations must be assigned an appropriate beyond-use date (BUD) in compliance with USP-NF standards (Major Deficiencies 25 and 33). In the absence of sterility testing, the BUD for low, medium, and high-risk CSPs are:

	Low Risk	Medium Risk	High Risk
Controlled Room Temperature	48 hours	30 hours	24 hours
2° to 8°C (36° and 46°F)	14 days	9 days	3 days
-25° to -10°C (-4° and 14°F) or colder	45 days	45 days	45 days

If performed, sterility and endotoxin testing must comply with USP Chapters <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, or <85> *Bacterial Endotoxin Testing* in addition to USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*. The inspector will ask for documentation for sterility or endotoxin testing.

Concern for Contemporary Practice: Evidence Requested

During the June 2012 full Board meeting, the Board expressed concern for several identified contemporary practices such as the advertising of a guarantee for how quickly prescriptions will be dispensed, or corporate production quotas regarding prescription dispensing or immunization administration. However, the Board determined that there was insufficient evidence proving that the identified practices can or have created patient harm. Such evidence is legally necessary for the promulgation of regulation. Therefore, the Board voted to encourage pharmacists to submit evidence to the Board when contemporary pharmacy practices can or have created patient harm and remind everyone of the following relevant sections of 54.1-3434 and Regulation 18VAC110-20-110 B:

- ◆ The pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy.

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, www.livertox.nih.gov, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to ‘Double Check, Don’t Double Up’ on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition’s “Double Check, Don’t Double Up” message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the KnowYourDose.org Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis



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.

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state’s regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an “unexpected occurrence involving death or serious physical or psychological injury or

risk thereof,” and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves “Why did this happen?” until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask “Why do our systems allow these types of mistakes to happen so easily?” or “What factors set this person up to make this error?”

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer “What normally happens?” (Question 2, in the above table). The difference between “What normally happens?” and “What do the policies and procedures require?” (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. “Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a ‘patient-centered’ manner that best reflects how most patients seek out and understand medication instructions,” as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients



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misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- ◆ Emphasizing instructions and other information important to patients
- ◆ Improving readability
- ◆ Giving explicit instructions
- ◆ Including purpose for use
- ◆ Addressing limited English proficiency
- ◆ Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at <http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010>.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law “prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or \$1 million.” According to the Coalition for Patient Safety and Medicine Integrity, “current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips.” By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong

commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards’ collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP’s member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies’ e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

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

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- ◆ If the owner is not a pharmacist, he or she shall not abridge the authority of the pharmacist-in-charge (PIC) to exercise professional judgment relating to the dispensing of drugs.
- ◆ The PIC or pharmacist on duty shall control all aspects of the practice of pharmacy, and any decision overriding such control shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

Evidence of possible patient harm resulting from contemporary pharmacy practice or any violation of law, to include 54.1-3434 and Regulation 18VAC110-20-110 B, may be submitted to the Virginia Department of Health Professions, Enforcement Division by following the directions for “How to file a Complaint” found at www.dhp.virginia.gov/Enforcement/complaints.htm.

Regulations for Continuous Quality Improvement Programs

On October 1, 2012, emergency regulations for continuous quality improvement (CQI) programs became effective. As emergency regulations, they will remain in effect for one year with an option for the Board to request a six-month extension, if permanent replacement regulations have not been approved by the governor at that time. Regulations were promulgated pursuant to §54.1-3434.03 of the Code of Virginia. This law requires each pharmacy to implement a program for CQI in compliance with Board regulations or actively report to a patient safety organization (PSO) that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). To provide sufficient time for pharmacies to come into compliance, the Board instructed staff to not cite a deficiency during a routine inspection for the first six months from the date the regulations became effective. Thus, through March 31, 2013, if the pharmacy is not in compliance with CQI requirements, the inspector will simply note this as a comment on the inspection report rather than citing a deficiency. As of April 1, 2013, the inspector will cite a deficiency for noncompliance.

In a pharmacy that chooses to comply with CQI requirements by actively reporting to a PSO, the inspector will look for a record indicating the date a report was submitted to the PSO. If no dispensing errors occurred within the past 30 days, the record must indicate a zero report with date. The record is to be maintained for 12 months from the date of reporting. In a pharmacy that chooses to implement its own CQI program in compliance with Board regulations, the inspector will look for a record that includes the following general information: (1) dates the analysis was initiated and completed; (2) names of the participants in the analysis; and (3) general description of remedial action taken to prevent or reduce future errors. A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. The record is to be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors. The report is not intended to be punitive by revealing patient-specific information associated with dispensing errors, but is intended to demonstrate to the inspector the pharmacy's compliance with CQI requirements.

For more information, the emergency CQI regulations may be accessed at www.dhp.virginia.gov/Pharmacy/leg/EmergencyRegs_QualityImprovementPrograms.doc.

Pre-Populating Refill Authorization Forms for Prescribers

Drug Enforcement Administration (DEA) has recently indicated that a pharmacy, to include community and long-term care pharmacies, may not send a refill request to a prescriber that contains partially or fully pre-populated information within the “prescription” portion of the refill reminder. DEA does not characterize

the pharmacy as acting as the prescriber's agent for the purposes of preparing the prescription since federal regulations require the prescriber to direct the agent as to the required elements of a valid prescription and not vice-versa. Refill reminders for drugs in Schedules III through V should instruct the prescriber to prepare and transmit a prescription to the pharmacy if the prescriber wishes to issue a new prescription for the patient. Please remember when a prescriber faxes a written prescription to a pharmacy it must bear the prescriber's manual signature. A faxed prescription containing an electronic or computer-generated signature is not a valid prescription.

Interoperability of the Virginia Prescription Monitoring Program With Other States

A report from the Virginia Prescription Monitoring Program (VPMP) reveals only those drugs in Schedules II through IV that a specific patient was dispensed by a pharmacy located in Virginia. If the patient resides in another state but is using a Virginia pharmacy to obtain a prescription drug, a query to the VPMP may not reveal a complete dispensing history assuming the patient also receives prescriptions from pharmacies in his or her home state. However, the VPMP is becoming increasingly more interoperable with other states. By sharing dispensing information across the borders, prescribers and pharmacists are able to receive a more comprehensive patient dispensing history and make more meaningful decisions regarding the appropriateness for prescribing or dispensing a controlled substance. Currently, Virginia is interoperable with nine states: Ohio, Indiana, Connecticut, Michigan, North Dakota, Kansas, Arizona, Kentucky, and South Carolina. To request PMP information from these states, a registered user of the VPMP selects the corresponding box for the state from which information is desired when submitting the request to the VPMP. The request for information is sent to the selected states. Dispensing information, if available, reported by that state(s) is provided to the requestor along with information from the VPMP.

Because other states such as West Virginia, Tennessee, and North Carolina are not currently interoperable with the VPMP, a Virginia pharmacist must directly register as a user with the other state's PMP program in order to access a patient's dispensing history within that state. It is hoped that these states will be able to implement interoperability in the near future. Information for becoming a registered user of these surrounding states' PMP programs may be accessed at:

- ◆ West Virginia: <https://65.78.228.163>
- ◆ Tennessee: <https://prescriptionmonitoring.state.tn.us>
- ◆ North Carolina: www.ncdhhs.gov/mhddsas/controlledsubstance/index.htm

Maryland and Washington DC do not have operational PMPs at this time. For more information, see the “Prescriptions from Out-of-State Prescribers and Patients” article, in the July 2012 Board *Newsletter*; available at www.dhp.virginia.gov/Pharmacy/newsletters/VA072012.pdf.

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