



North Carolina Board of Pharmacy

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6015 Farrington Rd, Suite 201 • Chapel Hill, NC 27517 • Tel: 919/246-1050
Fax: 919/246-1056 • www.ncbop.org

Item 2252 – Pharmacy Compounding Updates

Pharmacists are undoubtedly aware of the national tragedy that has unfolded as a result of contaminated drug products compounded by the New England Compounding Center (NECC). In light of that tragedy, North Carolina Board of Pharmacy staff wishes to update North Carolina pharmacists on various matters related to pharmacy compounding.

The Board's Immediate Response to the NECC-Caused Fungal Meningitis Outbreak

The Board summarily suspended NECC's out-of-state pharmacy permit on October 3, 2012, one hour after receiving confirmation that NECC products were suspected in the fungal meningitis outbreak.

Board investigative staff cooperated closely with North Carolina Division of Public Health staff to visit and/or telephone every clinic in North Carolina identified as having received potentially contaminated methylprednisolone products from NECC. The Board staff specifically thanks Amanda Fuller Moore and her staff at the Division of Public Health for their superb efforts. During these in-person and telephone contacts, Board and Division of Public Health staff ensured that the clinics were aware of the recall, had removed NECC products from inventory, and were notifying potentially affected patients. When the NECC recall was extended to all sterile products produced by that pharmacy, Board investigative staff again cooperated closely with Division of Public Health staff to ensure that all affected clinics had pulled every NECC product from inventory and were notifying patients as recommended by Food and Drug Administration (FDA).

Immediately upon learning that FDA had urged Ameridose to recall all compounded products produced at that facility, the Board members summarily suspended Ameridose's out-of-state pharmacy permits.

The Pharmacy Compounding Working Group

The Board has also created, empaneled, and charged a Pharmacy Compounding Working Group to conduct a comprehensive review of all aspects of compounding pharmacy regulation including (1) whether and to what extent changes are needed in either or both of the North Carolina Pharmacy Practice Act and Board of Pharmacy rules governing compounding pharmacy;

(2) whether and to what extent United States Pharmacopeia Chapter <797> standards should be specifically incorporated into state law; (3) whether and to what extent North Carolina law should mandate or recognize any form of "accreditation" for compounding pharmacies; (4) whether and to what extent changes are needed in Board investigator training or inspection methods with respect to compounding pharmacies; and (5) what particular issues, if any, with respect to out-of-state compounding pharmacies, require different or additional regulatory approaches. Each of these broad topics will encompass numerous subsidiary issues. The working group will provide a report and recommendation to the full Board on these issues.

Inspections of Compounding Pharmacies Stepped Up

Board staff has stepped up inspections of North Carolina pharmacies that specialize in compounding to ensure compliance with relevant law. In addition, Board staff is collecting information from out-of-state pharmacies permitted in North Carolina that specialize in compounding for the same purpose.

Already, Board inspectors have noted another uptick in the compounding of "over-the-counter" drugs for general resale. **This is not a legal practice.** This activity was the subject of a lengthy item in the April 2008 *Newsletter*: www.ncbop.org/Newsletters/Apr2008.pdf. Given the clarity of the law and Board staff's repeated emphasis on this issue, instances of this practice will no longer be treated as an "educational" matter. They will be treated as a disciplinary matter.

Involvement in National Pharmacy Compounding Efforts

Board staff is working closely with National Association of Boards of Pharmacy® (NABP®) staff on the NABP compounding action plan, a broad-gauge national effort aimed at supporting state boards of pharmacy in providing effective oversight of compounding pharmacy practices.

In addition, committees in both the US Senate and US House of Representatives have convened to analyze the causes of the NECC tragedy and to explore potential federal regulation in the area of pharmacy compounding. In response to requests from these committees, Board staff provided substantial information on North Carolina's regulation of pharmacy compounding.



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



Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

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.

Item 2253 – Reminder of Proposed Amendments to Rules Governing Hospital and Long-Term Care Pharmacy

On October 11, 2012, the Board published notice of amendments to a number of rules governing hospital and long-term care pharmacy practice. The proposed amendments are aimed at simplifying and clarifying various rule-based requirements and are the product of a year-long review and recommendation process. The text of the proposed amendments is found on the front page of the Board's Web site, www.ncbop.org. Pharmacists from all practice areas are encouraged to review the rules and provide comments.

A public hearing on the proposed amendments will be held at 5 PM on Monday, January 14, 2013, at the Board office, 6015 Farrington Rd, Suite 201, Chapel Hill, NC 27517. Pharmacists (or others) need not attend the public hearing to provide comments. Written comments may be submitted to the Board office by letter, fax, or e-mail. All comments are due by January 14, 2013.

Item 2254 – E-Prescribing: The Good, the Bad, and the Ugly

Editor's Note: Thank you to Mary Walker, executive director of the Wyoming State Board of Pharmacy, and to Erin Nemece, PharmD candidate, who published this item in the Wyoming State Board of Pharmacy Newsletter. The information is timely and well-presented.

At least 25% of all medication-related injuries are preventable, and at least 1.5 million preventable adverse drug events occur each year in the US.¹ E-prescribing use by prescribers and pharmacists was expected to improve the safety, quality, and efficiency of patient care. Electronic prescribing systems have been used to decrease inappropriate medication use as well as polypharmacy, specifically in the geriatric population. E-prescribing of prescriptions, along with computerized physician order entry, has helped to minimize the need to call physicians due to legibility on prescriptions and physician orders. However, did e-prescribing just replace some issues with others?

Many pharmacists have said that e-prescribing brings its own set of issues that result in calling the physician's office several times a day. E-prescriptions auto-populate the fields that can be missed when prescriptions are entered. This allows for errors in the directions or even the drug itself. Also, the patient's profile is not necessarily visible when the e-prescription comes through. A special effort must be taken to review the profile. "Pharmacists must intervene on electronic prescriptions as often as they do on handwritten prescriptions because this technology still poses threats to both medication safety and effectiveness . . . e-prescription error rates are not lower than prescription error rates reported before the electronic era."² However, while the overall error rate may not be lower, the serious error rate has decreased.³ If the error rate due to e-prescriptions could be lowered, it would have a dramatic effect on the reduction of overall medication errors. How can providers help to minimize medication errors due to electronic prescribing?

Providers need to take time and double check the medication order before sending it to the pharmacy. Pharmacists and pharmacy technicians should be diligent about looking at the

patient profile when any prescription arrives at the pharmacy. Has the patient been on this medication before? Has the medication strength or the directions changed? "Techniques such as reporting near-miss errors can be used to identify systems errors and are indicative of the error types that reach patients."² Each pharmacy should have a protocol in place about how to report errors and near-miss errors. This record should be reviewed often. Is the same problem happening again and again? A continual quality improvement process should be undertaken to review the problems, make a plan, and then implement the plan, to reduce the medication errors from occurring. This plan should be reviewed and changed as needed.

Finally, establish and maintain a strong provider-patient relationship. The patient should be empowered as a partner in his or her care, and should know and act on patients' rights. Use the time during counseling of prescriptions for meaningful communication about the safe and effective use of medications. Counseling is the last check before the patient receives the medication and is a great way to gain that provider-patient relationship.

1. Aspden P, Wolcott J, Bootman JL, Cronenwett LR eds. Preventing medication errors: quality chasm series. Institute of Medicine. Washington DC: National Academies Press. 2007.
2. Hincapie AL, Warholak TL. Electronic prescribing errors: do they exist? JAPhA. 2012; 52(3):302-3.
3. Westbrook JI, Reckmann M, Li L, Runciman WB, Burke R, Lo C, et al. Effects of two commercial electronic prescribing systems on prescribing error rates in hospital inpatients: a before and after study. PLoS Med. 2012; 9(1): e 1001164. Doi:10.1371/journal.pmed.1001164.

Item 2255 – Licenses, Permits, and Registrations Not Renewed Are Now Late

All persons or entities licensed by, permitted by, or registered with the Board are reminded that all licenses, permits, and registrations expired on December 31, 2012. By operation of law, a person or entity is not deemed to be engaged in the "unlicensed practice of pharmacy" until 60 days after expiration. But any license, permit, or registration not renewed by March 1, 2013, will be moved to inactive status.

Remember that as of May 1, 2012, the Board accepts payment via Visa, MasterCard, and Discover **only**. Cash, checks, and American Express cards will not be accepted.

Page 4 – January 2013

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Jack W. "Jay" Campbell IV, JD, RPh - State News Editor
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