



Minnesota Board of Pharmacy

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Pharmacy Technician Training Requirement

Effective **January 1, 2014**, the Minnesota Board of Pharmacy will not renew the registration of a pharmacy technician who was **initially** registered after **January 1, 2013**, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual has completed a pharmacy technician training program. There are several types of training that will be acceptable, including:

- ◆ a pharmacy technician training program offered by a Board-approved, accredited vocational/technical institution or college;
- ◆ a pharmacy technician training program accredited by a Board-approved, national organization that accredits pharmacy technician training programs;
- ◆ a pharmacy technician training program provided by a branch of the United States Armed Forces or Public Health Service; or
- ◆ an employer-based program that includes a minimum of 240 hours in a one-year period of both theoretical and practical instruction.

The Board is aware of only one national organization that accredits pharmacy technician training programs at this time: the American Society of Health-System Pharmacists (ASHP). Pharmacy technician training programs accredited by ASHP are automatically approved.

The Board is currently developing the standards for approval of accredited vocational/technical institutions and colleges. It is likely that the standards will include, at a minimum, the following:

- ◆ The program must be offered by an institution that is accredited by a legitimate accrediting organization;
- ◆ The institution must be approved by the federal government so that its students can receive federal financial aid for completing the program; and
- ◆ The program must include an experiential component, with the students completing some of the training in a licensed pharmacy, under the supervision of a pharmacist.

Programs that are offered strictly online and that have no requirement for completing "hands on" training in a licensed pharmacy will most likely not be approved. The Board will prob-

ably adopt standards for accredited vocational/technical institutions and colleges at its January 30, 2013 meeting.

An employer-based program must include a minimum of 240 hours in a one-year period of both theoretical and practical instruction. An employer that uses an internal training program **must** develop and regularly update a technician training manual that must be available for Board inspection. The following standards for employer-based training programs were adopted by the Board at the June 20, 2012 meeting:

I. General considerations

- a. The content areas, listed in Section II, are required for all employer-based technician training programs.
- b. Minnesota Rules 6800.3850 contains the provision that "(n)otwithstanding the fact that a technician has completed a training program as specified in item B, it is the responsibility of the pharmacist-in-charge of a pharmacy to ensure that a technician receives adequate training in the tasks performed by technicians working at that pharmacy." Consequently, pharmacies may have to include additional content in their technician training program. For example, a pharmacy that utilizes technicians to assist in sterile compounding must include training that covers what technicians need to know about United States Pharmacopeia (USP) Chapter 797 standards. Similarly, a pharmacy that utilizes technicians to assist in nonsterile compounding must include training that covers what technicians need to know about USP Chapter 795 standards. Other examples include, but are not limited to, the use of automated drug distribution systems and unit-dose packaging or prepackaging of drugs.
- c. These are the minimum standards that must be met in order for a technician training program to be considered Board approved. However, pharmacies may develop training programs that include additional content areas.

II. Minimum content areas required for all employer-based pharmacy technician training programs

- a. Legal and ethical content
 - i. Differences between the permissible duties, activities, and roles of pharmacists, pharmacy technicians, pharmacy interns, and unregistered supportive personnel. Duties and activities which may not be performed by a pharmacy technician.

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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



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.*

- ii. Requirements for a valid prescription drug order.
 - iii. Requirements for a valid controlled substance prescription drug order.
 - iv. Pharmacy technician registration and continuing education requirements.
 - v. Activities that constitute unprofessional conduct or unethical behavior, including diversion of drugs.
 - vi. Patient privacy (may be completed as separate training).
- b. Pharmacy and medical terminology, abbreviations, and symbols: sufficient to accurately complete data entry of prescription drug orders.
 - c. Basic pharmaceutical calculations necessary for the preparation and dispensing of drug products.
 - d. Basic information about commonly available drug dosage forms and routes of administration.
 - e. Trade and generic names and the common indications for medications frequently dispensed by the pharmacy.
 - f. Error prevention, reporting, and follow-up (may be completed as separate training).
 - g. Dispensing processes:
 - i. Data entry
 - ii. Retrieval of medication
 - iii. Filling of containers/packaging of medications
 - iv. Affixing labels
 - v. Pharmacist certification requirement
 - h. Basic knowledge of proper and safe handling, storage, and disposal of drugs.

So far, the Board has approved two programs that can be used as **part** of an employer-based training program. These programs can only be used for the written or didactic portion of the training. A pharmacy that relies on one of these programs must also develop a formal experiential or “hands on” training component. The details concerning all aspects of an employer-based training program **must** be specified in a **formal** technician training manual. The manual must list **specific** activities that the technicians will be doing as part of the training, list how many hours of training will be provided in each training area, list who will do the training (which for the most part should be a pharmacist), and describe how the technician will be assessed for competency in each area. A pharmacy that is using an employer-based training program must provide the technician with a document certifying that the training has been completed and must maintain records of which technicians have completed the training for at least two years after the training is complete. The two programs that have been approved are:

- ◆ **Pharmacy Technicians University:** This is an online program that has been developed by the publisher of *Pharmacist's Letter*. The link to the program Web site is <http://pharmacytechniciansuniversity.therapeuticresearch.com/home.aspx?cs=&s=PTU&mobile=0>.
- ◆ **The National Pharmacy Technician Training Program (7th Edition):** There are two versions of this program. The Web site for the online version is www.learnsomething.com/. The Web site for a hard copy version is www.ataliiedhealth.com/ati_store/product.aspx?zpid=1347.

Employers will **not** be required to send any documents to the Board, such as certificates of completion of training programs – and neither will technicians. The Board’s licensing system is being modified to track newly registered technicians. Upon their first renewal, such technicians will have to check a box certifying that they have completed the required training – with a warning that they will be subject to discipline if they have not completed the training (note that technicians who register in the last half of the year will be allowed to renew their registration once without having completed training – but will have to complete the training before their second renewal). The Board will conduct an audit of technicians annually. Those individuals who have indicated during the renewal process that they completed a training program but who cannot prove it will be subject to disciplinary action. While the Board will not require employers to send in copies of training certificates, employers **may** be held accountable if they continue to employ a technician who has not met the training requirement. Consequently, employers would be well-advised to make sure that any technician that they hire has either met the training requirement or is exempt from it as a result of being continuously registered since before January 1, 2013. Additional information about these and other requirements related to pharmacy technicians can be found on the Board’s Web site at www.pharmacy.state.mn.us/pharmtec.htm.

Compounding

Pharmacists are **strongly** encouraged to read an urgent memorandum that was sent out by the Board on November 15, 2012. The memo can be found by visiting www.pharmacy.state.mn.us/cmpdmemo.pdf. The tragedy involving an outbreak of meningitis linked to contaminated, compounded methylprednisolone acetate injections has so far claimed nearly 40 lives, sickened more than 600 people, and potentially exposed thousands more to a fungus that can remain dormant within the body as spores for years. The Board has worked and will continue to work with the US Food and Drug Administration, relevant Congressional committees, the National Association of Boards of Pharmacy®, the Minnesota Department of Health, and other organizations to address this issue. The Board is well aware of the complexities involved due to related issues such as drug shortages and the need for certain compounded products to be available for immediate use within clinics and other health care facilities. It is almost certain that Congress will amend federal statutes to address at least certain types of “compounding.” It is likely that the Board will also be pursuing changes to state statutes and rules. In the meantime, pharmacies and pharmacists **must** follow existing statutes and rules, as outlined in the urgent memo mentioned above.