



North Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1906 E Broadway Ave • Bismarck, ND 58501-4700 • Phone: 701/328-9535
 Fax: 701/328-9536 • www.nodakpharmacy.com

Change in Technician-in-Training Standards

During the November 2014 North Dakota State Board of Pharmacy meeting, the Board entertained a discussion regarding progress of technician-in-training registrants. The Board was concerned with the minimal progress in the education portion of students enrolled in the North Dakota State College of Science (NDSCS) Pharmacist-Assisted Technician Self-Instructional Modules (PATSIM) training module program. In looking for ways to ensure educational progress is being made, the Board discussed ways in which it could ensure that technician-in-training registrants are obtaining the education they need to practice.

The Board felt it is essential that the technicians-in-training are completing educational material throughout the two-year limit on their registration. The Board made a motion to require technician-in-training registrants enrolled in the NDSCS PATSIM program to prove completion of at least four education modules in order to obtain a renewal of their registration for the second year of their two-year registration.

It is important that the preceptor pharmacist works with his or her technicians-in-training to ensure progress is being made and completion will be obtained in the two-year period. Please work with your technicians-in-training to ensure that they will accomplish the standards set for a full technician registration. The Board holds the responsibility not only on the technician-in-training, but also on the preceptor pharmacist in the success of these individuals.

Changes in PTCB Recertification Requirements Take Effect in 2015

Article taken from PTCB

In 2015, the Pharmacy Technician Certification Board (PTCB) is implementing changes in recertification requirements for certified pharmacy technicians (CPhTs). The 2015 changes are intended to ensure that CPhTs are continually educated through programs specific to the knowledge required of pharmacy technicians in today's pharmacy settings. The new requirements apply to CPhTs who have a renewal date in 2015 or later.

Pharmacy Technician-Specific CE

All recertification and reinstatement candidates eligible for recertification or reinstatement in 2015 and beyond are required to submit pharmacy technician-specific continuing education (CE) hours.

- ◆ To facilitate the transition to this new CE requirement, PTCB will continue to accept CE hours in pharmacy-related subject matter that were completed on or before December 31, 2014.
- ◆ Any CE hours earned after January 1, 2015, must be in a pharmacy technician-specific subject matter. PTCB will not accept CE completed in 2015 or later that is not pharmacy technician-specific.
- ◆ For example, if you are due to recertify in March 2015 and you already completed some CE hours before the end of 2014, the new requirements will not apply to those hours, and you may submit them when you apply to recertify. Only hours earned after January 1, 2015, will be affected by the new requirements.

As before, CPhTs must complete 20 hours of CE. For recertification candidates, one of the 20 CE hours must be in the subject of pharmacy law, and one hour must be in the subject of patient safety. For reinstatement candidates, two of the 20 hours must be in the subject of pharmacy law and one hour must be in the subject of patient safety. Pharmacy law CE and patient safety CE must be pharmacy technician-specific.

PTCB has determined that all CE programs offered by Accreditation Council for Pharmacy Education-accredited providers with the target audience designator "T" satisfy the requirement of pertaining to pharmacy technician-specific subject matter. CE programs intended for pharmacists and pharmacy technicians will have an identical Universal Activity Number with a target audience designator of either "P" or "T" as the last digit. Non-accredited CE programs are accepted if PTCB determines that the program objectives assess or sustain the competency critical to pharmacy technician practice as stated in PTCB's Pharmacy Technician Certification Exam Blueprint, available at www.ptcb.org/docs/get-certified/new_ptce_blueprint.pdf?sfvrsn=6 (PDF).

continued on page 4



DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

System-Based Causes of Vaccine Errors

 This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at www.njconsumeraffairs.gov/press/05012013.pdf.

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.

continued from page 1

CE Hours Earned Through In-Service Projects or Training

Beginning in 2015, the maximum number of CE hours a CPhT may earn through in-service projects and training (earned at a certificant's workplace under the direct supervision of a pharmacist) is reduced to five hours from the previous level of 10. Credit for in-service projects is not awarded for the performance of a pharmacy technician's regular work duties. Credit is granted for the completion of specially assigned in-service projects or training outside of the certificant's regular responsibilities. Specific requirements are set forth in the Universal Continuing Education Form, available at <https://www.ptcb.org/docs/default-source/renew/universalcontinuingeducationform.pdf?sfvrsn=6> (PDF).

Update on Registration With the North Dakota PDMP

The number of pharmacy registrants and requests made by pharmacy registrants has increased quite substantially during the past year. Below you will see charts showing the increase. The Board is proud of the increase in utilization of the North Dakota Prescription Drug Monitoring Program (PDMP) and it is continuing to prove to be the most powerful patient care tool to prevent and deter prescription drug abuse.

Registrants by Quarter 2014		
Quarter	Pharmacist	Pharmacy Technician
2	431	81
3	599	118
4	667	131

Report Requests by Quarter 2014	
Quarter	Pharmacy Queries Requested
2	12,674
3	19,995
4	23,505

The Board will expect to see further increases in utilization for our profession due to the implementation of the administrative rules for pharmacies to utilize the PDMP. If you have not created an account for direct access to the PDMP, if applicable, you should follow the steps below to receive online access and ensure that you utilize it in your practice.

To create your North Dakota PDMP account:

1. Visit <https://northdakota.pmpaware.net/identities/new>.
2. Enter your email address and password (must contain at least eight characters, upper and lower case letters, and punctuation or symbol) and then click register.
3. Select your role; for example, click the arrow next to Healthcare Professional, then select the box next to Pharmacy Technician or Pharmacist, and then click on the Update User Roles and Continue button.
4. Fill in the online form. If you are a pharmacy technician, please select the "I am a delegate for..." box and enter the email address of your pharmacist-in-charge or any other pharmacist who already has an account and you work with (from any location). Click the Finish button.
5. You will receive two emails: one with an email verification link you must click on, and the other contains an agreement that requires a notary signature and needs to be uploaded or faxed back to 701/328-9536.

The administrator will review your application and, if everything is in order, will approve it. You can then visit <https://www.nodakpharmacy.com/pdfs/AWARxErequest.pdf> for a one-page "how to" for pulling the best results when you make a request.

If you have questions, please contact 701/328-9537 for assistance, or call the 24-hour support line at 855/563-4767.

Page 4 – March 2015

The *North Dakota State Board of Pharmacy News* is published by the North Dakota State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

Mark J. Hardy, PharmD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Deborah Zak - Communications Manager