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Pharmacy Technicians and CE: National Certification Requires It, West Virginia Registration Does Not, So What Is the Deal?

Inspectors have been fielding questions about continuing education (CE) requirements for a pharmacy technician (PT) registered in West Virginia as a result of the changes in the law and rules for national certification of newly registered PTs. Is CE required? The answer is yes and no. Hopefully, this article will clear up any confusion on this matter. To begin with the statutory requirements for becoming a registered PT in West Virginia, West Virginia Code §30-5-11 provides, in part:

(a) To be eligible for registration as a pharmacy technician to assist in the practice of pharmacist care, the applicant shall: . . .

(4) Have:

(A) Graduated from a competency-based pharmacy technician education and training program as approved by legislative rule of the board; or

(B) Completed a pharmacy provided, competency-based education and training program approved by the board;

(5) Effective July 1, 2014, have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the board; . . .

(c) A person registered to assist in the practice pharmacist care issued by the board prior to June 30, 2014, shall for all purposes be considered registered under this article and may renew pursuant to the provisions of this article.

As you can see from Subsection (c), anyone who was already registered as a PT prior to June 30, 2014, does not have to be nationally certified, and is grandfathered in. There are no requirements in the West Virginia law or rules to require these PTs to obtain CE. However, as of July 1, 2014, and going forward, every newly registered PT must pass a national certification exam. Prior to taking the exam, one must get training, either from a proper school-based program or from an on-the-job program. New rules allow for an in-store pharmacy training program of 960 hours in 15 months or less, and then give three months to pass a national exam.

There are currently two accredited programs recognized by the West Virginia Board of Pharmacy that nationally certify PTs by testing as listed in West Virginia Code §30-5-11(a)(5). They are the Pharmacy Technician Certification Board (PTCB), which administers the Pharmacy Technician Certification Exam; and the National Healthcareer Association (NHA), which administers the Exam for the Certification of Pharmacy Technicians. Upon passing his or her respective exam, these organizations bestow a national PT certification to the candidate, which is called a certified pharmacy technician (CPhT) designation. In order to maintain his or her CPhT certification, these organizations have both implemented CE requirements; both organizations require 20 hours of PT-related CE every two years. The Board's rules require these PTs to maintain their CPhT certification in order to be eligible for renewal, so although the state law and rules do not specify particular CE requirements for PTs, those required to have national certification must complete the CE and report it to the PTCB or the NHA, whichever provides his or her CPhT certification.

If you are certified by either of these bodies and wish to maintain that CPhT certification, then you will be required to have the 20 hours of PT-related CE reported to PTCB or NHA, not to the Board. If you were grandfathered in, do not have a CPhT certification, and only wish to

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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*.

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maintain your West Virginia registration as a PT, there is no current requirement for CE at this time.

Does the PIC of a Nonresident Pharmacy Also Have to Be the PIC of the West Virginia Mail-Order Permit?

Although West Virginia Code §30-5-23 requires each pharmacy to have a pharmacist-in-charge (PIC) who is responsible for the pharmacy's compliance, which has long been the law in this state, and although the law requires pharmacists practicing pharmacist care in West Virginia, including dispensing into this state from outside of this state, to have a West Virginia pharmacist's license, the Board in the past found that most nonresident mail-order pharmacies had no one licensed in West Virginia. In 2013, the West Virginia Legislature amended the Pharmacy Practice Act and added language to the Board's rulemaking authority to make it clear that nonresident pharmacies dispensing into West Virginia, ie, mail-order pharmacies, must have a PIC licensed to practice in West Virginia (see West Virginia Code §30-5-7(a)(13)). That provision, effective July 1, 2013, also gives the Board the authority to provide differently in some respects by rule. So, as a reasonable accommodation to nonresident pharmacies, West Virginia Code §30-5-7(a)(13) allows for just the nonresident PIC to be licensed in West Virginia, and all the other pharmacists in that pharmacy to just hold a license in the home state where the mail-order pharmacy is located. The Board set a full implementation date of July 1, 2014, to allow pharmacists to get license transfers done; further, for the first couple of years of this new enforcement, the Board has not required the actual PIC of the nonresident pharmacy to be the PIC of the mail-order permit, but, if it so chooses, allows the nonresident mail-order pharmacy to have any pharmacist on staff working there to get licensed in West Virginia and take responsibility as PIC for the mail-order permit, and, as such, be considered the PIC for all prescriptions dispensed into this state. So, while in a perfect world it would be one pharmacist as PIC of the pharmacy and PIC of the mail-order permit, and it can be so, the Board has allowed some flexibility as it adjusts to this new statute.

Legislature in Full Swing

At the time of this writing, the West Virginia Legislature is in full swing, with more than five weeks left in the Regular Legislative Session. The Board has four sets of rules pending in Series 1, 7, 8, and 12 to, among other details: update testing requirements for licensure; update the PT registration process; add some clarifications to confidentiality of the Controlled Substances Monitoring Program data and work of the Advisory and Review Committees; and add meningococcal vaccine to those vaccines permitted to be administered by immunization pharmacists, and permit properly certified interns to do immunizations under the immunizing pharmacist's personal supervision. The Board is watching these things diligently, and as always, will have to be ready to adjust to whatever changes are eventually passed. If you want to follow along, visit the West Virginia Legislature's web page and look up the various bills' statuses.

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