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Delaware State Board of Pharmacy News

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Continuing Education Requirements

With the renewal deadline approaching, the Delaware State Board of Pharmacy and the Delaware Division of Professional Regulation would like to ensure that all pharmacists understand their continuing education (CE) requirements. This article will explain the requirements and how to make sure they have been met.

Pharmacist CE Requirements

The Board Rules and Regulations (Section 1.4) state the CE requirements for each biennial renewal period. These requirements are summarized below:

- The pharmacist must acquire 3.0 CE units (30 hours) per biennial licensure period. No carry-over of credit from one registration period to another is permitted. The 30 hours must include the following:
  - At least two hours of CE must be completed in the area of medication safety/errors.
  - At least two hours of CE in: 1) the distribution, dispensing, or delivery of controlled substances (CS); or 2) the detection and recognition of symptoms, patterns of behavior, or other characteristics of impairment and dependency resulting from the abusive or illegal use of CS.
  - For immunizing pharmacists, a minimum of two hours dedicated to the administration of injectable medications, biologicals, and immunizations.
- Approved providers of CE for pharmacists licensed in Delaware are:
  - Any provider approved by the Accreditation Council for Pharmacy Education (ACPE)
  - An in-state organization that meets criteria approved by the Board.
- Identifying medication safety and immunization CE courses.
  - The quickest and most effective way to determine whether a CE activity counts as patient safety or immunization CE is to look at the Universal Activity Number (UAN). Each CE activity provided by an ACPE-accredited provider of CE has a unique UAN and providers are required to include this number in official program announcements. The last two numbers of the UAN are the topic designator. A UAN with "05" as the topic designator is a medication safety program. A UAN with "06" as the topic designator is an immunization program. UAN examples are shown below:

    Medication safety: 0159-0000-15-009-L**05**-P

    Immunization: 0159-0000-15-009-L**06**-P

The Board Rules and Regulations are available online at *http://regulations.delaware.gov/AdminCode/title24/2500.shtml.*

Inactive Status for Pharmacist Licenses

The Board and the Division of Professional Regulation would like to clarify the inactive status requirements for pharmacist licenses. This article explains how to request inactive status, how long you can remain inactive, and the process for reactivating your license.

Inactive Status

The Delaware Code, Title 24, Section 2512 states the requirements for a pharmacist to place his or her license on inactive status. The requirements are summarized below:

- A pharmacist must make the request in writing to the Board to place the license on inactive status.
- A license may be placed on inactive status for **no more** than a total of four years.
  - This total is a cumulative total over the duration of the license. For instance, if a licensee is on inactive status for three years and then reactivates his or her license, he or she is only allowed to place the license in an inactive status for one more year for the duration of the time he or she is licensed.
- If a license is in an inactive status for more than four years, the licensee must reapply in order to be relicensed.
- A licensee wishing to reactivate an inactive license must do the following:
  - Submit a letter stating that he or she wishes to reactivate the license; and
  - Submit an application with a renewal fee, a criminal background check, and proof of completion of CE credits.

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National Pharmacy Compliance News

August 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

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

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The statute and application are available online via the Board's website:

- Statute: *http://delcode.delaware.gov/title24/c025/sc02/index.shtml*
- Application: *https://dprfiles.delaware.gov/pharmacy/Pharmacist_Exam-Score-Trans_App.pdf*

Medication-Assisted Treatment

The following excerpts are taken from the Substance Abuse and Mental Health Services Administration (SAMHSA) website at *https://www.samhsa.gov/medication-assisted-treatment/treatment#medications-used-in-mat.*

Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery. Learn about many of the substance use disorders that MAT is designed to address by visiting SAMSHA's website.

MAT is primarily used for the treatment of addiction to opioids such as heroin and prescription pain relievers that contain opiates. The prescribed medication operates to normalize brain chemistry, block the euphoric effects of alcohol and opioids, relieve physiological cravings, and normalize body functions without the negative effects of the abused drug. Medications used in MAT are approved by Food and Drug Administration, and MAT programs are clinically driven and tailored to meet each patient's needs.

Opioid treatment programs (OTPs) provide MAT for individuals diagnosed with an opioid use disorder. OTPs also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs, potential criminal activity, and/or the spread of infectious disease. OTPs focus on improving the quality of life for those receiving treatment.

The ultimate goal of MAT is full recovery, including the ability to live a self-directed life. This treatment approach has been shown to:

- Improve patient survival
- Increase retention in treatment
- Decrease illicit opiate use and other criminal activity among people with substance use disorders
- Increase patients' ability to gain and maintain employment
- Improve birth outcomes among women who have substance use disorders and are pregnant

Unfortunately, MAT is greatly underused. For instance, according to SAMHSA's Treatment Episode Data Set (TEDS) 2002-2010, the proportion of heroin admissions with treatment plans that included receiving medication-assisted opioid therapy fell from 35% in 2002 to 28% in 2010. The slow adoption of these evidence-based treatment options for alcohol and opioid dependence is partly due to misconceptions about substituting one drug for another. Discrimination against MAT patients is also a factor, despite state and federal laws clearly prohibiting it. Other factors include lack of training for physicians and negative opinions toward MAT in communities and among health care professionals.

A common misconception associated with MAT is that it substitutes one drug for another. Instead, these medications relieve the withdrawal symptoms and psychological cravings that cause chemical imbalances in the body. MAT programs provide a safe and controlled level of medication to overcome the use of an abused opioid. Research has also shown that when provided at the proper dose, medications used in MAT have no adverse effects on a person's intelligence, mental capability, physical functioning, or employability.

Buprenorphine treatment happens in three phases:

1. **The induction phase** is the medically-monitored start-up of buprenorphine treatment performed in a qualified physician's office or certified OTP using approved buprenorphine products. The medication is administered when a person with an opioid dependency has abstained from using opioids for 12 to 24 hours and is in the early stages of opioid withdrawal. It is important to note that buprenorphine can bring on acute withdrawal for patients who are not in the early stages of withdrawal and who have other opioids in their bloodstream.
2. **The stabilization phase** begins after a patient has discontinued or greatly reduced their misuse of the problem drug, no longer has cravings, and experiences few, if any, side effects. The buprenorphine dose may need to be adjusted during this phase. Because of the long-acting agent of buprenorphine, once patients have been stabilized, they can sometimes switch to alternate day dosing instead of dosing every day.
3. **The maintenance phase** occurs when a patient is doing well on a steady dose of buprenorphine. The length of time of the maintenance phase is tailored to each patient and could be indefinite. Once an individual is stabilized, an alternative approach would be to go into a medically supervised withdrawal, which makes the transition from a physically dependent state smoother. People then can engage in further rehabilitation – with or without MAT – to prevent a possible relapse.

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