



Kentucky Board of Pharmacy

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Drug Manufacturer and Wholesale Distributor Renewal Deadline Is September 30, 2018

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2018. A drug manufacturer or wholesale distributor may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy's website at www.pharmacy.ky.gov. If you have any questions concerning the renewal process please contact the Board office. A drug manufacturer or wholesale distributor application with only a United States Post Office Box address will not be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2018.

Protocols and Collaborative Care Agreements: What Is the Difference?

The Board recently passed 201 Kentucky Administrative Regulations (KAR) 2:380, Board Authorized Protocols. 201 KAR 2:220, Collaborative Care Agreements has been around for several years. So, what is the difference?

Protocols

201 KAR 2:380 specifically mentions 13 conditions for which the Board may authorize a protocol. Adding these conditions to the immunization protocol authorized by Kentucky Revised Statute (KRS) 315.010(22) and the naloxone protocol authorized by 201 KAR 2:360, brings the total to 15 specific conditions in which a protocol may be utilized. The immunization and naloxone protocols do not have to be authorized by the Board, but the other 13 conditions must have a Board-authorized protocol. Once the Board authorizes a protocol, it is available on the Board's website, www.pharmacy.ky.gov, for any pharmacist to use. If any changes are made to a Board-authorized protocol, the altered protocol must be presented to the Board for authorization before using. Protocols are between a physician and pharmacist(s) in the case of naloxone and any prescriber and pharmacist(s) in the case of the other protocols. The pharma-

cist is able to utilize the protocol for any patient coming into the pharmacy wishing to partake of this particular service. For example, any patient wanting a flu vaccine may request one; if the patient meets the qualifications outlined in the protocol, the pharmacist may administer the vaccine. A protocol gives the pharmacist who signed the protocol the authority to assess the patient and dispense or administer any authorized medication.

Collaborative Care Agreements

Collaborative Care Agreements (CCAs) are between practitioner(s) and pharmacist(s) to treat the specific patients of the practitioner(s). There is no list of conditions for a CCA. It can be for any disease or condition but typically is used to treat an ongoing disease, whereas a protocol is typically more episodic. The Board does not have to authorize or review CCAs. A pharmacist may implement a CCA by following KRS 315.010(5) and 201 KAR 2:220. A common example of a CCA is an anticoagulation clinic. Unlike a protocol, the CCA is not as self-contained. A pharmacist working under a CCA may authorize a prescription to be dispensed at a community pharmacy by a pharmacist not associated with the CCA. The Board voted at the July 18, 2018 Board meeting that these prescriptions may be written, verbally authorized, or electronically prescribed by the pharmacist under a CCA. The community pharmacist dispensing the prescription may not be informed that the prescription was authorized as part of a CCA, but this information may be requested from the patient or health system.

The Board inspection staff will be requesting protocols and CCAs for review during inspections.

KASPER Report Change for Buprenorphine Prescriptions

*Submitted by David R. Hopkins, KASPER Business Analyst,
Kentucky Cabinet for Health and Family Services*

Buprenorphine prescriptions currently included on Kentucky All Schedule Prescription Electronic Reporting (KASPER) reports include the daily morphine equivalent dose (MED). The KASPER MED calculation is based on a morphine milligram equivalent (MME) conversion table distributed by the Centers for Disease Control and Prevention (CDC).

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National Pharmacy Compliance News

September 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 display-

ing 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 Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- ◆ Verifying how much CPE credit must be earned to satisfy renewal requirements;
- ◆ Receiving alerts when a license is nearing the end of a CPE cycle;
- ◆ Uploading non-ACPE credits to a licensee’s e-Profile;
- ◆ Viewing consolidated transcripts for each state license;
- ◆ Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- ◆ Connecting to the Pharmacists’ Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of \$29.95, regardless of how many licenses a pharmacist has or adds at a later date. It 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 plan 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 CDC recently released a new MME conversion table that does not include conversion factors for any buprenorphine products. The following is the guidance provided by the CDC related to this change:

Buprenorphine products are listed in this file but do not have an associated MME conversion factor. The conversion factors for drugs prescribed or provided as part of medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain. These buprenorphine products, as partial opioid agonists, are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.

The Cabinet for Health and Family Services plans to begin using the new CDC MED conversion table effective October 1, 2018. Please be aware that after that date, KASPER reports will no longer show a MED value for any buprenorphine product, and they will not be included in the active cumulative morphine equivalent calculation. If you have questions, please email ekasper.admin@ky.gov.

Medication Guides and Patient Package Inserts

Submitted by Rhonda Hamilton, PharmD, Pharmacy and Drug Inspector

Medication guides, which are developed by a particular drug's manufacturer, convey information to patients in a physical format. The guides are approved by Food and Drug Administration (FDA) to educate patients in an effort to help them avoid serious adverse events associated with certain medications. FDA requires these guides to be distributed with these medications and biological products each time they are dispensed, whether the prescription is new or a refill, per Title 21 (Food and Drugs) of the Code of Federal Regulations (CFR), Part 208 (Medication Guides for Prescription Drug Products).

Medication guides are required to be supplied with medications when the information contained therein is essential to avoid serious adverse events, when patient decision making should be informed by data about a serious side effect with a medication, or patient adherence to directions for the use of a medication is vital to its efficacy. An authorized dispenser (eg, a pharmacist) is required to distribute medication guides to either the patient or his or her agent unless FDA determines that the content, with the exception of requirements listed in 21 CFR 208.20 (a)(2) and (a)(6), is inapplicable, unnecessary, or against a patient's best interests, or the prescriber determines that it is not in a specific patient's best interest

to receive the medication guide. However, the authorized dispenser must provide a medication guide to any patient who requests it, regardless of direction from the prescriber.

Common medications that require medication guides include some atypical antipsychotics, proton pump inhibitors, bisphosphonates, nonsteroidal anti-inflammatory drugs, psychostimulants, and antidepressants. A complete list of medications that require medication guides can be found on FDA's website.

Patient package inserts are part of FDA-approved prescription drug labeling. Like medication guides, they are a physical format to provide information to patients, are developed by the drug's manufacturer, are approved by FDA, and are mandatory to be distributed with certain drugs or drug classes. These specifically are oral contraceptives and estrogen-containing products, per 21 CFR 310.501 and 21 CFR 310.515. Patient package inserts for other medications or products may be submitted to and approved by FDA, but their distribution is not required.

Important CE Information

- ◆ The Board audits every continuing education (CE) account every year for every Kentucky-licensed pharmacist. The Board uses CPE Monitor® to ensure everyone has completed 15 hours of CE.
- ◆ The CE year is the calendar year, not the license renewal to license renewal year.
- ◆ Please check your CPE Monitor transcript well in advance of December 31 to ensure that you have the required 15 hours.
- ◆ CE that is not Accreditation Council for Pharmacy Education (ACPE)-accredited must be approved by the Board.
- ◆ CE not accredited by ACPE [including Kentucky Board-approved CE] will not appear on your CPE Monitor transcript unless you have subscribed to CPE Monitor Plus and uploaded the credits yourself.
- ◆ Please note that ACPE-accredited continuing pharmacy education (CPE) providers have up to 60 days to report your credits to CPE Monitor.

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