MARCH 2023

KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

2023 Board Officers

The Kentucky Board of Pharmacy has elected John Fuller as president and Jonathan Van Lahr as vice president for 2023. This is Fuller's first term as president and his fifth year on the Board. This is Van Lahr's first term as vice president and his third year as a Board member.

2023 Board Calendar

2023 Board meetings will begin at 10 AM ET. The meeting location is subject to change but will be posted on the Board's website in advance. Pharmacists and the public are invited to attend. Should you wish to have a matter considered by the Board, kindly provide the information to the Board office no less than 14 days before the meeting date. Board agendas will be posted prior to the meeting date.

- March 22, 2023
- May 24, 2023
- July 26 and 27, 2023 Board meeting and retreat located at Sullivan University College of Pharmacy and Health Sciences
- September 20, 2023
- November 29, 2023

National Pharmacy Compliance News
A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

2023 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2023. As a reminder, no person shall assist in the practice of pharmacy unless they are duly registered as a pharmacy technician or are exempt under Kentucky Revised Statutes 315.135(2). Every pharmacy technician shall keep their current

certificate of registration conspicuously displayed in the technician's primary place of employment. The Board encourages online registration renewal. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website:** *www.pharmacy.ky.gov.*

Resident Mail-Order Pharmacies Dispensing Nonresident Prescriptions

If a Kentucky mail-order pharmacy receives a prescription for an out-of-state patient from a practitioner with prescriptive authority under the professional licensing laws of that state, the pharmacy is permitted to recognize the prescription order as valid and may dispense to the out-of-state resident. The applicable prescriptions could be those issued from collaborative practice agreements not allowed for Kentucky patients. Examples include:

1. oral contraceptive prescription for a California patient issued by an authorized California pharmacist;
2. blood pressure medication for a North Carolina patient prescribed by a North Carolina clinical pharmacist practitioner; or
3. prescription vitamin to a Washington patient from a prescription issued by a Washington-licensed naturopathic physician.

This guidance was developed in collaboration with the Drug Enforcement and Professional Practices Branch at the Commonwealth of Kentucky Cabinet for Health and Family Services.

Removal of the Federal Waiver Requirement for Prescribing Buprenorphine

As part of the fiscal year 2023 omnibus legislation to fund the federal government that passed into law in December 2022, Congress passed the Mainstreaming Addiction Treatment Act, which will remove the federal "DATA 2000" or "X-waiver" requirement for clinicians who prescribe medication for opioid use disorder (OUD) or buprenorphine. The bill also removed all limits or caps on the number of patients a prescriber may treat for OUD. Drug Enforcement Administration has issued guidance on the impact of the bill and the timeline for new training requirements.

The Kentucky Board of Medical Licensure (KBML) and the Kentucky Board of Nursing (KBN) have both issued guidance on the impact to current Kentucky prescribing regulations:

KBML guidance

KBN guidance

The Board will continue to issue guidance to all Kentucky-licensed pharmacists as updates become available.

USP Publishes Revisions to General Chapters <795> and <797>

On November 1, 2022, United States Pharmacopeial Convention (USP) published revisions to pharmaceutical compounding standards Chapters <795> (nonsterile preparations) and <797> (sterile preparations) with an anticipated implementation date of November 1, 2023, for both. This article highlights a few of the changes in each chapter.

USP Chapter <795> Nonsterile Compounding

In general, the 2022 revision to USP Chapter <795> is easier to read and provides clear and specific requirements and procedures. One of the changes is the removal of the following categories: simple, moderate, and complex. Per USP, these categories often led to confusion among users on how to apply the criteria, and the chapter did not provide standards on how to use these categories in applying compounding standards.

A new term has now been introduced: the "designated person." The designated person is one or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded preparations.

Gloves must be worn for all compounding activities, and other garb worn (eg, shoe covers, head or hair covers, face masks, gowns) must be appropriate for the type of compounding performed.

The revision requires a space that is specifically designated for nonsterile compounding. This space is to have a visible perimeter to establish the boundaries; however, it does not require a separate room. Other activities may be performed in the compounding space when compounding is not occurring.

Cleaning and sanitizing of the surfaces in the nonsterile compounding area must occur on a regular basis, and a table is provided with the minimum frequencies. Additionally, a spill kit is required.

The compounding record no longer requires a duplicate label.

There is a new system to determine beyond-use dates (BUDs) using water activity (a_w) of the components. The a_w is the measure of free water that is available to participate in chemical reactions, such as hydrolysis, or may provide an environment that can support microbiological growth. The chapter provides several tables to assist with determining the a_w of a compounded nonsterile preparation and provides a chart to then determine the BUD. Additionally, the maximum BUD for any preparation is 180 days.

There are several processes explicitly required by the new revision: quality assurance and quality control, recalls, complaint handling, and adverse events.

Several sections were removed, such as patient counseling and compounding for animals. However, the introduction of the 2022 revision states that it is the minimum standard for preparation of nonsterile preparations for humans and animals.

USP Chapter <797> Sterile Compounding

As mentioned above, the 2022 revision is easier to read and provides clear and specific requirements and procedures as compared to the previous version, and several items introduced in the revision for USP Chapter <795> are also in the revision for USP Chapter <797> (eg, the designated person, quality assurance, quality control, complaint handling, adverse events).

The 2022 revision clearly states the types of preparations required to be sterile and the conditions required to prepare a conventionally manufactured sterile product in accordance with the directions in the labeling.

The risk categories (low, medium, and high) have been eliminated, and the 2022 revision introduces Category 1, Category 2, and Category 3 compounded sterile preparations (CSPs). The new categories are distinguished primarily by the conditions under which they are made and the time within which they are used.

- Category 1: compounded in the least controlled environment and assigned a BUD of 12 hours or less at controlled room temperature (CRT) or 24 hours or less when refrigerated. These CSPs must be prepared in a primary engineering control (PEC) that may be placed in an unclassified segregated compounding area or in a cleanroom suite.
- Category 2: compounded in a more controlled environment and may be assigned a BUD of more than 12 hours at CRT or more than 24 hours if refrigerated. These CSPs must be prepared in a PEC within a cleanroom suite.
- Category 3: compounded in a controlled environment with environment, personnel, and CSPs undergoing additional testing and qualifications. CSPs may be assigned a longer BUD than those for Category 2 and must undergo sterility testing and endotoxin testing (when applicable). These CSPs are prepared in a PEC within a cleanroom suite by personnel using sterile garb.

In addition to starting ingredients, BUDs are also based on environmental quality, personnel hygiene and garbing, physicochemical stability, and requirements for release testing. There are tables provided for determining the BUDs for Category 1, 2, and 3.

For immediate-use CSP, the revision allows for administration to begin within four hours (an increase from the one hour of the previous version) following the start of the preparation based on the four to six hour lag phase of microbial growth.

Garbing competency frequency and air and surface sampling frequency have been increased to help mitigate risks of inadvertent contamination to help support the extended BUDs.

For additional information on USP Chapter <795> and USP Chapter <797> and the revisions, including frequently asked questions and a fact sheet, visit *https://go.usp.org/2022_Revisions_795_797.*

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