The Kentucky PHARMACIST

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The Official Publication of the Kentucky Pharmacists Association

"Now is our time to Thrive!"

KPhA Welcomes our New President
Dr. Brooke Hudspeth, PharmD, CDCES

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Mission Statement:
To advocate and advance the pharmacy profession to improve the health of Kentuckians

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- How to talk to a legislator
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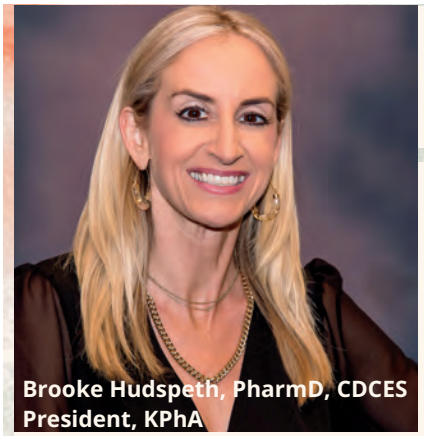
- Love Pharmacy but feel stuck? Hear from a panel of pharmacists living their dream in non-traditional career paths.
- Tips & Tricks of the Trade from successful Pharmacy owners

Presidents Perspective

"It's Our Time To Thrive "



Brooke Hudspeth, PharmD, CDCES
President, KPhA

As I settle into my new role as KPhA's President, it's hard not to reflect on the professional connections and friendships the Association has offered me. Some of the greatest pharmacists and technicians in Kentucky--arguably in the nation--are KPhA members. I am honored to begin this journey as your President to help to advocate and advance the pharmacy profession to improve the health of Kentuckians.

We are certainly facing a difficult period for pharmacy. Tough workplace conditions exacerbated by the pandemic, draconian PBM practices, attacks on our scope of practice, and both a reluctance and, in some cases, refusal to compensate us for our services are daily issues hindering our ability to provide patients with the best care. And, perhaps, most disheartening to see are the blows to the confidence of our colleagues as we grapple with the ever-growing fear we are fighting battles that we cannot overcome. Yet, despite these obstacles, we remain the medication experts and continue continue to be the most accessible healthcare provider. We remain steadfast largely because of KPhA's tireless work to persevere, gain ground and help maintain our profession's relevance. We are seeing a movement toward PBM reform We are continuing our work to implement payment for pharmacist services. We stopped legislation that would have rolled back our scope of practice and harmed countless Kentuckians in the process. I know—firsthand--that we did everything in our power to limit the negative impact on our profession and our patients. We have continued to survive in the face of adversity and have shown just how durable pharmacists truly are.

Now is the time to do more than survive. Now is our time to thrive! It is our time to show our colleagues, our patients, our politicians, and our communities that pharmacists will lead the change we believe in and live out our oath to embrace and advocate change in the profession of pharmacy that improves patient care. Pharmacists are special, pharmacists are important, and pharmacists are necessary. Many politicians, providers, and, most importantly, our patients recognize and value this fact. We have helped expand access to care, improve patient outcomes, and create healthier communities across Kentucky.

Over the next year, I want to build off our successes and use the resources we have gathered to achieve our goals. I want to ensure that we are engaged in ways we have never been before. That we engage with not just the same colleagues but new ones as well. That we engage our communities and other stakeholders across Kentucky so that we can get to the heart of these issues and address them once and for all. To build a unified profession with pharmacists valued as the medication experts in an interprofessional healthcare, we must engage our fellow pharmacists from every corner of the state and in every area of practice. We must engage our communities to make sure they truly know and understand how pharmacists are trained, what pharmacists do, and what pharmacists are capable of. Our patients should know that we do more than simply put their pills in a bottle. Our fellow healthcare providers should know that we are highly trained and educated and can assist them in ensuring optimal outcomes. Our politicians should know the great value we bring to their constituents and how our services save the state money. We need to engage our committees and members in novel ways to ensure we do everything possible to set ourselves up for success before the legislative session starts.

I have no doubt that we will face obstacles over the next year. I know we will not win every battle. What we will do, however, is not be threatened by issues. In fact, we are going to put them front and center, and we are going to engage our colleagues, our patients, and our communities. We will remind them that we are some of the most highly educated healthcare professionals who have proven themselves time and time again and answered their call when they needed us the most. If you take away one thing from my time as President, I want you to take the challenge to do more than survive. I want you to THRIVE. Thrive back to your practice, your patients, and your communities.

I am looking forward to this year with you and the exciting work that is to come.

ATTENTION PHARMACISTS:

Know the 5 common coverage gaps that could cost you your career.

With its fast pace and massive volume of medications, the pharmacy profession is ripe for claims and litigation. If you think your employer's coverage will protect you in the event of an error (actual or alleged), complaint, or legal claim, consider the following:

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GAP #3: If a court judgment exceeds your employer's limits, you may be responsible for paying the difference. That could cost you tens of thousands of dollars.

GAP #4: Employer insurance may not help when a patient files a complaint to the Board of Pharmacy. This could put you at risk of a disciplinary action without proper representation.

GAP #5: You may be fully responsible for suits against you if you leave that company. This is especially true if your employer uses a claims-made based policy.

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Welcome to our NEW KPhA Members. We are stronger together!

This list reflects all new members
October 1- August 7, 2023

All members reside in Kentucky unless noted

Cynthia Akers, Grayson

Rhiannon Baker, Lily

Martha Bandy, Ponte Vedra Beach, FL

Elizabeth Bernauer, Louisville

Jamie Biliter, Nicholasville

Jay Brainard, Somerset

Derek Cannon, Owensboro

Aimee Chambers, Philpot

Jennifer Cherian, London

Randy Clark, Coxs Creek

Chelsey Couch, Garrett

Jordan Craft, Louisville

John Creech, Corbin

Alathea DiGrandi, Richmond

Weston Dungan, Somerset

Ashley Ferris, Cypress, TX

Jennifer Grove, Crestwood

Emily Hardrick, Dixon

Terrice Hooks, Indianapolis, IN

Sam Howard, Paducah

Onileola Llesanmi, Louisville

Shonna Irvin, Tompkinsville

Meredith Johnson, Dresden, TN

Danielle Kromer, Providence

Sandra Lawson Cookeville, TN

Kelsie Ledford, Nicholasville

Priscilla Nichols, Bowling Green

Danielle O'Mara, Louisville

Holly Osborne, Ironton, OH

Tonya Parsons, Virgie

Maulik Patel, Hopkinsville

Harita Patel Cary, NC

Faith Percival, Lexington

Allison Potts, Louisville

Kayla Prewitt, Corbin

Travis Prewitt, Corbin

Amanda Prine, Bowling Green

Gregory Richardson, Nashville, TN

Morgan Roberts, New Albany, IN

Rebecca Ruby, Bowling Green

Brook Rucker, Glasgow

Karla Salnoris, Corbin

Tameron Shaw, Glasgow

Ryan Sheldon, Bowling Green

Kelsey Simpson, Hickman

Jen Sparks Ona, WV

Stephen Tipton, Lexington

Diane White, Springfield

Alondra Wilson, Bowling Green

John Winnett, Washington DC

John Wright, Shepherdsville

2023-2024

Meet KPhA's New Board Members

President-elect:
Kyle Harris

Treasurer:
Lakin Marr

Kyle Bryan

Steve Sheldon

Jordan Smith

Student Representatives

Siddharth Sheth
SUCOPHS

Noah Stallins
UKCOP

Kentucky Pharmacists Association

House of Delegates at the 145th KPhA Annual Meeting

Bowling Green, KY

June 9-10, 2023

Kyle Bryan, Speaker of the House
Nicole Miracle, Vice Speaker of the House
Ronnah Alexander, Secretary
Joe Fink, Parliamentarian

Speaker Kyle Bryan called the House of Delegates to order at 1:40 p.m. on Friday, June 9, 2023. Secretary Ronnah Alexander gave the credentials report. There were 48 Delegates present. 24 votes for a majority, 36 votes for 2/3 majority and 32 votes for 3/4 majority.

The minutes from the June and October 2022 House of Delegates meetings were provided online to members prior to the Annual Meeting. **The motion was made by Scotty Reams to approve the minutes as presented. The motion was seconded. Motion carried.**

At this time in the meeting, there are no reports or action items to be sent before a Reference Committee. Speaker Kyle Bryan requested a motion from members to table to review the Reference Committee until such time, if required, at this Annual Meeting. **Taylor Williams made the motion to table the review of the Reference Committee. The motion was seconded. Motion carried.**

Speaker Kyle Bryan called for nominations for the 2023-2024 Vice Speaker of the House of Delegates. A nomination was made for Joel Thornbury; he accepted the nomination. No other nominations were presented at today's meeting. Voting will be held at the Closing House of Delegates tomorrow. **Trish Freeman made the motion to table the appointment of the Reference Committee until such time as one is needed during this meeting. The motion was seconded. Motion carried.**

Those appointed to the Reference Committee, if needed at this Annual Meeting, were as follows: Trish Freeman, Chair of Reference Committee, Kim Croley, Joe Carr, Kyle Harris, Lakin Marr, and Joel Thornbury. **Joel Thornbury made the motion to approve the reference committee. The motion was seconded. Motion carried.**

Craig Martin gave a report from the Government Affairs Committee. It was a challenging Legislative Session with monthly and then weekly meetings during the session. The committee was surprised by a few legislative moves during the session and had to be defensive of the profession throughout. The bill that attempted to remove board-authorized protocols being used by pharmacists, through the efforts of all, did not come up for a vote. The committee monitored the pharmacist's role in the gender transition bill that received a lot of press and medical cannabis in Kentucky. Our role was not to advocate for or against either bill but to ensure that the pharmacist's role was protected and maintained.



Pharmacists were not able to be a part of the process in the medical cannabis bill, but the bright side is that the bill does not take effect until 2025. There were some successes in the session. The opioid wording expanded on naloxone and the professional conduct of pharmacy permit holders. Special thanks to Representative Danny Bentley for his work during the session.

KPhA Chair Cathy Hanna presented a request from the KPhA Board of Directors for a Policy Change in how Continuing Education is presented by KPhA.

Recommendation: Remove policy 2.8.2 and create a new policy under Section 5 Continuing Education that reads**:**

The Kentucky Pharmacists Association, through KPERF shall offer KPhA members a minimum of 15 hours (1.5 CEUs) of free continuing education on an annual basis through publication of written articles in The Kentucky Pharmacist, online modules, webinars, or other methods.

The motion from the KPhA Board of Directors to update the Continuing Education Policy was passed unanimously by the House of Delegates. (Reference: 2023.01)

KPhA President Misty Stutz gave a brief report on her year as KPhA's President. The year began with a KPhA Membership ROAD Trip with President Stutz, KPhA Staff, and Board Members. We visited as many pharmacies and pharmacy settings as we possibly could in two days a week over six weeks. It was great to connect with members across the state. We have provided so much education in the last year to advance the profession, including medical billing and colorectal cancer screening protocols. Our Advocacy was intense this year! Meeting with legislators and representatives across the state and Pharmacy Day at the Capitol in February was successful. KPERF presented (5) $1,000 Incentive grants

Presentations on those grants occured at the Annual Meeting. Advanced technician roles are in the works with the Board of Pharmacy. The KPhA Board and Staff really made the role of President easy with all of their support. 2022-2023 was our first year with an Executive Fellow, Emily Wilkerson. Emily will be staying on as a KPERF Staff member, so you will still see her around! Taylor Williams will begin her role as the second Executive Fellow on July 1st. Special thanks to Ben Mudd for a great year; he's the best hire we've ever had!

KPhA Treasurer Chris Killmeier gave the 2022 Financial Report. KPhA continues to find ways to strengthen the Association. The Association completed its 12th consecutive financial report from Harrod & Associates in 2022. The 2022 year was an Agreed Upon Procedure. There were no material weaknesses or deficiencies found by the Auditors. All financial documents are available on the website for all members to view at any time.

KPhA Executive Director Ben Mudd presented a brief report from the Staff of KPhA and KPERF for the past year. The KPhA Strategic Plan will be extended by one year as the Board of Directors has supported Executive Director Mudd's commitment to Leadership Kentucky through the end of 2023.

Thank you to the Board for their support of this commitment.

Shannon Stiglitz from the Kentucky Retail Federation spoke to the House of Delegates about the advocacy efforts in the 2023 legislative session and how the Legislators and Representatives have changed in the last year. There are many new members that need educating on pharmacy issues.

KPhA Chair Cathy Hanna recognized the outgoing KPhA Officers and Board of Directors. Treasurer Chris Killmeier and Directors Kyle Harris, Steve Sheldon, Cory Smith, Jenna Brophy, Lauren Williams, and Past President Representative Joel Thornbury.

The motion was made by Steve Sheldon to recess until the closing House of Delegates. The motion was seconded. Motion carried.

The House of Delegates reconvened on Saturday, June 10, at 1:30 p.m. Secretary Ronnah Alexander gave the credentials report. There were 49 House of Delegates present. 25 votes for a majority, 37 votes for 2/3 majority and 33 votes for 3/4 majority. There were no additional nominations for Vice Speaker of the House of Delegates.

Ben Mudd made the motion to close nominations for Vice Speaker. The motion was seconded. Motion carried. Voting was held in person for the 2023-24 Vice Speaker of the House of Delegates. All votes were tabulated by the Credentialing Committee. Joel Thornbury will be our Vice Speaker of the House. Congratulations, Joel!

KPhA Chair Cathy Hanna reported that the Kentucky Board of Pharmacy will not have any open seats this year. Considering that KPhA is not required to submit the five names to the Governor. The Reference Committee did not have any policy statements referred to the committee. They did not meet at this

Annual Meeting. Therefore, the Reference Committee does not have a report or require voting on any action items.

KPhA President Misty Stutz installed the 2023-2026 Board of Directors Kyle Bryan, Steve Sheldon, Jordan Smith. President Stutz also installed new student representatives Noah Stallins and Siddharth Sheth. The 2023-2024 Speaker of the House, Nicole Miracle, will be installed at the next KPhA Board Meeting. Joel Thornbury was installed as the 2023-2024 Vice Speaker of the House of Delegates. Lakin Marr was installed as the 2023-2025 Treasurer. 2023-2024 President-Elect Kyle Harris will be installed at the next KPhA Board Meeting. Trish Freeman was installed as the 2023-2024 Past President Representative. Congratulations to all incoming KPhA Board of Directors and Officers! President Misty Stutz recognized the outgoing Speaker of the House, Kyle Bryan. Kyle, thank you for your dedication to the House of Delegates for the 2021-2023 years.

Michele Pinkston made a motion to adjourn the KPhA House of Delegates meeting. The motion was seconded. Motion carried.

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Summary of USP Requirements for Nonsterile, Sterile, and Hazardous Drug Compounding

Martika Martin, PharmD, MBA, BCGP

Pharmacist Objectives:

- **Recall the requirements of USP <795> for nonsterile compounding.**
- **Recall the requirements of USP <797> for sterile compounding.**
- **Recall the requirements of USP <800> for hazardous drug handling.**
- **Summarize proposed changes to 201 KAR 2:076.**

Introduction:

In June 2023, the Kentucky Board of Pharmacy filed a revision to 201 KAR 2:076, the regulation for the practice of compounding. Currently, by regulation, Kentucky pharmacists compounding nonsterile preparations are required to comply with the 2014 version of USP <795> and those compounding sterile preparations are required to comply with the 2008 version of USP <797>. New versions of USP <795> and USP <797> are scheduled to become an official part of the compendium on November 1, 2023. If the proposed regulation passes through the regulatory process, pharmacists will be required to comply with the updated versions of USP <795> and <797> by January 1, 2026, which includes compliance with USP <800>. The following will summarize the key parts of the 2023 versions of USP <795> and USP <797> and the 2020 version of USP <800>. The following is a summary of the requirements of USP <795>, <797>, and <800>. Pharmacies subject to these practices should read and understand the chapters themselves.

Nonsterile Compounding

JUSP<795> describes the minimum standards to follow when compounding nonsterile preparations. Nonsterile compounding does not include flavoring of medications if the flavoring is in-date, inert, nonallergenic, produces no effect other than modifying the flavor, and is not greater than 5% of the product's total volume. Nonsterile compounding also does not include reconstituting or mixing as directed by the manufacturer's labeling.

Table 1: Examples of Nonsterile Preparations

Solid oral preparations, such as tablets or capsules
Liquid oral preparations, such as suspensions or solutions
Rectal preparations, such as suppositories
Vaginal preparations, such as suppositories or cream
Topical preparations, such as creams, gels, and ointments
Nasal and sinus preparations for local application, such as nasal sprays and irrigations
Otic preparations, except when used in perforated eardrums

Table 2: Acts Not Subject to USP <795>

Preparation of a single dose for a single patient when administration is within 4 hours of the preparation
Compounding of nonsterile radiopharmaceuticals (subject to USP <825>)
Repackaging of conventionally manufactured drug products
Splitting tablets

Each pharmacy engaging in compounding must identify a designated individual or individuals who will oversee the compliance of the compounding program. This individual does not have to be a pharmacist but must be identified in the pharmacy's standard operating procedures. The responsibilities of the designated individual are listed in Table 3.

Table 3: Responsibilities of Designated Individual

Overseeing personnel training for compounding
Selecting compounding components
Monitoring and overseeing compounding activities and correcting deficiencies
Ensure implementation of standard operating procedures
Establishing, monitoring, and documenting procedures for handling and storage of components of compounded products and/or the compounded product.

All personnel involved in the compounding process, including oversight of the preparing and dispensing of compounded products, must be trained initially and every 12 months. This training must be documented and must include reading and understanding USP <795> and other applicable standards, understanding and interpreting safety data sheets and certificates of analysis, and reading and understanding procedures related to their duties. The core competencies that must be covered in the training are listed in Table 4.

Table 4: Nonsterile Compounding Training Core Competencies

Hand hygiene
Garbing
Cleaning and sanitizing
Handling and transporting components and compounded products
Measuring and mixing
Proper use of equipment and devices selected to compound
Documentation of the compounding process

Individuals entering the compounding area must follow proper hygiene and garbing. Before entering the compounding area, personnel must remove personal outer garments, exposed piercings that could interfere with the effectiveness of garbing or hand hygiene, and earbuds or headphones. Following this preparation, appropriate hand hygiene must be followed, which includes washing the hands with soap and water for at least 30 seconds and drying hands completely with towels or wipes before donning gloves. Using hand sanitizers alone is not considered sufficient hand hygiene. Gloves must be worn for all compounding activities and should be wiped or replaced before beginning a compound that has different components. Other garb must be appropriate for the type of compounding performed to prevent chemical exposure to personnel and contamination of the compound. Required garbing and the frequency of changing garb are to be determined by the pharmacy and documented in the facility's standard operating procedure. Visibly soiled or damaged garb should be cleaned or disposed of. Gloves, shoe covers, head or hair covers, facial hair covers, and face masks cannot be re-used. Non-disposable garb should be cleaned and sanitized. There must be a designated space for nonsterile compounding and this designation must be described in the pharmacy's standard operating procedures. No other activities may occur in the designated compounding space while compounding is occurring. The space must be well-lit and maintained in a clean, orderly, sanitary condition and in a good state of repair. The floors cannot be carpeted, and surfaces should be resistant to damage from cleaning and sanitizing agents. Storage areas for compounding components must be temperature monitored manually at least daily on days the pharmacy is open or continuously with a temperature recording device. The compounding area must have a source of hot and cold water and an easily accessible sink.

Equipment used for compounding must not be reactive, additive, or sorptive and must be stored in a manner that minimizes the risk of contamination. Equipment must be inspected before use and verified for accuracy as recommended by the manufacturer or at least every 12 months, whichever is more frequent. If manipulating a component that could produce airborne chemical particles, the process must be assessed to determine if these activities must be performed in a closed-system processing device

to reduce exposure to personnel or contamination of the facility or other compounds. Closed-system processing devices include containment ventilated enclosures, biological safety cabinets, and single-use containment glove bags. The assessment must be conducted in accordance with the pharmacy's standard operating procedures and must be documented.

The designated individual is responsible for selecting components used in compounding. All ingredients used in compounding must have a certificate of analysis and be obtained from an FDA-registered facility. Active pharmaceutical ingredients must comply with the criteria in the USP-NF monograph, if one exists. The water used in compounding must be purified water or better quality. When components are received in the pharmacy, the certificate of analysis must be reviewed to ensure it meets the acceptance criteria in the USP-NF monograph, if one exists. Table 5 lists the documentation requirements for receiving compounding components. If a component lacks a vendor expiration date, the date of receipt by the pharmacy must be clearly and indelibly marked on the packaging system and the component must not be used after 3 years from the date of receipt.

Table 5: Documenting Compounding Components

Receipt date
Quantity received
Supplier name(s)
Lot number
Expiration date
Results of any in-house or third-party testing performed

When handling components during compounding, the compounder must abide by the manufacturer's instructions or appropriate laws and regulations. Handling must be done in a way that minimizes the risk of contamination, mix-ups, and deterioration. Once removed from the container, any component not used in compounding, such as excess after weighing, should be discarded and not returned to the original container. The pharmacy must maintain chemical hazard and disposal information and must document the review and update the the information at least every 12 months. There must be a readily accessible spill kit in the compounding area, with its contents affixed to its packaging system. For each unique formulation of a compound, a master formulation record must be created. Table 6 lists the requirements for a master formulation record. The master formulation requirements detail the procedures that describe how the compound is to be prepared.

Table 6: Master Formulation Requirements

Name, strength or activity, and dosage form
Identities and amounts of all components; if applicable, relevant characteristics of components
Container closure system(s)
Complete instructions for preparing the compound, including equipment, supplies, and description of compounding steps
Physical description for the final compound
Assigned beyond-use date (BUD) and storage requirements
Reference source to support the assigned BUD and storage requirements
If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the active pharmaceutical ingredients
Labeling requirements
Quality control procedures and expected results
Other information needed to describe the compounding process and ensure repeatability

For each compound made in the pharmacy, a compounding record documenting the compounding of the product must be created. Before the compound is released, the compounding record must be reviewed for completeness. The name or unique identifier of the reviewer and the date of the review must be documented on the compounding record. The compounding record must allow traceability for all components in the case of a recall or quality issue. The master formulation record can be used as the basis for the compounding record by making a duplicate of the master formulation record with blank fields for recording necessary information to complete the compounding record.

Table 7: Compounding Record Requirements

Name, strength or activity, and dosage form
Date and time or preparation
Assigned internal identification number (prescription, order, or lot number)
Method to identify the individuals involved in the compounding process and individuals verifying the final product
Name, vendor or manufacturer, lot number, and expiration date of each component
Weight or measurement of each component
Total quantity of the compounded product
Assigned beyond use date and storage requirements
If applicable, calculations to determine and verify quantities and/or concentrations of components and strength or activity of the active pharmaceutical ingredient
Physical description of the final product
Results of quality control procedures
Master formulation record reference for the compound

After the compound is complete, the product must be visually inspected before being dispensed to determine if the physical appearance is as expected and confirm that the product and its labeling match the compounding record and prescription or medication order. Table 8 lists the labeling requirements. All checks, inspections, and tests required to determine the quality of the product must be detailed in the master formulation record. Inspection must also include a review of the container to ensure there is no leakage, cracks, or improper seals. Any compound not meeting inspection expectations must be labeled as rejected, and segregated from active stock before being disposed of.

Table 8: Labeling Requirements

LABEL ON IMMEDIATE CONTAINER OF THE COMPOUND
Assigned internal identification number (barcode, prescription, order, or lot number)
Active ingredient(s) and their amount(s), activity(ies), or concentration(s)
Storage conditions if other than controlled room temperature
Beyond-use date
Dosage form
Total amount or volume if not obvious from the container
LABELING OF COMPOUNDED NONSTERILE PRODUCT
Route of administration
Indication that the preparation is compounded
Any applicable special handling instructions
Any applicable warning statement
Name, address, and contact information of the compounding facility if the compound is to be sent outside the facility or healthcare system where it was compounded

The beyond-use date of a compounded product is the date and/or hour beyond which the compound cannot be used and must be discarded. Beyond-use dates should be conservative to ensure that the compound maintains its required characteristics and minimize contamination or degradation. Parameters that affect stability such as chemical and physical stability of the active ingredients and any added components, the compatibility of the container and the finished compound, and the potential for microbial contamination.

In the 2023 version of USP <795>, aqueous and nonaqueous dosage forms have a beyond-use date based on the water activity (aw). This considers the susceptibility of compounds to microbial contamination and potential degradation due to hydrolysis. Water activity is not the same as water content. Instead, it is the available water to support microbial growth and hydrolytic reactions. Nonaqueous preparations do not support spore germination or microbial growth because of their low water activity. A compound does not have to be tested for water activity unless it is needed to determine if the compound is aqueous or nonaqueous. A nonaqueous dosage form is defined by USP as a dosage form with a water activity less than 0.60, such as oil-filled capsules, powder-filled capsules, glycol-based gels and oral solutions, lollipops, ointments, fixed oil suspensions, suppositories, gelatin and glycol-based troches, and compressed and triturated tablets. Aqueous dosage forms are defined as having a water activity of at least 0.60 and include creams, foams, water-based gels, lotions, nasal sprays, water-based oral solutions, shampoos, rinses, and simple syrups. The beyond-use date by the type of preparation is listed in Table 9. If a compound has a beyond-use date in the monograph or from a product-specific stability test, that beyond-use date must be used if the product was compounded as directed by the monograph or master formula of the product with stability information. A shorter beyond-use date would be necessary if the components of the compound have an expiration date earlier than the beyond-use date that could be assigned based on water activity, monograph, or stability information. This includes if a preparation includes, as a component, another compounded product. The beyond-use date cannot exceed the shortest remaining expiration date or beyond-use date of any component.

Table 9: Beyond Use Date by Preparation Type without Monograph or Stability Information

Preparation Type	Beyond-Use Date	Storage Temperature
Nonaqueous Dosage Forms		
Non-preserved aqueous dosage form	14	Refrigerator
Preserved aqueous dosage form	35	Controlled room temperature or refrigerator
Aqueous Dosage Forms		
Oral liquids (nonaqueous)	90	Controlled room temperature
Other nonaqueous dosage forms	180	Controlled room temperature or refrigerator

All compounding pharmacies must have a quality assurance and quality control program. Quality assurance is the system of procedures, activities, and oversight to ensure consistent compounding that meets quality standards. Quality control includes the sampling, testing, and documentation of results that ensure the compound meets its standards before being dispensed. The quality assurance and quality control programs must be established in the standard operating procedures. The requirements of the quality assurance and quality control programs are listed in Table 10.

Table 10: Quality Assurance and Quality Control Programs

Adherence to procedures
Prevention and detection of errors and other quality problems, evaluation of complaints and adverse events
Appropriate investigations and corrective actions such as: **·Determination of when recalls must be initiated** **·Determination of the distribution of any affected compounded product** **·Identification of patients who have received the compounded product** **·Recall any unused dispensed stock and quarantine any remaining stock** **Disposal of the recalled compound and documentation of disposal**

Written or electronic documentation must be maintained to demonstrate compliance with the requirements of USP <795>. In the proposed version of 201 KAR 2:076, pharmacies must maintain these records for five years (USP <795> says the longer of three years or as required by laws and regulations). Documentation requirements are listed in Table 11.

Table 11: Documentation Requirements

Personnel training, competency assessments, and qualification records including corrective actions for any failures
Equipment records
Receipt of components
Standard operating procedures, master formulation records, and compounding records
Release inspection and testing records
Information related to complaints and adverse events including corrective actions take
Results of investigations and corrective actions
Records of cleaning and sanitizing the designated compounding area

Sterile Compounding

USP <797> describes the minimum standards required for sterile compounding. Sterile compounding requires the use of aseptic techniques and there must be processes and procedures to minimize contact with nonsterile surfaces, introduction of particulates or biological fluids, and mix-ups with other products. Sterile compounding includes repacking a sterile product from its original container into another container. Sterile compounding does not include mixing or reconstituting in accordance with directions in the approved labeling provided by the product's manufacturer if it is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the strength, the container system, and storage time.

Table 12: Types of Sterile Products

Injections, including infusions
Irrigations for internal body cavities
Ophthalmic dosage forms
Aqueous preparations for pulmonary inhalation
Baths and soaks for live organs and tissues
Implants

Compounding for immediate use is not subject to the requirements of other categories of sterile compounds as long as the requirements in Table 13 are met.

Table 13: Conditions for Immediate-Use Compounded Sterile Products

Aseptic techniques, processes, and processes are followed, and standard operating procedures are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulates or biological fluids, and mix-ups with other products
Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the pharmacy's standard operating procedures
The compounding is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs
The preparation involves no more than 3 different sterile products
Any unused starting component from a single-dose container must be discarded after preparation for the individual patient is complete. Single-dose containers must not be used for more than one patient
Administration begins withing 4 hour following the start of preparation
Unless administered by the person who prepared it or administration is witnessed by the preparer, the compound must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the exact 4-h time period within which administration must begin

USP <797> divides sterile compounds into three categories. Table 14 defines the three categories and their associated beyond-use dates.

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Table 14: Sterile Compound Categories

Category	Description	Beyond-Use Date
Category 1	Compounded under the least controlled environmental conditions	Controlled room temperature: 12 h Refrigerated: 24 h
Category 2	Compounded with more environmental controls and testing than category 1	See Table 27
Category 3	Undergo sterility testing, possible endotoxin testing, and have greater requirements than category 2	See Table 27

All personnel involved in sterile compounding, or the direct oversight of the compounding, must be initially trained and qualified by demonstrating knowledge and competency before being allowed to perform independently. The pharmacy must identify a designated individual or individuals to oversee personnel training. Personnel training must be repeated at least every 12 months. The training program must be documented in the standard operating procedures. Training and evaluation of personnel must be documented. Table 15 lists the required competencies of the training program.

Table 15: Sterile Compounding Training Competencies

Hand hygiene
Garbing
Cleaning and disinfection
Calculations, measuring, and mixing
Aseptic technique
Achieving and/or maintaining sterility and pyrogenicity
Use of equipment
Documentation of the compounding process
Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow with the ISO class 5 area
Proper use of primary engineering controls (PECs)
Principles of movement of materials and personnel withing the compounding area

Training must include a competency evaluation for garbing (must be completed successfully at least 3 times and include evaluation of a visual observation and gloved fingertip and thumb sampling) and a competency evaluation on aseptic technique, which must consist of a media-fill test. The media-fill test must simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person. Table 16 describes the gloved fingertip and thumb sampling procedures and table 17 describes the media-fill testing procedures.

Table 16: Gloved Fingertip and Thumb Sampling

Use one sampling device per hand containing general microbial growth agar, supplemented with neutralizing additives to support both bacterial and fungal growth.
Label each sampling device with a personal identifier, right or left hand, and date and time of sampling.
Do not apply sterile 70% isopropyl alcohol to gloves immediately before touching the sampling device because this may cause a false-negative result. Using a separate sampling device for each hand, collect samples from all gloved fingertips and thumbs by rolling fingertip pad and thumb pad over the agar surface.
Incubate the sampling device at 30-35º for at least 48 hours and then at 20-25º for at least 5 additional days.
Record the number of colony-forming units per hand.
Determine whether the colony forming unit action level is exceeded by counting the total number of colony forming units from both hands. • After garbing: >0 • After media-fill testing: 3

Table 17: Media-Fill Testing Procedures

If all of the starting materials are sterile, manipulate in a manner that simulates sterile-to-sterile compounding activities and transfer the media into the same types of container closure systems commonly used by the pharmacy. Do not further dilute the media unless specified by the manufacturer.
If some of the starting materials are not sterile, dissolve a commercially available nonsterile soybean-casein digest powder in non-bacteriostatic water to make a 3% nonsterile solution and manipulate it in a manner that simulates nonsterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion.
Once the compounding simulation is complete and the final containers are filled with the test media, perform a gloved fingertip and thumb sample on each hand and surface sample of the direct compounding area inside the PEC before disinfecting gloves and PEC.
Incubate containers at 20-25º for 7 days, then 7 days at 30-35º.
Failure is indicated by visual turbidity or other visual manifestations of growth in the media in one or more containers on or before 14 days.

All personnel compounding Category 1, 2, or 3 sterile products must properly garb to minimize contamination. Prior to entering the compounding area, personnel must remove all personal outer garments, cosmetics, jewelry, and piercings that could interfere with the effectiveness of garbing or increase the risk of contamination, and earbuds or headphones. Personnel cannot bring electronic devices not necessary for compounding, must keep nails clean and neatly trimmed (including no nail products such as polish or artificial nails), and must wipe eyeglasses if worn. All personnel entering the compounding area must engage in proper hand hygiene. They must wash hands and forearms up to the elbows with soap and water under warm, running water for at least 30 seconds and dry with low-lint disposable towels or wipes. The order of handwashing and garbing depends on sink placement and must be determined by the pharmacy. It is to be done in a way that reduces the risk of contamination and is documented in the standard operating procedures. Prior to donning sterile gloves, personnel must sanitize their hands with alcohol-based hand sanitizer, following the manufacturer's instructions and allowing them to dry completely before donning gloves. When compounding Category 1 sterile products, all garb must be donned within the perimeter of the segregated compounding area. When compounding Category 2 or 3 sterile products, all garb must be donned in a classified area before entering the buffer room. Skin must be covered inside the ISO Class 5 PEC. Donning and doffing garb should not occur in the anteroom or the segregated compounding area at the same time. Minimum garbing requirements are listed in Table 18.

Table 18: Minimum Garbing Requirements

Category 1 and Category 2
Low lint garment sleeves that snuggly fit around the wrists and an enclosed neck
Low lint covers for shoes
Low lint cover for head that covers the hair and ears, and if applicable, for facial hair
Low lint face mask
If using a restricted-access barrier system (RABS), such as a compounding aseptic isolator, disposable gloves should be worn inside the gloves attached to the system's sleeves. Sterile gloves must be worn over the gloves attached to the system's sleeves.
Additional Garb Requirements for Category 2
Not allow any exposed skin in the buffer room
All low-lint garb must be sterile
Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle

Garb must be replaced if visibly soiled or compromised. Garb must be stored in a way that minimizes contamination. If compounding Category 1 and 2 products, gowns may be reused within the same shift if the gown is maintained in a classified area or inside the perimeter of the segregated compounding area. Only gowns may be reused. All other garb must be discarded or laundered before reuse. The pharmacy's standard operating procedures must describe disinfection

procedures for reusing reusable equipment such as goggles and respirators.

Gloves used for sterile compounding must be sterile and powder-free. Seventy percent sterile isopropyl alcohol must be applied to gloves before entering the ISO class 5 PEC every time and regularly throughout compounding. Gloves and RABS sleeves should be changed according to the manufacturer's recommendations and the pharmacy's standard operating procedures.

Required air quality for sterile compounding must be achieved and maintained through PECs and secondary engineering controls.

Compounding areas, including the anteroom, buffer room, and SCA must be separated from areas not directly related to compounding. Sterile compounding facilities must be designed so that air quality improves with movement through separate operational areas to the PECs. Table 19 lists air quality requirements for specific areas of the compounding facility.

Table 19: Air Quality Requirement

Area	Air Quality
Anterooms to positive-pressure buffer rooms	ISO Class 8
Anterooms to negative-pressure buffer rooms	ISO Class 7
Buffer room	ISO Class 7
PEC	ISO Class 5
Category 1 only	PEC may be placed in unclassified segregated compounding area

The temperature and humidity of the cleanroom suite must be monitored each day that compounding is performed either manually or by a continuous recording device. The temperature and humidity readings must be documented at least once daily or stored in the continuous recording device and be readily retrievable. Classified rooms must also be equipped with a pressure-differential monitoring system to ensure at least a 0.020-inch water column differential between each ISO classified area. In addition to air quality requirements, cleanroom suites must have adequate HEPA-filtered airflow, measured by the number of air changes per hour (ACPH), to the buffer room(s) and anteroom(s) to maintain the ISO classification during compounding. The number of necessary ACPH is determined by the number of personnel permitted to work in the area, the number of particulates that may be generated, the equipment located in the room, the room pressure, and the effects of temperature. At least 30 ACPH is required in ISO Class 7 rooms, with at least 15 ACPH coming from the HVAC through HEPA filters located in the ceiling.

The remaining 15 ACPH must come from the PEC. If the PEC is necessary to meet the minimum number of ACPH, the PEC must not be turned off except for maintenance. At least 20 ACPH are required in ISO Class 8 rooms, with at least 15 ACPH coming from the HVAC through HEPA filters in the ceiling. The total ACPH for each area must be documented in the certification report.

All surfaces in the cleanroom suite must be smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected. This means junctures between the ceiling and the walls and between the walls and the floor must be sealed to eliminate crevices where dirt can accumulate.

Certification of the compounding area for Category 1, 2, or 3 sterile compounds must be certified before and recertified at least every 6 months, and if there are changes to the area, such as redesign, construction, replacement, or relocation of any PEC or alteration in the room configuration that could affect airflow or air quality. Certification must include airflow testing, HEPA filter integrity, total particle count testing, and dynamic airflow smoke pattern test using procedures in the current Controlled Environment Testing Association ***Certification Guide for Sterile Compounding Facilities.*** If any results from the certification are out of range, a corrective action plan must be implemented and documented.

The pharmacy must have a monitoring program for total airborne particles to measure the performance of engineering controls used to provide the specified air cleanliness. Total airborne particle count testing must be conducted in all classified areas during dynamic operating conditions at least every 6 months and must be conducted in locations where there is the greatest risk to the exposed sterile products, containers, and closures. All sampling sites and procedures must be described in the pharmacy's standard operating procedures. If the results exceed the requirements for the specified ISO classification,

there must be an investigation, and corrective action must be taken and documented. The pharmacy is also required to conduct volumetric active air sampling of all classified areas using an impaction device during dynamic operating conditions. For pharmacies compounding Category 1 and 2 sterile products, this must be completed at least every 6 months. For Category 3 sterile products, active air sampling must be performed within 30 days prior to the start of compounding Category 3 compounding and at least monthly thereafter, regardless of the frequency of compounding Category 3 sterile products. The colony-forming unit counts must be examined to ensure that they do not exceed the action levels based on ISO classification listed in Table 20.

Table 20: Action Levels for Viable Airborne Particle Sampling

ISO Class	Action Levels (cfu/cubic meter of air/plate)
5	>1
7	>10
8	>100

Sterile compounding pharmacies must develop and implement written procedures for microbiological air and surface monitoring. All procedures, test results, and corrective action must be documented, and the records maintained as required. Each classified area must be sampled, including the interior of the PEC and the equipment contained in it, the staging or work area(s) near the PEC, and frequently touched surfaces. Surface sampling must also be performed in conjunction with media-fill testing. Surface sampling must be conducted at the end of a compounding activity or shift but before the area has been cleaned and disinfected. For Category 1 and 2 sterile compounding, surface sampling must be performed at least monthly, and for Category 3 compounding, surface sampling must be completed at least weekly, regardless of the frequency of Category 3 compounding.

Table 21 lists the action levels for surface sampling. If results from the surface sampling exceed this amount, corrective action must be taken

Table: 21 Action Levels for Surface Sampling

ISO Class	Action Levels (cfu/cubic meter of air/plate)
5	3
7	>5
8	>50

Surfaces used during sterile compounding must be cleaned, disinfected, and have sporicidal disinfectants applied. The frequency of cleaning and disinfecting are listed in Table 22.

Table 22: Cleaning and Disinfecting for Sterile Compounding

Site	Cleaning	Disinfection	Sporicidal Disinfectant
PEC(s) and equipment inside the PEC(s)	• ·Equipment and all interior surfaces on days when compounding occurs and when surface contamination is known or suspected	• ·Equipment and all interior surfaces on days when compounding occurs and when surface contamination is known or suspected • Apply sterile 70% isopropyl alcohol to horizontal work surface at least every 30 minutes or immediately after compounding if the process takes greater than 30 minutes	• ·Monthly for pharmacies compounding Category 1 and/or Category 2 products • Weekly for entities compounding Category 3 products
Removable work tray of the PEC, when applicable	• Work surface of the tray daily on the days when compounding occurs • All surfaces and the area underneath the work tray monthly	• ·Work surface of the tray before compounding on days when compounding occurs • ·Apply sterile 70% isopropyl alcohol to the horizontal work surface at least every 30 minutes or after compounding if the compounding takes longer than 30 minutes • ·All surfaces and the area underneath the work tray monthly	• ·Work surface of the tray monthly • ·All surfaces and the area underneath the tray monthly
Passthrough(s)	• Daily on the days when compounding occurs	• Daily on the days when compounding occurs	• Monthly for pharmacies compounding Category 1 and/or Category 2 products • Weekly for entities compounding Category 3 products

Work surface outside the PEC	• ·Equipment and all interior surfaces on days when compounding occurs and when surface contamination is known or suspected	• ·Equipment and all interior surfaces on days when compounding occurs and when surface contamination is known or suspected • Apply sterile 70% isopropyl alcohol to horizontal work surface at least every 30 minutes or immediately after compounding if the process takes greater than 30 minutes	• ·Monthly for pharmacies compounding Category 1 and/or Category 2 products • Weekly for entities compounding Category 3 products
Floor(s)	• Daily on the days when compounding occurs	• Daily on the days when compounding occurs	• ·Monthly for pharmacies compounding Category 1 and/or Category 2 products • Weekly for entities compounding Category 3 products
Wall(s), door(s), and door frame(s)	• Monthly	• Monthly	• Monthly
Ceiling	• Monthly	• Monthly	• Monthly
Storage shelving and bins	• Monthly	• Monthly	• Monthly
Equipment outside the PEC(s)	• Monthly	• Monthly	• Monthly for pharmacies compounding Category 1 and/or Category 2 products • Weekly for entities compounding Category 3 products

Like nonsterile compounding, sterile compounding requires the maintenance of master formulation records and compounding records. The requirements for master formulation records are listed in Table 22 and the requirements for compounding records are listed in Table 23 and the requirements for compounding records are listed in Table 24.

Table 23: Master Formulation Requirements

Name, strength or activity, and dosage form of the product
Identities and amounts of all ingredients
Type and size of container closure systems
Complete instructions for preparing the product, including equipment, supplies, a description of the compounding steps, and any special precautions
Physical description of the final product
Beyond use date and storage requirements
Reference source to support the stability of the product
Quality control procedures
Other information as needed to describe the compounding process and ensure repeatability

Table 24: Compounding Record Requirements

Name, strength or activity, and dosage form of product
Date and time of preparation of the product
Assigned internal identification number (prescription, order, or lot number)
A method to identify the individuals involved in the compounding process and individuals verifying the final product
Name of each component
Vendor, lot number, and expiration date for each component for the products prepared for more than one patient and for products prepared from nonsterile ingredient(s)
Weight or volume of each component
Strength or activity of each component
Total quantity compounded
Final yield (quantity, containers, number of units)
Assigned beyond use date and storage requiremnts
Results of quality control procedures
If applicable: • Master formulation reference for the product • Calculations made to determine and verify quantities and/or concentrations of components

All testing to be performed before release or dispensing must be included in the pharmacy's documentation. Any unexpected results must be investigated, and a corrective action plan must be implemented and documented. The final inspection must include a visual inspection. Sterility testing is not required for Category 1 compounds but is required for Category 2 compounds assigned a beyond-use date that requires sterility testing and all Category 3 compounds. The quantity of each container to be sterility tested, if performed, is listed in Table 25.

Table 25: Sterility Testing Quantities

Batch of 1-39: 10% of the number prepared, rounded up to the next whole number
40 or greater: sample size indicated in USP <71>

Category 2 injectable sterile compounds made from one or more nonsterile components and assigned a beyond-use date that requires sterility testing, and all Category 3 sterile compounds compounded from one or more nonsterile component(s) must be tested for bacterial endotoxins.

All Category 1, 2, and 3 sterile products must be labeled with appropriate information. Table 26 lists the label and labeling requirements for sterile compounds.

Table 26: Sterile Compound Label and Labeling

Label on immediate container
Assigned internal identification number (barcode, prescription, order, or lot number)
Active ingredient(s) and their amount(s), activity(ies), or concentration(s)
Storage conditions if other than controlled room temperature
Beyond use date
Route of administration
Total amount or volume if not obvious from container
If single-dose container, a statement stating such when space permits
If it is a multiple-dose container, a statement stating such
LABELING
Any applicable warning statements
Any applicable special handling instructions
Contact information of the compounding facility if the product is to be sent outside of the facility or healthcare system in which it was compounded

Beyond-use dates for sterile compounded products are determined by the chemical and physical stability properties of the drug and its formulation, compatibility of the container and finished preparation, conditions of the environment in which the product is prepared, aseptic processing and sterilization method, starting components, whether sterility testing is performed, and storage conditions. Table 27 describes the beyond-use date limits for sterile compounds.

27: Sterile Compound Beyond Use Date Limits

CATEGORY 1 PRODUCTS		
Controlled Room Temperature	Refrigerator	
≤12hours	≤24 hours	

CATEGORY 2 PRODUCTS				
Compounding Method	Sterility Testing Performed	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed	No	Prepared from one or more nonsterile starting component: 1 day	Prepared from one or more nonsterile starting component: 4 days	Prepared from one or more nonsterile starting component: 45 days
	No	Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45
	Yes	30 days	45 days	60 days
Terminally sterilized	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days
CATEGORY 3 PRODUCTS				
Compounding Method	Sterility Testing Performed	Controlled Room Temperature	Refrigerator	Freezer
Aseptically processed	Yes	60 days	90 days	120 days
Terminally sterilized	Yes	90 days	120 days	180 days

Sterile compounding pharmacies must maintain written or electronic documentation to demonstrate compliance with <797>. In the proposed regulation, these records must also be kept for at least 5 years. Table 28 lists the required documentation that must be maintained.

Table 28: Sterile Compounding Documentation

Personnel training, competency assessments, and qualification records including corrective actions for any failures
Certification reports, including corrective actions for any failures
Environmental air and surface monitoring procedures and results
Equipment records
Receipt components
Standard operating procedures, master formulation records, and compounding records
Release inspection and testing records
Information related to complaints and adverse events including corrective actions taken
Results of investigations and corrective actions

Hazardous Drug Handling

USP <800> deals with the handling of hazardous drugs. At a minimum, pharmacies compounding with hazardous drugs, must incorporate the standards of USP <800> into their safety management system. Table 29 lists the minimum requirements of the safety management system

Table 29: Safety Management System Requirements

A list of hazardous drugs
Facility and engineering controls
Competent personnel
Safe work practices
Proper use of appropriate personal protective equipment (PPE)
Policies for hazardous drug waste disposal

Pharmacies compounding with hazardous drugs must keep a list of all the hazardous drugs they handle. This list must be reviewed at least every 12 months. USP <800> uses the National Institute for Occupational Safety and Health definition of hazardous drugs, which includes drugs that exhibit one or more of 6 characteristics:

- Carcinogenicity
- Teratogenicity or other developmental toxicity
- Reproductive toxicity
- Organ toxicity at low doses
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

These criteria must be used to identify hazardous drugs that enter the market. Any active pharmaceutical ingredient and antineoplastic requiring hazardous drug manipulation is subject to the containment requirements described in USP <800>. Drugs on the NIOSH list that are in their final dosage forms of compounded hazardous drug preparations and conventionally manufactured products are not subject to USP <800> handling requirements, unless specified by the manufacturer. For other dosage forms of drugs on the NIOSH list, the pharmacy may perform a risk assessment to determine alternative containment strategies and work practices. The risk assessment must document the alternative strategies and/or work practices being used for specific dosage forms to minimize occupational exposure. The risk assessment must be reviewed at least every 12 months and the review must be documented. The requirements for the risk assessment are listed in Table 30.

Table 30: Hazardous Drug Risk Assessment

Type of hazardous drug (antineoplastic, non-antineoplastic, reproductive risk only)
Dosage form
Risk of exposure
Packaging
Manipulation

Each pharmacy handling hazardous drugs must have a designated person qualified and trained to be responsible for developing and implementing appropriate procedures, overseeing compliance with the chapter and other regulations and standards, ensuring personnel competency, and ensuring environmental control of the storage and compounding areas.

Hazardous drug handling areas must be located away from breakrooms and refreshment areas and clearly marked with signs prominently displayed before the entrance notifying the hazard. Access to hazardous drug handling areas must be restricted to authorized personnel.

A pharmacy must have designated areas for receipt and unpacking, storage, nonsterile compounding (if performed), and sterile compounding (if performed). Some areas require negative pressure. Table 31 lists the pressure differential and other engineering requirements for hazardous drug handling areas.

Table 31: Engineering Requirements

Receipt	Neutral/normal or negative
Storage: Antineoplastics requiring manipulation or API	Negative pressure, externally ventilated, 12 ACPH
Storage: Non-antineoplastic, reproductive risk only, final dosage forms of antineoplastics	May be stored with other inventory if policy permits
Compounding: Containment-secondary engineering control (C-SEC) – nonsterile compounding	Negative pressure, externally ventilated, 12 ACPH
Compounding: Containment-secondary engineering control (C-SEC)- sterile ISO 7 buffer room and anteroom	Negative pressure, externally ventilated, 30 ACPH
Compounding: Containment-secondary engineering control (C-SEC)- sterile unclassified	Negative pressure, externally ventilated, 12 ACPH
Compounding Containment-primary engineering control (C-PEC)	Located in negative pressure C-SEC, may contribute to negative pressure, externally ventilated or redundant-HEPA filtered in series

Hazardous drugs cannot be stored in a way that could lead to spills or breaks if the container falls and they cannot be stored on the floor. Antineoplastics requiring manipulation other than counting or repackaging of the final dosage form and any hazardous drug active ingredient must be

stored separately from non-hazardous drugs. Refrigerated antineoplastics must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.

Compounding of hazardous drugs must occur in a containment primary engineering control (C-PEC) that is in the containment secondary engineering control (C-SEC). A C-PEC is a ventilated device that minimizes worker and environmental exposure while directly handling hazardous drugs. The C-SEC is the room in which the C-PEC is located. The C-PEC used for sterile compounding and C-PEC used to supply some or all the negative pressure, must run continuously. Pharmacies that compound sterile and nonsterile products with hazardous drugs, must place their C-PEC in separate rooms unless those C-PECs used for nonsterile compounding do not interfere with the ISO classification and they are placed at least 1 meter apart. Occasional nonsterile compounding may be performed in a C-PEC used for sterile compounding, but it must be decontaminated, cleaned, and disinfected prior to resuming sterile compounding.
Assigning beyond-use dates for compounded hazardous drugs follows the guidelines set out in USP<795> and <797>.

PPE must be used throughout the hazardous drug handling process. The NIOSH list provides general guidance for PPE in different possible scenarios. Disposable PPE must never be re-used and re-useable PPE must be decontaminated and cleaned after use. Gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves must be used for compounding with hazardous drugs. PPE requirements for the pharmacy must be documented in the policies and procedures. Chemotherapy gloves must meet American Society for Testing and Materials standard D6978 or its successor. They must be powder free and must be inspected for defects before use. When compounding sterile hazardous drugs, the outer glove must be sterile. Chemotherapy gloves should be changed every 30 minutes or as recommended by the manufacturer. They must be changed when torn, punctured, or contaminated. After removal, personnel must wash their hands with soap and water.

Gowns used during hazardous drug handling must be disposable and shown to resist permeability by hazardous drugs. Gowns are selected based on the hazardous drugs handled by the pharmacy. Gowns must close in the back, be long-sleeved, and have closed cuffs that are elastic or knit and must not have seams or closures that could allow hazardous drugs to come in contact with the employee. Gowns must be changed as directed by the manufacturer. If there are no manufacturer recommendations, they should be changed every 2-3 hours or immediately after a spill or splash. Gowns worn in hazardous drug handling areas must not be worn in other areas. During compounding, a second pair of shoe covers must be donned before entering the C-SEC and doffed with exiting the C-SEC. Shoe covers worn in hazardous drug handling areas must not be worn in other areas.

Appropriate eye and face protection must be worn when there is a risk of spills or splashes. A full-face respirator provides eye and face protection. Goggles must be used for eye protection when needed. Eyeglasses alone or safety glasses with shields do not adequately protect the eye from splashes. Respirators must be fit tested and workers trained on their use.

All PPE worn during hazardous drug handling must be considered contaminated with at least a trace amount of hazardous drugs and must be placed in an appropriate waste container and disposed of per local, state, and federal regulations. PPE used during compounding should be disposed of before leaving the C-PEC. Chemotherapy gloves and sleeve covers used during compounding must be removed and discarded immediately into a waste container inside the C-PEC or contained in a sealable bag for discarding outside of the C-PEC.

All pharmacies compounding with hazardous drugs must establish a hazard communication program that includes policies and procedures to ensure proper training for labeling, transport, storage, and disposal of hazardous drugs and the use of Safety Data Sheets based on the Globally Harmonized System of Classification and Labeling of Chemicals. A hazard communication program must include the following:

- Pharmacies must ensure that Safety Data Sheets for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas.
- Personnel who may be exposed to hazardous chemicals when working must be provided with information and training before the initial assignment to work with a hazardous chemical, and whenever the hazard changes
- Personnel of reproductive capability must confirm, in writing, that they understand the risks of handling hazardous drugs.

All personnel who handle hazardous drugs must be trained based on their job functions. Training must occur initially before independently handling hazardous drugs and reassessed at least every 12 months. Table 32 lists the requirements of training related to hazardous drugs.

Table 32: Hazardous Drug Training

Overview of the pharmacy's list of hazardous drugs
Review of the pharmacy's standard operating procedures related to handling hazardous drugs
Proper use of PPE
Proper use of equipment and devices
Response to known or suspected hazardous drug exposure
Spill management
Proper disposal of hazardous drugs and trace-contaminated materials

All areas where hazardous drugs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Sterile compounding areas and devices must also be disinfected. Written procedures for decontamination, deactivation, cleaning, and disinfection, must be established. Agents used for decontamination, deactivation, and disinfection must be appropriate for the type of hazardous drug contaminate, location, and surface materials. Agents for deactivation, decontamination, and cleaning should be applied with wipes of wetted solution and not by a spray bottle to avoid spreading hazardous residue.

Spills of hazardous drugs must be contained and cleaned immediately by qualified personnel with appropriate PPE. Qualified personnel must always be available while hazardous drugs are being handled. Signs must be available to restrict access to the spill area. Spill kits must be readily available in all areas where hazardous drugs are routinely handled. All spill materials must be disposed of as hazardous waste. The circumstances and management of spills must be documented. Anyone potentially exposed during the spill or spill cleanup or who has direct skin or eye contact with hazardous drugs requires immediate evaluation. Standard operating procedures must be developed to prevent spills and direct the clean-up of spills, including addressing the size and scope of the spill and the person responsible for spill management. PPE is required.

Pharmacy's must maintain standard operating procedures for the handling of hazardous drugs. These must be reviewed at least every 12 months. The review must be documented. Table 33 lists the requirements for hazardous drug handling standard operating procedures.

Table 33: Hazardous Drug Standard Operating Procedures

Hazard communication program
Occupational safety program
Designation of hazardous drug handling areas
Receipt
Storage
Compounding
Use and maintenance of proper engineering controls
Hand hygiene and use of PPE based on activity
Deactivation, decontamination, cleaning, and disinfection
Dispensing
Transport
Administering
Environmental monitoring
Disposal
Spill control
Medical Surveillance

USP chapters <795>, <797>, and <800> set the standards for nonsterile compounding, sterile compounding, and hazardous drug handling. Kentucky compounding pharmacies may be subject to these requirements if the revisions to 201 KAR 2:076 are passed. A public hearing is to be held on August 30, 2023. Anyone wishing to speak at the public hearing must notify the Board of Pharmacy in writing at least 5 business days prior. Written comments on this proposed regulation are being accepted through August 31, 2023.

Continuing Education Update:

Starting in January 2024, some CE articles and programs may transition to online only through the KPhA website. However, KPhA will continue to provide all members with a minimum of 15 CE hours annually as part of your KPhA membership. See back cover for more CE details.

Questions:

1. Which of the following would have to be compounded under the practices defined in USP<795>?
a. Amoxicillin 250mg/mL suspension, reconstituted per manufacturer instructions
b. Progesterone 200mg oral capsule
c. Clotrimazole 1% ophthalmic suspension
d. Gentamycin sulfate 10mg, neomycin 50mg, polymyxin B sulfate 10,000 unit per 100mL bladder irrigation

2. Which of the following would have to be compounded under the practices defined in USP<797>?
a. Amoxicillin 250mg/mL suspension, reconstituted per manufacturer instructions
b. Progesterone 200mg oral capsule
c. Estradiol vaginal cream
d. Gentamycin sulfate 10mg, neomycin 50mg, polymyxin B sulfate 10,000 unit per 100mL bladder irrigation

3. Which of the following would have to be compounded under the practices defined in USP<800>?
a. Amoxicillin 250mg/mL suspension, reconstituted per manufacturer instructions
b. Progesterone 200mg oral capsule
c. Clotrimazole 1% ophthalmic suspension
d. Gentamycin sulfate 10mg, neomycin 50mg, polymyxin B sulfate 10,000 unit per 100mL bladder irrigation

4. What would be the correct beyond-use date for non-preserved rosuvastatin 4mg/mL oral suspension?
a. 14 days refrigerated
b. 35 days refrigerated
c. 90 days refrigerated
d.180 days room-temperature

5. What would be the correct beyond-use date for chlorhexidine digluconate 0.05% in normal saline bladder irrigation compounded in an appropriate cleanroom suite and terminally sterilized via filtration with an appropriate quantity sent for sterility testing? Assume this was compounded as a Category 2 preparation.
a. 1 day refrigerated
b. 45 days refrigerated
c. 60 days refrigerated
d. 90 days refrigerated

6. How often does training have to occur for nonsterile compounding?
a. Only initially
b. Initially and monthly
c. Initially and biannually
d. Initially and annually

7. How often does training have to occur for sterile compounding?
a. Only initially
b. Initially and monthly
c. Initially and biannually
d. Initially and annually

8. Which of the following is true regarding the master formulary record?
a. It details the procedures for how to prepare a specific preparation
b. It documents the compounding of a product
c. It must allow for tracing of all components used in the compounding of a product
d. It is given to the patient when a compound is dispensed

9. Which of the following is true regarding the compounding record?
a. It details the procedures for how to prepare a specific preparation
b. It never has to be reviewed
c. It may be created from a duplicate of the master formulation record with blank fields for recording
d. It is given to the patient when a compound is dispensed

10. Under the proposed version of 201 KAR 2:067, how long must compounding records be kept and maintained?
a. 1 year
b. 3 years
c. 5 years
d. 10 years

11. How often must policies and procedures be reviewed?
a. Monthly
b. Every 6 months
c. Annually
d. There is no requirement for review of policies and procedures

12. Which of the following is true of garbing?
a. Gloves must be worn when compounding nonsterile, sterile, nonhazardous or hazardous drugs.
b. There are no requirements for garb for sterile or nonsterile compounding. It is up to the pharmacy.
c. Gowns for hazardous drug handling may close in the front or the back
d. Garb for hazardous drug compounding may be reused as long as it is never removed and can be worn even while not in the hazardous drug area

Answer Sheet

2023 CONTINUING EDUCATION

This activity is a **FREE** service to members of the Kentucky Pharmacists Association. The fee for non-members is $30. Mail completed forms to: KPERF, 96 C Michael Davenport Blvd., Frankfort, KY 40601, **or SCAN THE QR CODE below and save time and money**. Credit will be applied to your CPE Monitor Profile.

Title: Summary of USP Requirements for Nonsterile, Sterile, and Hazardous Drug Compounding

Name: _____

Email: _____

NABP eProfile ID #: _____

Birthdate (MM/DD): _____

Completion Date: _____

Please circle: Pharmacist or Technician

UNIVERSAL ACTIVITY #: 0143-0000-23-063-H03-P/T | **CONTACT HOUR**: 3 | **EXPIRES**: 7/5/2026

PLEASE CIRCLE THE APPROPRIATE ANSWERS:

1. A B C D	2. A B C D	3. A B C D	4. A B C D	5. A B C D
6. A B C D	7. A B C D	8. A B C D	9. A B C D	10. A B C D
11. A B C D	12. A B C D			

INFORMATION PRESENTED IN THE ACTIVITY:

MET MY EDUCATIONAL NEEDS __ YES __ NO
FIGURES AND TABLES WERE USEFUL __ YES __ NO
ACHIEVED THE STATED OBJECTIVES __ YES __ NO
POSTTEST WAS APPROPRIATE __ YES __ NO
WAS WELL WRITTEN __ YES __ NO
IS RELEVANT TO MY PRACTICE __ YES __ NO
COMMERCIAL BIAS WAS PRESENT __ YES __ NO
UNMET OBJECTIVES: _____ IF YES, PLEASE EXPLAIN ON A SEPARATE SHEET

Scan the QR Code to Submit CE

The Kentucky Pharmacy Education & Research Foundation is accredited by The Accreditation Council for Pharmacy Education as a provider of continuing Pharmacy education.

Pharmacy Law Brief

International Importation of Prescription Medications

Author:
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Submit Questions: jfink@uky.edu

Question:
From time to time, I hear on the news or read in professional publications about legislative attempts to authorize programs for state governments to establish programs to import prescription medications, nearly always from Canada. I'd not heard or read much for several years until this past May when the legislature in Texas authorized that state to create such a program. What's the legal status of that?

Response:
For more than a century, following the adoption of the Pure Food and Drug Act of 1906, the United States has viewed the importation of unapproved new drug products as violative of the law. Despite this, the U.S. Food and Drug Administration has been exercising its enforcement discretion, generally refraining from pursuing legal action against patients who import medication for personal use.

In response to the escalation of prices for federal legend medications over the recent decades, several state governments developed programs enabling their residents to participate in medication importation programs. One such multistate initiative was to serve residents of Illinois, Kansas, Missouri, Vermont, and Wisconsin. This was designated "I-Save Rx" and was designed to arrange the importation of prescription medications from Canada and European countries. Established in 2004, the program was abandoned in 2009. Currently, Colorado, Florida, and New Mexico are pursuing this.

The 2004 launch of this multistate initiative was prompted by a 2003 Congressional authorization for the U.S. Department of Health and Human Services to "develop regulations permitting pharmacists and wholesalers to import prescription drugs from Canada to the U.S." This was tied to the enactment of the Medicare Modernization Act of 2003 which also launched Part D of Medicare to create a program benefit to cover pharmaceuticals prescribed for beneficiaries being treated as outpatients. The 2003 legislative authorization for FDA to develop standards for testing and labeling applicable to such imported products came to be referred to as a "Section 804 Program." It is noteworthy that following the 2003 statutory change, implementation of a pilot project was pursued by neither the administrations of President George Bush nor President Barack Obama.

In October 2020, HHS promulgated a final regulation on the topic. However, rather than having the federal government develop the relevant policy, the publication directed that certain specified elements be included in a state- or tribal-operated program. That framework would then require FDA approval prior to activation. What would FDA be looking for and reviewing?

- Imported products must be approved by Canada's Health Products and Food Branch
- A foreign seller in Canada must be identified
- An importer in the U.S. to purchase the products must be identified
- These products may only cross the border at a single point of entry

- Excluded categories of products ineligible for importation are biologics, controlled substances, and medications to be administered by infusion
- The state or tribal agency must have a plan for validating the authenticity of the product and its lack of degradation, specifying where the testing laboratory doing this service is located

In February of this year, a federal judge in the U.S. District Court for the District of Columbia considered a case designated Pharmaceutical Research and Manufacturers of America v. U.S. Department of Health and Human Services. PhRMA had mounted a legal challenge to block the creation of regulatory steps to facilitate the importation of medications from Canada by state-operated programs. The judge dismissed the case because PhRMA lacked standing, i.e., it was not a manufacturer whose products might be adversely affected.

What is often overlooked, or even ignored, by those who advocate the creation of such programs is the potential negative impact on the Canadian pharmaceutical supply chain. One potential very important limitation for the operation of such programs is that the government of our neighbor to the north has indicated it will ban exporting drug products to the U.S. if such actions lead to decreased access to those resources for Canadian citizens.

References:

1] P.L. 59-384 (1906).

2] Feder J. CRS Report for Congress. Prescription drug importation and Internet sales: A legal overview. October, 2004. https://www.everycrsreport.com/files/20041004_RL32191_68b159b11 e0c2bc1a4c21c779a25ed9919d1f992.pdf.

3]Illinois Governor Blagojevich loses his much-touted I-Save Rx foreign prescription program. PR Web. 2009. https://www.prweb.com/releases/2009/01/prweb1917784.htm.

4] Brennan TA. New life in drug importation. Health Affairs, March 24, 2023. https://www.health affairs.org/content/forefront/new-life-drug-importation.

5] 21 U.S.C. 384: Importation of prescription drugs. https://uscode.house.gov/view.xhtml?req=(title:21%20section:384%20edition:prelim.

6] Pharm. Research & Manufacturers of Am. v. Dep't of Health & Human Servs., Civil Action 20-3402 (TJK) (D.D.C. Feb. 6, 2023).

Campus Corner

New APhA Eboard: Lindsey McDaniel, Kolton Miller, Siddharth Sheth, Mackenzie Harmon, Jamie Wells-Kingsbury

Sullivan University
College of Pharmacy and Health Sciences

Student Pharmacists had a busy wrap-up to their academic year. The P1 cohort finished off their community and institutional rotations before transitioning into their P2 year, closing off the Spring quarter with a bang. Many students went to the KPhA annual conference in Bowling Green and had an amazing time networking with many decorated pharmacists as well as being involved in current issues. Shout out to the first- and second-year pharmacy students getting first and second place, respectively, in the OTC competition. Can't wait for next year's competition to see if our first-year students can 3-peat.

We also welcomed our new P1 class, which saw an increase in enrollment by 44% compared to last year. As we are in the heat of the summer weather and the heat of the summer quarter, we have a few events that took place at SUCOPHS, with many future events to come that we are excited about!

This quarter marks the start of the new academic year for our students. Our goal for our term is to help students build their resumes, more specifically, help them become better public speakers. We believe that public speaking is a skill that will accelerate you professionally and is a fear many students share. For that reason, we decided to roll out the Student Presenter Series. This series allows students to present in a low-stake, low-stress environment on disease states covered in class. Not only will this serve as a review, but it will provide students the confidence they need on their road to being contributing members of our pharmacy community.

In addition to the Student Presenter Series, Sullivan students have also begun giving presentations at the Humana Neighborhood Center. Students are covering topics ranging from knowing your medicine to the truth about carbs.

Additionally, while Twitter has rebranded to X and overstock.com has rebranded to Bed Bath and Beyond, we have rebranded our Instagram page. Check us out at @aphs_asp-sucophs. On the page, we post NAPLEX review questions, share current events, and helpful clinical pearls. Come join us!

Organization Fair Barbie Dreamhouse-Themed Room

P1 and P2 class placing 1st and 2nd at KPhA's OTC Competition

Campus Corner

Bluegrass Community Health Center (BCHC) has been dedicated to providing comprehensive healthcare to underserved central Kentucky communities for over two decades. Through its partnership with the University of Kentucky.

Since 2013, BCHC and UKCOP have collaborated to offer clinical pharmacy services. Under the leadership of then-Executive Director Susan Fister, Ph.D., RN, and Medical Director Alan Wrightson, MD, the partnership enlisted the expertise of two UKCOP faculty members, Melanie Dicks, PharmD, and Holly Divine, PharmD. Together, they developed protocols and policies to assist patients with chronic disease management, hepatitis C, substance use disorder treatment, and other conditions requiring pharmacy expertise. The team grew to include five pharmacists who integrated seamlessly with the BCHC care team, working alongside medical and behavioral health providers, nurses, care coordinators, and peer support specialists. Working alongside medical and behavioral health providers, nurses, care coordinators, and peer support specialists.

Skaggs (right) was awarded KPhA's Distinguished Young Pharmacist Award at the June 2023 Annual Meeting.

In July 2022, BCHC welcomed its first full-time clinical pharmacist, Kelsie Skaggs, PharmD. Skaggs expanded clinical pharmacy services at BCHC and established a retail pharmacy exclusively for BCHC patients. In March 2023, the team further expanded with the addition of its first full-time staff pharmacist, Molly Carr, PharmD, MBA. Their dedication to BCHC's mission culminated in opening the first onsite pharmacy at the Eagle Creek Drive location in Lexington in April 2023. The expansion of services at BCHC ensures access to affordable medications for all individuals in need, regardless of insurance status. Through an income-based sliding fee discount, uninsured patients can obtain medications at significantly reduced costs. Additionally, BCHC's medical and pharmacy staff prioritize Spanish-speaking services for Kentucky's migrant and seasonal farm workers and provide other languages in facilitating access to clinic and pharmacy services in patients' native languages.

The pharmacy team at BCHC offers a wide range of services, including medication education and review, vaccine administration, and convenient home delivery. Skaggs' appointment as a full-time clinical pharmacist highlights BCHC's recognition of the value brought by clinical pharmacy faculty members and the community-based pharmacy residency program. Skaggs attributes her success in assuming a role as BCHC's first full-time clinical pharmacist to her experiences training at UKCOP. The College's PharmD and residency programs played a pivotal role in developing my skills for direct patient care in both the community pharmacy and clinic settings," she states. "I am honored to have contributed to opening BCHC Pharmacy, which works to serve communities facing barriers. I am excited to continue to expand BCHC's services and make a meaningful impact in this setting."

Skaggs has recently been accepted into the prestigious American Diabetes Association (ADA) Scholar Program, a comprehensive career development program focused on diabetes treatment and research for early-career professionals. Over the course of five years, Skaggs will engage with an interdisciplinary cohort of healthcare professionals, gaining practical guidance on career advancement, networking opportunities, and direct interaction with esteemed leaders in the field of diabetes.

The ongoing collaboration between Bluegrass Community Health Center and the University of Kentucky College of Pharmacy is transforming healthcare delivery, paving the way for a healthier and more equitable future for the people of Kentucky.

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Invoice Audits Are on the Rise – Are You Prepared for Success?

Most pharmacies have grown accustomed to desk audits and providing copies of prescriptions, signature logs, and even copay collection records to PBMs upon request. Additionally, many pharmacies can recount their most recent experience with an onsite auditor visiting their pharmacy and the numerous questions related to operations, policies & procedures, and credentialing. However, not as many pharmacies have experienced an invoice audit – the stakes are higher and honest mistakes can lead to very expensive lessons in the process.

PAAS National® analysts have helped our members navigate countless invoice audits. Our analyst team is here to assist you through the audit process from start to finish and that includes getting things done correctly long before the audit ever comes your way. Follow the tips below to have the most success.

PAAS Tips:

- Carefully evaluate your wholesalers/suppliers to ensure they are legitimate
  - NABP Accredited Drug Distributors can be found here[1]
  - Wholesalers licensed in your state can be found here[2]
  - Remember that OTC diabetic test strip manufacturers only sell their products to "authorized distributors".
    - Abbott https://www.diabetescare.abbott/support/distributors.html
    - Ascensia https://www.ascensiadiabetes.com/ (click on "distributors" at the bottom of the page)
    - LifeScan www.genuineonetouch.com
    - Roche https://rxvp.accu-chek.com/welcome/adr_list
    - Trividia Health™ https://www.trividiahealth.com/where-to-buy/
- Limit purchases from other pharmacies to the minimum necessary
  - Drug Supply Chain Security Act (DSCSA) pedigree information is required unless purchase is (1) intra-company or (2) to fulfill a specific patient need
  - Full transaction details are required for audit purposes. Documentation should include:
    - Pharmacy name, address, and NCPDP number transferring from
    - Drug name, quantity, lot number, expiration date, and NDC number should all be included on the transfer invoice
    - Date of transfer and date of receipt of drug
    - Reason for transfer (e.g., complete Rx #1234)
    - Method or proof of payment (check # or credit card receipt)
- Ensure pharmacy staff are billing the correct quantity based on NCPDP billing standards – when in doubt, call PAAS for help
- Every claim billed must have NDCs that match the physical product being dispensed
  - No exceptions, all 11 digits matter
  - Includes all compound ingredients
  - PAAS recommends using barcode scanner to confirm NDC accuracy in pharmacy workflow
- Confirm the pharmacy is appropriately reversing claims that are not dispensed

PAAS National® is committed to serving community pharmacies and helping keep hard-earned money where it belongs. Contact PAAS today at (608) 873-1342 or info@paasnational.com to see why PAAS Audit Assistance membership might be right for you.

By Trenton Thiede, PharmD, MBA, President at PAAS National®, expert third party audit assistance and FWA/HIPAA compliance.

References:
1. https://nabp.pharmacy/programs/accreditations-inspections/drug-distributor/accredited-drug-distributors/
2. https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses

Continuing Education Update:

Starting in January 2024, a minimum of 15 hours of continuing education will continue to be included with your KPhA membership package. However, some articles and programs will transition to our online learning portal (via the KPhA website) and will not be published in *The Kentucky Pharmacist*. It is important that members login to your NABP CPE Monitor account and confirm completion of applicable CE requirements on a regular basis.

Please contact our continuing education staff if you have any questions regarding this transition.

WHY Choose KPhA for Continuing Education?

- **15 CE HOURS AVAILABLE INCLUDED WITH MEMBERSHIP**
- **Objectives provided for Pharmacists and Technicians**
- **In-person CE Hours at the Fall Conference & Annual Meeting**
- **New CE updated monthly ONLINE**
- **Articles are written by and for Kentucky pharmacists & techs**
- **KPhA staff available for online assistance**