The Kentucky PHARMACIST

SPRING 2023

The Official Publication of the Kentucky Pharmacists Association

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Mission Statement:

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

Editorial Office:

Publisher:
Benjamin Mudd

Editor:
Jessica Faye Mohler

Contributing Writers:
Dr. Kimberly G. Elder
Dr. Alexa R. Filley
Dr. Joseph L Fink
Dr. Martika Martin
Dr. Madeline M. Mitchell
Dr. Sarah E. Raake

Jenna Brophy
Mya Desai
Jana R. Hostetler
Lindsey Long

Warm your engine for this year's Annual Meeting. Learn more on pages 22-26

2023 Annual Meeting

RevUp. GearUp. TeamUp.

Congratulations
2023 Scholarship Winners

Each student listed
received a $3,000 scholarship.

Cameron Buss	University of Mississippi
Caitlin Rohrbaugh	University of Iowa
Andrew Smith	Auburn University
Alexandria Ocker	Binghamton University
Destiny Rogers	Samford University
Caroline Eason	Univ. of North Carolina at Chapel Hill
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Jackson Beach	Southwestern Oklahoma State Univ.
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Mohit Kumar	University of Georgia
Moriah Willis	University of Oklahoma
Makenna Rose	Southwestern Oklahoma State Univ.
Olukemi Omotola	University of Charleston
Ngozi Ihemeson	University of Illinois at Chicago
Olivia Hanna	Nova Southeastern University
Rui Hua Zheng	Northeastern University

Pharmacists Mutual is proud to support pharmacy students interested in serving in an independent or small chain community pharmacy or an underserved geographic or cultural community.

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The New Landscape of Pharmacy

Misty Stutz, PharmD
President
Kentucky Pharmacists Association

Given the current landscape in pharmacy, it should come as no surprise that the number of pharmacists across the U.S. is decreasing. Applicants applying to pharmacy school have fallen by over 36% since 2013. While the U.S. Bureau of Labor Statistics projects a need for 13,600 new positions annually, NABP reports that there were only 12,548 NAPLEX test takers in 2022, down from 14,087 in 2017. And the trend is continuing. Fewer students are entering the pharmacy profession. This has led to a decrease in the number of pharmacists. And pharmacies are forced to close or shorten operating hours without pharmacists. In a recent article, CVS Health told Forbes[1]1 that it expects to cut hours at two-thirds of its 9000 locations. And CVS is not alone. Across the U.S., pharmacists and pharmacy personnel need help to keep up with the never-ending growth of prescription volume while yearning to utilize their doctorate-level education to care for patients.

Companies have moved toward automation to combat this volume of prescriptions beyond what the current workforce can accomplish. Walgreens is a good example, creating robot-powered micro-fulfillment centers across the U.S. with a goal to fill half of the total prescription volume at these centers by 2025[2]. With current technology, prescriptions can be processed and filled with limited need for human intervention. Even traditional human tasks such as transcription, bottling, and labeling can be done efficiently and effectively with computer-driven automation. While pharmacists are still responsible for drug utilization reviews, there is also an expanded exploration of how the use of artificial intelligence (AI) will be used in pharmacy practice to assist in assessing treatment patterns, alerting to potential medication errors, screening for potential adverse reactions or drug-drug interactions and pharmacokinetic monitoring.[3]

If automation and AI take over the dispensing role of pharmacists, how will this change the landscape of the traditional pharmacy? Just as the pharmacist's education has moved from chemist to clinician, so must the practicing pharmacist evolve from dispenser to patient care. Tomorrow's pharmacists will spend little to none of their time filling prescriptions but will spend most of their time collaborating with patients to achieve optimal medication therapy as well as preventative health. This change will lead to pharmacies evolving from dispensing centers to one of patient care, which will create a need for the composition of the pharmacy team also to change. There is a growing trend to expand the pharmacy technician role and include other specialists on the pharmacy team. Many states have increased the responsibility of the pharmacy technician to allow for things like product verification, physical assessment, and point-of-care testing.

While additional education may be required, the technician is taking on more roles to assist the pharmacist in the technical skills, allowing the pharmacist to concentrate on the more clinical patient-care aspects of their job. Technicians have also moved into other aspects of health care, including community health workers and medical billing. Some pharmacies have expanded their healthcare services to include dieticians, wellness coaches and others. This expansion of patient care services gives the community pharmacy a larger-scale approach to holistic patient care. While the pharmacist remains the medication expert, there is a growing shift to optimize the pharmacist's high level of education and skill away from product dispensing and more toward patient care. While some may worry that this change will have a negative impact on current practices, this is exactly what we need. We, as a profession, need to continue to mold our landscape into one where the pharmacist is the primary professional for medication optimization, preventative care, and acute self-limiting conditions, while our team provides care for our community to lead healthy and productive lives.

1.Tellez A. A pharmacist shortage has caused CVS, Walgreens, and Walmart to cut pharmacy hours-here's what we know. Forbes. https://www.forbes.com/sites/anthonytellez/2023/01/30/a-pharmacist-shortage-has-caused-cvs-walgreens-and-walmart-to-cut-pharmacy-hours-heres-what-we-know/?sh=8cd13574ecf4. Published January 31, 2023. Accessed April 10, 2023.
2.Repko M. Walgreens turns to robots to fill prescriptions, as pharmacists take on more responsibilities. CNBC. https://www.cnbc.com/2022/03/30/walgreens-turns-to-robots-to-fill-prescriptions-as-pharmacists-take-on-more-responsibilities.html. Published March 30, 2022. Accessed April 10, 2023.
3. Executive summary of the 2019 ASHP Commission on Goals: Impact of artificial intelligence on Healthcare and pharmacy practice. American Journal of Health-System Pharmacy. 2019;76(24):2087-2092. doi:10.1093/ajhp/zxz205

My KPhA Rx

A Letter from Ben Mudd, PharmD
Executive Director Kentucky Pharmacists Association

Dear Colleague,

For this issue, I will dedicate my small piece of real estate in *The Kentucky Pharmacist* to highlight the group of Kentucky advocates that attended the NCPA fly-in on April 26-27, 2023. KPhA members from across the Commonwealth sacrificed to gather in DC to meet with our elected representatives and to tell their stories. Pharmacy owners shared their struggles with DIR and the anticompetitive tactics of the PBM industry, while students shared their knowledge and urged Congress to pass legislation that would fairly reimburse pharmacists for the services we provide to test and treat our patients. All told, we were able to meet in-person with five of the six congressmen from Kentucky and staff with each of our Kentucky senators.

As the voice of Kentucky pharmacy, KPhA spoke loud and clear that we need change and we need it quickly. This is all possible because of members like you who provide the needed resources to share our message. However, we are up against well-funded opposition. Groups like the AMA and PCMA are increasing their own lobbying efforts to diminish the critical care your provide to your patients.

The good news is that our Kentucky delegation is leading the way to help the profession. As Chair of the Oversight Committee, Congressman Comer (R-KY) is leading an investigation into the fraudulent, wasteful and abusive behaviors of vertically integrated PBMs. In his keynote address to the NCPA attendees he stated that "A good community pharmacist is invaluable, especially in rural America." Congressman Guthrie (R-KY) shared with our Kentucky group that momentum is in our favor. As chair of the Health Subcommittee, Rep Guthrie is also positioned to shakeup the wrongdoings that have plagued our profession for decades.

Positive change is coming, you could feel it throughout the visit to our nation's capitol. Thanks again to those members that were able to make the trip. If you weren't able to join us, please consider adding it to your calendar and travel budget for 2024. In the meantime, I urge you to write a letter or schedule a virtual meeting with your congressman and continue telling our story. There is strength in numbers and it's going to take us all.

I always welcome the opportunity to connect with our members. Please reach out directly to ben@kphanet.org, and let's schedule a time to chat about your story and our KPhA. Until next time: keep being awesome, choose kindness, and stay involved.

Professionally yours,

Ben Mudd

Board of Directors Nominees

Open Positions: President-Elect, Treasurer, Three (3) Directors

Self-nominated candidates provide their own statement of interest
Nominated candidates received statement of support from their nominators

Kyle Bryan, PharmD
Self-Nominated
Education: University of Kentucky College of Pharmacy 2019
Practice Setting: Academia
Current KPhA Involvement: Speaker of the House, Government Affairs Committee Member

Statement of Interest:

My interest in serving on the Board of Directors comes from my passion for helping to advance the practice of pharmacy and ensure that pharmacists are recognized as the highly trained and educated healthcare providers that we are. I have had the privilege of pursuing these goals with KPhA by serving on the Government Affairs Committee for several years and as Vice-Speaker and Speaker of the House of Delegates for the past two. I am eager to continue this work and my involvement with KPhA in a director position.

In my relatively short time in this profession, I have had the opportunity to work alongside some of the most dedicated and passionate pharmacists in the state. Through my Community Pharmacy Residency with the American Pharmacy Services Corporation, an Executive Fellowship with the National Association of Chain Drug Stores, and in my current role as practice implementation pharmacist at the UK College of Pharmacy, I have seen how much change can be brought about by a small group of passionate people working together. My current job has allowed me to work closely with pharmacists and other stakeholders throughout the state to help advance pharmacy practice and implement billing for pharmacy services. These relationships have given me a unique perspective that I have used to help strengthen efforts to address problems facing our profession in multiple practice settings.

I would not be in the position I am today if it were not for KPhA and the amazing leaders that first welcomed me while I was in school. They inspired me to become more involved and run for Vice-Speaker of the House of Delegates and my continued work has only increased my desire to contribute to the association and our profession. If I am elected, I will continue to bring my experience and relationships to assist KPhA in helping to ensure we are a unified pharmacy profession empowered to maximize patient and public health as fully integrated members of the healthcare team.

Jamie Biliter, PharmD
Self-Nominated
Education: University of Cincinnati College of Pharmacy 2003
Practice Setting: Retail Community Pharmacy
Current KPhA Involvement: Active Member

Statement of Interest:

I would love to be involved in this thinking- forward, patient-focused organization. I'm very interested in membership engagement to find ways to get our profession more involved. I'm on the Cystic Fibrosis Foundation board, very involved with American Heart Association and Leukemia/Lymphoma Society, I love showing others how our profession can be involved.

Travis Hudnall, PharmD
Self-Nominated
Education: Samford McWorter School of Pharmacy 2003
Practice Setting: Independent Community Pharmacy
Current KPhA Involvement: Active Member

Statement of Interest:

With a clinical and community pharmacy background, I would like to help continue to move the pharmacy profession forward. Treating every Kentuckian like I would my own family is a passion that I cannot undo. I feel KPhA seeks to intertwine these two values and I would love to participate in this journey.

Steve Sheldon, RPh
Self-nominated
Education: University of Kentucky College of Pharmacy 1983
Practice Setting: Independent Community Pharmacy
Current KPhA Involvement: KPhA Board of Director

Statement of Interest:

I wish to continue to be a KPhA Board of Director. As a former member of the Kentucky State House of Representatives and having been a pharmacist and independent pharmacy owner for over 35 years, I feel like I have a lot to offer KPhA to help our profession.

Jordan Smith, PharmD
Self-Nominated
Education: Appalachian College of Pharmacy 2016
Practice Setting: Retail Community Pharmacy
Current KPhA Involvement: Active Member

Statement of Interest:

My pursuit of this position is driven by my desire to be a voice and advocate for the profession of pharmacy in Kentucky. I aspire to lead the advancement of pharmacy in our state by promoting legislation and innovations that enhance patient care, patient safety, and the overall health of our communities. I am passionate about provider status and payment, improving patient outcomes and bridging the gap in health disparities, by elevating and expanding the role of the pharmacist and pharmacies, providing patients access to high level care through medication management and clinical services.

President-Elect Nominee

Kyle Harris, PharmD
Nominated by Scotty Reams
Education: University of Kentucky College of Pharmacy 2010
Practice Setting: Long-term Care
Current KPhA Involvement: KPhA Board of Director, Public Health, Professional Affairs, and Organizational Affairs Committee Member, Emergency Preparedness District Coordinator, Center of Excellence Workgroup Member

Statement of Support:

It is my utmost privilege to nominate Dr. Kyle Harris for KPhA president-elect. Kyle, a tenured pharmacist with a track record of commitment to KPhA, will bring a unique background to the position, having worked as an independent pharmacist and now in long-term care. In addition, he has an extensive history of service to the organization, serving in emergency preparedness, various committees, and the board of directors. As president, I have no doubt Kyle will use his skills and collaborative style to further the organization and advance its mission and goals. Please allow this nomination to serve as my full support of Kyle Harris for KPhA president-elect.

Join us at the Annual Meeting to meet and welcome our newly elected board members. Learn more Conference details on pages 22-26

Julie Anderson, PharmD
Self-nominated
Education: University of Charleston School of Pharmacy 2010
Practice Setting: Specialty Mail Order Pharmacy
Current KPhA Involvement: Active Member

Statement of Interest:

I feel that I would be a good fit for the KPhA board of directors because I am a well-rounded pharmacist who has worked in multiple pharmacy practice settings over the last thirteen years. I am uniquely positioned to be able to advise on recent law and regulation changes across multiple states. I am an intellectually curious individual who loves to learn. Finally, and most importantly, I am passionate about patient care and patient safety and will be an advocate for their health and welfare.

Treasurer Nominee

Lakin Marr, PharmD, MBA
Self-nominated
Education: University of Kentucky College of Pharmacy 2018
Practice Setting: Independent Community Pharmacy
Current KPhA Involvement: KPhA Board of Director, Membership Engagement and Finance Committee Member

Statement of Interest:

My professional goals are guided by two practice principles: serve my local community by providing innovative care in independent pharmacy and serve the Commonwealth by promoting and advancing the profession of pharmacy. Nearly two years ago I applied for the Board of Directors position with this leading statement, that still holds true today.

During my time as a Board member at KPhA I have been honored to share my passion of pharmacy advocacy through devotion of my time, ideas, and lived experiences. Our association leadership is hungry for the advancement of all areas of pharmacy and it is my desire to join that team. I believe that my educational background in Business Administration paired with my current professional experience of opening an independent pharmacy have established a good foundation for becoming KPhA's next Treasurer. It is my goal to ensure the KPhA continues advancing our goals of representing all Kentucky pharmacists in pharmacy practice advancement and advocacy.

SGLT2 Inhibitors for Heart Failure: To Diabetes and Beyond

Madeline M. Mitchell, PharmD[1], 2022-2023 PGY2 Internal Medicine Pharmacy Resident
Alexa R. Filley, Pharm D[1], 2022-2023 PGY2 Internal Medicine Pharmacy Resident
Kimberly G. Elder, PharmD, BCPS[2], Associate Professor & Teaching and Learning Curriculum Coordinator
Sarah E. Raake, PharmD, MSEd, BCACP, LDE[2], Associate Professor & Direction of Instructional Effectiveness

[1]UofL Health – UofL Hospital, Louisville, KY
[2]Sullivan University College of Pharmacy and Health Sciences, Louisville, KY

Pharmacist Objectives:

- *Explain the clinical benefits and safety profile of SGLT2i for heart failure*
- *Describe proposed mechanisms of clinical benefits of SGLT2i in heart failure*
- *Recommend therapy based on current guideline recommendations for SGLT2i for heart failure*
- *Describe trials related to SGLT2i for heart failure*
- *Identify potential barriers to SGLT2i use in heart failure*

Pharmacy Technician Objectives:

- *Explain the clinical benefits and safety profile of SGLT2i for heart failure*
- *Describe the mechanism of action of SGLT2i in diabetes*
- *Identify potential barriers to SGLT2i use in heart failure*

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Longitudinal Case

JK is a 66-year-old male (actual body weight: 90 kg) who presented to the emergency department with complaints of fatigue, shortness of breath, and bilateral swelling in his legs and ankles. He has a past medical history which includes hypertension, hyperlipidemia, and heart failure with reduced ejection fraction (HFrEF). He currently takes lisinopril 40 mg PO daily, carvedilol 25 mg PO BID, spironolactone 25 mg PO daily, furosemide 20 mg PO daily, and atorvastatin 80 mg PO daily. On physical examination, the physician notes pulmonary crackles and an elevated jugular venous pressure indicating fluid overload. Following a thorough workup, JK is admitted to the internal medicine service for acute decompensated heart failure (ADHF) and treated with an IV diuretic.

On hospitalization, day 4, JK's symptoms have improved, and he has transitioned from an IV diuretic to a PO diuretic. In preparation for discharge, the internal medicine service asks you to review and optimize JK's heart failure medication regimen. Pertinent labs include: Sodium 137 mEq/L, Potassium 5.1 mEq/L, and SCr 0.7 mg/dL (baseline). What recommendations would you make to optimize JK's heart failure regimen?

Background

Sodium-glucose cotransporter-2 inhibitors (SGLT2i) were initially developed as glucose-lowering agents to treat type 2 diabetes mellitus (T2DM). The first drug of this class was canagliflozin, which received FDA approval in 2013. This class of medications works by inhibiting the SGLT2 receptor in the proximal convoluted renal tubule, thereby inducing glucosuria. Since their FDA approval, these agents have shown additional clinical benefits, beyond glucosuria, in T2DM, chronic kidney disease, and heart failure with or without diabetes.[1–4] Additional benefits include weight loss, blood pressure-lowering effects, slowing progression of kidney disease, and reduced risk of major cardiovascular events, including death.[5] SGLT2i currently available in the United States include dapagliflozin, canagliflozin, empagliflozin, and ertugliflozin (see Table 1). Safety profiles of SGLT2i suggest these agents are generally well-tolerated. Frequent adverse events of SGLT2i include genitourinary fungal infections (2% to 6%) and urinary tract infections (8% to 9%). Rare (<1%) but serious adverse events of SGLT2i, such as hypotension, euglycemic diabetic ketoacidosis, bone fractures, and lower limb amputations, have been reported. Patients with renal impairment have been found to have reduced efficacy of SGLT2i for the treatment of hyperglycemia.[1–4] Given the lack of data on severe renal impairment, initiation of these agents is typically not recommended for any indication if the estimated glomerular filtration (eGFR) rate is below 20 mL/min/1.73 m^2 and use is contraindicated in dialysis.[1–4]

Table 1. Available SGLT2i in the United States[1–4]

Brand (Generic)	General Dosing	FDA-Approved Indications	Dosing in Patients with Heart Failure
Farxiga® (dapagliflozin)	5-10 mg PO daily	• Type 2 diabetes • Chronic kidney disease • Heart failure with reduced ejection fraction	Target dose: 10 mg daily eGFR < 25 mL/min/1.73 m²: initiation not recommended Dialysis: use contraindicated
Invokana® (canagliflozin)	100-300 mg PO daily	• Type 2 diabetes	Not FDA-approved for heart failure
Jardiance® (empagliflozin)	10-25 mg PO daily	• Type Diabetes • Heart failure with reduced or preserved ejection fraction	Target dose: 10 mg daily eGFR ≤ 20 mL/min/1.73 m²: use not recommended Dialysis: use contraindicated
Steglatro® (ertuglifozin)	5-15 mg PO daily	• Type 2 diabetes	Not FDA-approved for heart failure

Clinical Benefits in Heart Failure

The favorable cardiovascular outcomes observed in landmark trials of patients with T2DM sparked interest in SGLT2i as potential treatment options for heart failure. Several trials have now been conducted to evaluate the effects of SGLT2i for chronic heart failure in patients with and without diabetes (see Table 2). The results have shown a substantial reduction in heart failure hospitalizations and cardiovascular death when compared to placebo.[7–10] These clinical benefits have led to the FDA approval of dapagliflozin and empagliflozin for certain heart failure patients, even in the absence of T2DM.[2–3] Canagliflozin and ertugliflozin are not currently FDA-approved for heart failure but have shown some benefit in cardiovascular outcomes[5–6]; however, additional clinical trials are needed to evaluate their use.

Despite the robust clinical data supporting SGLT2i use, the underlying mechanism by which these agents exert their benefits in heart failure is unclear. While the glucose-lowering effect of SGLT2i is reduced in patients with renal dysfunction[1–4], the cardiovascular benefit seems to be preserved, implying that the mechanism is independent of the glucosuria effects of these agents.[8] Proposed mechanisms include stimulation of natriuresis, improved cardiac filling due to reductions in preload and afterload, autophagy induction, reduced arterial stiffness, and improved intracellular cardiac ion homeostasis.[8–13]

Table 2. Landmark Trials [9–12]

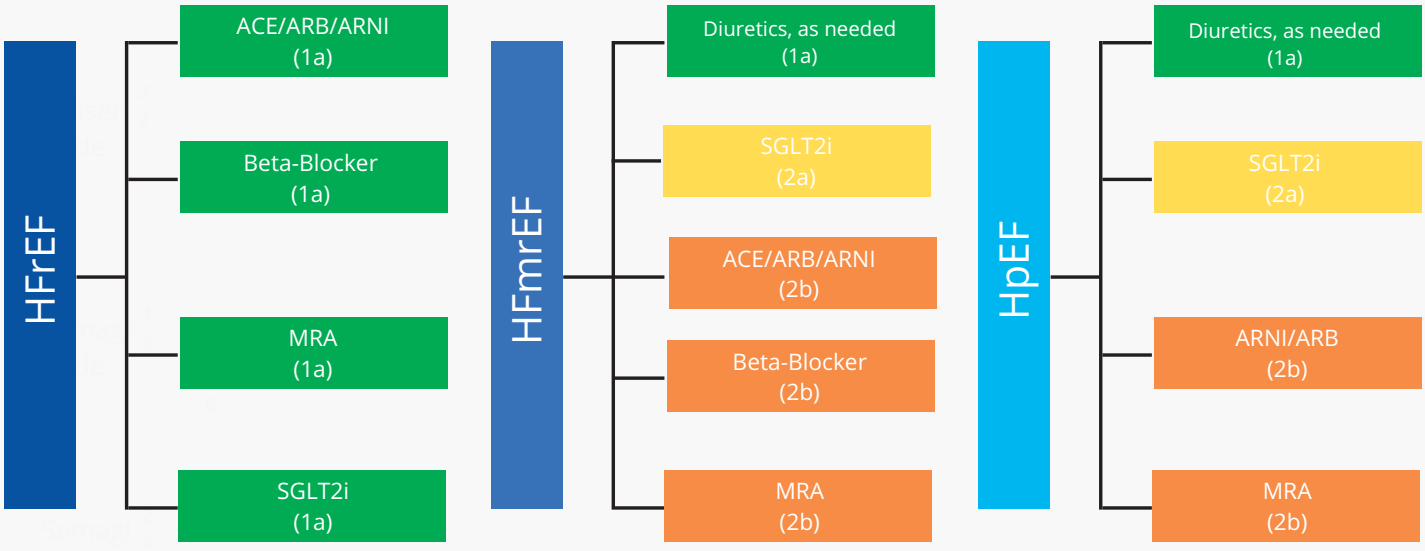
	DAPA-HF	DELIVER	EMPEROR-Reduced	EMPEROR-Preserved
SGLT2i regimen	Dapagliflozin 10 mg daily	Dapagliflozin 10 mg daily	Empagliflozin 10 mg daily	Empagliflozin 10 mg daily
Study population	Chronic HFrEF EF ≤ 40% (NYHA functional class II–IV)	Chronic HfpEF (EF ≥ 50%) and HFmREF (EF 41-49%) (NYHA functional class II–IV)	Chronic HfrEF (EF ≤ 40%) (NYHA functional class II–IV)	Chronic HfpEF (EF ≥ 50%) (NYHA functional class II–IV)
Key exclusion criteria	eGFR <30mL/min/1.7m² SBP <95 mm Hg	eGFR <25 mL/min/1.7m² SBP <95 mm Hg	eGFR <20 mL/min/1.73m² SBP <100 mm Hg	eGFR <20 mL/min/1.73 m² SBP <100 mm Hg
Sample size	n= 4744	n=6263	n=3730	n=5988
Median follow-up time	18 months	28 months	16 months	26 months
Primary outcome	Composite of worsening HF or cardiovascular death	Composite of worsening HF or cardiovascular death	Composite of cardiovascular death or hospitalization for HF	Composite of cardiovascular death or hospitalization for HF
Results (SGLT2i vs. placebo)	16.2% vs. 21.2% (HR: 0.74; 95% CI: 0.65-0.85, p<0.001)	16.4% vs. 19.5% (HR: 0.82; 95% CI: 0.73-0.92, p<0.001)	19.4% vs. 24.7% (HR: 0.75; 95% CI:0.65-0.86, p<0.001)	13.8% vs. 17.1% (HR: 0.79; 95% CI: 0.69-0.90, p<0.001)

eGFR: estimated glomerular filtration rate
NYHA: New York Heart Association
HR: hazard ratio
CI: confidence interval

Guideline Recommendations[14]

AHA/ACC/HFSA Heart Failure Guidelines have recently updated their recommendations for guideline-directed medical therapy (GDMT) for heart failure with reduced ejection fraction (HFrEF) to contain four medication classes, including SGLT2i, in addition to beta-blockers, angiotensin-converting enzyme inhibitors (ACEi) or angiotensin-receptor blockers (ARB), or angiotensin-receptor neprilysin inhibitors (ARNI), and mineralocorticoid receptor antagonists (MRA). SGLT2i are now recommended for patients with symptomatic chronic HFrEF, regardless of the presence of T2DM, to reduce heart failure hospitalizations and cardiovascular mortality. Due to the morbidity and mortality benefit, guidelines recommend that all patients with HFrEF should be initiated on all four GDMT agents unless contraindications exist. SGLT2i now have a moderate recommendation for heart failure with mildly reduced ejection fraction (HFmREF) and heart failure with preserved ejection fraction (HFpEF), which are stronger recommendations than those made for beta-blockers, ACEi, ARB, ARNI or MRA for these populations (Figure 1). For patients with heart failure with improved ejection fraction (HFimEF), guidelines recommend SGTL2i, in addition to other GDMT, be continued, even in asymptomatic patients. Table 3 summarizes guideline recommendations for SGLT2i in each heart failure classification by left ventricular ejection fraction (LVEF).[14]

Figure 1. Recommended GDMT per 2022 AHA/ACC/HFSA Guidelines



1a: Class 1 (strong) recommendation, Level a (High-quality) evidence
2a: Class 2a (moderate) recommendation
2b: Class 2b (weak) recommendation

Table 3. AHA/ACC/HFSA Heart Failure Guideline Recommendations for SGLT2i[14]

Classification by LVEF	Criteria	Recommended for Heart Failure	Class of Recommendation (Strength of Recommendation)
HFrEF	LVEF ≤40%	Yes	Class 1 (strong)
HFimpEF	Previous LVEF ≤40% and a follow-up measurement of LVEF >40%	Yes	Class 1 (strong)
HFmrEF	LVEF 41%–49%	Yes	Class 2a (moderate)
HFpEF	LVEF ≥50%	Yes	Class 2a (moderate)

AHA: American Heart Association; ACC: American College of Cardiology; HFSA: Heart Failure Society of America LVEF: left ventricular ejection fraction; HFrEF: HF with reduced EF; HFimpEF: HF with improved EF; HFmrEF: HF with mildly reduced EF; HFpEF: HF with preserved EF

The current AHA/ACC/HFSA Guidelines make no recommendation regarding the use of SGLT2i in the setting of acute decompensated heart failure (ADHF). Initiation of SGLT2i was originally avoided in patients with ADHF due to concerns of the transient effect on diuresis and eGFR; however, promising literature has emerged for SGLT2i use in this patient population.[15–16]

Summary of Evidence

DAPA-HF

The DAPA-HF (Dapagliflozin and Prevention of Adverse Outcomes in Heart Failure) trial, published in 2019, was a phase III, randomized, placebo-controlled trial of 4,744 patients with NYHA class II, III, or IV heart failure with HFrEF. Patients received dapagliflozin 10 mg daily or placebo, in addition to other GDMT, and were followed over approximately 18 months. The primary outcome was a composite of worsening heart failure, defined as hospitalization and/or an urgent visit for heart failure, and cardiovascular death. The primary composite outcome occurred in 16.3% of patients in the dapagliflozin group compared to 21.2% in the placebo group (HR: 0.74; 95% CI: 0.65-0.85, p<0.001). In other words, patients who took dapagliflozin were 26% less likely to experience the primary outcome. Additionally, the number needed to treat for this outcome was 21, meaning you would need to treat 21 patients to prevent one patient from experiencing the primary composite outcome. An event of worsening heart failure occurred in 10.0% of the dapagliflozin group compared to 13.7% in the placebo group (HR: 0.70; 95% CI: 0.59- 0.83). Death from cardiovascular causes occurred in 9.6% of the dapagliflozin group and 11.5% of the placebo group (HR: 0.82; 95% CI: 0.69-0.98). Secondary outcomes showed death from any cause occurred in 11.5% of patients in the dapagliflozin group and 13.9% of patients in the placebo group (HR: 0.83; 95% CI: 0.71-0.97). Overall, the composite risk of worsening heart failure or cardiovascular death in patients with HFrEF was lower with dapagliflozin.[9]

DELIVER

The DELIVER (Dapagliflozin Evaluation to Improve the Lives of Patients with Preserved Ejection Fraction Heart Failure) trial, published in 2022, was a randomized, placebo-controlled trial of 6,263 patients with HFmrEF or HFpEF. Patients received dapagliflozin 10 mg daily or placebo with a follow-up period of approximately 28 months or 2.3 years. The primary composite outcome of worsening heart failure or cardiovascular death occurred in 16.4% of patients in the dapagliflozin group compared to 19.5% of patients in the placebo group (HR: 0.82; 95% CI: 0.73-0.92, p<0.001). An event of worsening heart failure occurred in 11.8% of the dapagliflozin group and 14.5% in the placebo group (HR: 0.79; 95% CI: 0.69-0.91). No significant differences in death from cardiovascular causes were found between the dapagliflozin (7.4%) and placebo (8.3%) groups (HR: 0.88; 95% CI: 0.74-1.05). Similar results were observed when patients with HFmrEF and HFpEF were analyzed in individual groups. In summary, the combined risk of worsening heart failure or cardiovascular death in patients with HFmrEF or HFpEF was reduced with dapagliflozin.[10]

EMPEROR-Reduced

The EMPEROR-Reduced (Empagliflozin Outcome Trial in Patients with Chronic Heart Failure and a Reduced Ejection Fraction), published in 2020, was a double-blind, randomized controlled trial of 3,730 patients with NYHA class II, III, or IV HFrEF. Patients were followed for approximately 16 months and received either empagliflozin 10 mg daily or placebo, in addition to other GDMT. The primary outcome, a composite of cardiovascular death or hospitalization for worsening heart failure, occurred in 19.4% of patients who received empagliflozin compared to 24.7% of patients who received placebo (HR: 0.75; 95% CI: 0.65-0.86, p<0.001). This difference was driven by the decrease in hospitalization for heart failure, which occurred in 13.2% of the empagliflozin group and 18.3% of the placebo group (HR: 0.69; 95% CI: 0.59-0.81). No significant differences in cardiovascular death were observed with empagliflozin (10.0%) compared to placebo (10.8%) (HR: 0.92; 95% CI: 0.5-1.12). Overall, there was a lower combined risk of worsening heart failure or cardiovascular death in patients with HFrEF who received empagliflozin.[11]

EMPEROR-Preserved

The EMPEROR-Preserved (Empagliflozin Outcome Trial in Patients with Chronic Heart Failure with Preserved Ejection Fraction) trial, published in 2021, was a double-blind, randomized controlled trial of 5,988 patients with NYHA class II, III, or IV HFpEF. Patients were assigned to empagliflozin 10 mg daily or placebo with a follow-up period of approximately 26 months. The primary composite outcome of cardiovascular death or hospitalization for health failure occurred in 13.8% of patients in the empagliflozin group compared to 17.1% of patients in the placebo group (HR: 0.79; 95% CI: 0.69-0.90, p<0.001). Hospitalization for heart failure occurred in 8.6% of the empagliflozin group and 11.8% of the placebo group (HR: 0.71; 95% CI: 0.60-0.83). No significant differences were seen in cardiovascular death alone between the empagliflozin (3.4%) and placebo (3.8%) groups (HR: 0.91; 95% CI: 0.76-1.09). In summary, empagliflozin reduced the composite risk of cardiovascular death or hospitalization for heart failure compared to placebo in patients with HFpEF.[12]

Emerging Literature and Evidence Gaps

Recent clinical trials have attempted to explore the role of SGLT2i in acute decompensated heart failure (ADHF). The SOLOIST-WHF (sotagliflozin in Patients with Diabetes and Recent Worsening Heart Failure) trial, published in 2021, evaluated the use of sotagliflozin, a dual sodium-glucose cotransporter-2 and 1 inhibitor (SGLT2/1i), in patients with T2DM and a recent hospitalization for heart failure.[15] After a median follow-up of nine months, patients treated with sotagliflozin experienced a significantly lower risk of death from cardiovascular causes and hospitalizations for heart failure (HR: 0.67; 95% CI: 0.52 to 0.85). Despite the positive findings, the SOLOIST-WHF trial did have some shortcomings, including early cessation of the trial due to loss of funding during the COVID-19 pandemic. In addition, 51.2% of patients were administered the first dose of sotagliflozin after discharge, making the findings less applicable to patients in the early stages of ADHF. Furthermore, sotagliflozin has yet to be approved for use in the United States.

The EMPULSE (Empagliflozin in Patients Hospitalized for Acute Heart Failure) trial, published in 2022, evaluated the use of empagliflozin in patients with ADHF with or without T2DM.[16] The primary outcome was a clinical benefit which was defined as a hierarchical composite of death from any cause, number of heart failure events and time to first heart failure event, or a 5-point or greater difference in the Kansas City Cardiomyopathy Questionnaire Total Symptom Score at 90 days. By using a win ratio to evaluate the primary outcome, clinical benefit was more likely to occur in the empagliflozin group than placebo (stratified win ratio: 1.36; 95% CI: 1.09-1.68, p = 0.0054). In other words, empagliflozin was associated with significant clinical benefit at 90 days, with fewer deaths, heart failure exacerbations, and improvement in quality of life. The safety of empagliflozin was found to be similar to placebo. While the EMPULSE trial provides additional information on this patient population, there is still the question of the role of SGLT2i in more clinically unstable patients, which were excluded in this trial. Additional clinical trials are currently underway to explore the role of SGLT2i in ADHF[17–18] including the DICTATE-AHF (Efficacy and Safety of Dapagliflozin in Acute Heart Failure) trial, which will evaluate dapagliflozin initiation within the first 24 hours of hospitalization.[17]

Case Continued...

Based on the 2022 AHA/ACC/HFSA Guidelines, you recommend initiating JK on empagliflozin 10 mg PO daily. What considerations should be made prior to discharging JK on empagliflozin?

Therapy Considerations

With the expanded use of SGLT2i in heart failure, it is important to consider potential barriers to initiation. Both empagliflozin and dapagliflozin are currently brand name only, making cost a barrier for many patients, even those with commercial insurance. Despite the large out-of-pocket cost associated with SGLT2i, the cumulative cost is likely to be less than that of hospitalization due to heart failure, which averages around $13,418 in the United States.[20] Given that SGLT2i has been shown to reduce hospitalizations due to heart failure, it is important that patients be promptly evaluated for initiation. At the publication of this article, there are resources available to help mitigate costs associated with these agents (Table 4). While many of these apply only to those with commercial insurance, it is important that pharmacy providers advocate and assist with SGLT2i initiation through copay card enrollment, formulary substitutions, and other cost-saving measures.

Table 4. Available Cost Saving Options*

SGLT2i	Copay Card	Patient Assistance Program	Source
Empagliflozin	Yes	Yes	Copay card: Jardiance.com/heart-failure-support/savings/ Patient assistance program: Boehringer-ingelheim.us
Dapagliflozin	Yes	Yes	Farxiga.com/savings-support

***Refer to manufacturer's website for eligibility information**

Provider hesitancy is another potential barrier to SGTL2i initiation. Reasons for hesitancy include provider inertia, fear of patient intolerance and adverse effects, cost limitations, and co-management issues with other clinicians. Despite the proven reduction in morbidity and mortality observed with GDMT, studies have found that many heart failure patients are not receiving one or more of the recommended medications.[21–22] The AHA/ACC/HFSA Guidelines recommend optimizing and initiating GDMT whenever possible, including the inpatient setting.[14] With the favorable side effect profile and proven clinical benefits, SGLT2i should be recommended in all eligible heart failure patients whenever possible.

Case Continued...

JK presents to your community pharmacy to pick up his prescription for empagliflozin. He wants to know why he is taking this medication and what side effects he should expect. What would you counsel JK on regarding his new prescription?

Conclusion

SGLT2i have emerged as a promising first-line agent for most heart failure patients. Empagliflozin and dapagliflozin have both been shown to reduce cardiovascular death and hospitalizations due to heart failure in a wide range of patients.[9–12] In addition to the positive outcomes observed, SGLT2i appear to be safe and well-tolerated. Following the publication of the 2022 AHA/ACC/HFSA Guidelines, pharmacists and pharmacy technicians should expect to see an increase in the number of SGLT2i prescriptions for heart failure and should advocate for initiation whenever appropriate. Pharmacy providers can continue to play a pivotal role in ensuring the appropriate initiation and monitoring of SGLT2i and address potential barriers such as medication access and affordability.

Case Summary

Based on the 2022 AHA/ACC/HFSA Guidelines, JK should be initiated on GDMT for HFrEF. He is currently on three of four GDMT agents, including an ACEi, beta-blocker, and MRA. He should be initiated on an SGLT2i, such as empagliflozin, to optimize his heart failure medication regimen. Given your understanding of cost-saving resources and proven clinical benefits of SGLT2i, you can successfully reduce barriers to initiation. Based on your knowledge of this medication class and disease state, you counsel JK on the benefits of SGLT2i for heart failure and potential adverse effects such as euglycemic diabetic ketoacidosis, urinary tract infections, and bone fractures.

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Questions for Pharmacists:

1. Which of the following statements best describes the proposed mechanisms of SGLT2i in heart failure?

a. Decreases cardiac output
b. Relates directly to glucosuria effects
c. Inhibition of natriuresis
d. Independent of glucosuria effects

2. Which patient would be the most appropriate candidate to receive treatment with empagliflozin?

a. 56-year-old patient with type 1 diabetes (T1DM)
b. 65- year-old patient with heart failure preserved ejection fraction (HFpEF)
c. 75-year-old patient with heart failure reduced ejection fraction (HFrEF) on dialysis
d. 30-year-old patient with an improved heart failure ejection fraction (HFimEF), also with a history of frequent urinary tract infections (UTIs)

3. Which of the following are reported side effects of SGLT2i?

a. Bone fractures, hypoglycemia, GI disturbances
b. Euglycemic diabetic ketoacidosis, urinary tract infections, bone fractures
c. Urinary tract infections, weight gain, acute pancreatitis
d. Weight gain, peripheral neuropathy, lactic acidosis

4. What is the target dose of dapagliflozin for patients with heart failure?

a. 5 mg PO daily
b. 10 mg PO daily
c. 20 mg PO daily
d. 25 mg PO daily

5. Which landmark trial showed clinical benefits of dapagliflozin in patients with HFpEF and HFmrEF?

a. DAPA-HF
b. DELIVER
c. EMPEROR-Reduced
d. EMPEROR-Preserved

6. JP is a 56-year-old male with a history of type II diabetes, hypertension, heart failure, reduced ejection fraction (HFrEF), and gout. His home medications include the following: lisinopril 40 mg PO daily, carvedilol 25 mg PO BID, spironolactone 25 mg PO daily, and metformin 500 mg PO BID. His blood pressure is 135/80 mmHg and he reports tolerating his current medications. Which of the following would be the most appropriate recommendation for JP's heart failure to reduce morbidity and mortality based on the AHA/ACC/HFSA Guidelines?

a. Continue current regimen
b. Increase lisinopril dose
c. Add empagliflozin 10 mg daily
d. Add furosemide 20 mg daily

7. You are working as a community pharmacist when a patient begins complaining about the cost of their new heart failure medication, empagliflozin. The patient has commercial insurance but cannot afford to pay $100 every month. Which of the following actions would be most appropriate to assist this patient?

a. Provide patient with a copay card
b. Recommend the patient stop taking empagliflozin
c. Tell the patient that there is nothing to be done
d. Recommend that the patient be switched to canagliflozin

Questions for Pharmacy Technicians:

1. What is the mechanism of action for SGLT2i in diabetes?

a. Decrease gluconeogenesis
b. Increase insulin secretion
c. Increase glucagon secretion
d. Induce glucosuria

2. Which of the following represents a potential side effect of SGLT2i?

a. Weight gain
b. Frequent hypoglycemia
c. Peripheral neuropathy
d. Urinary tract infections (UTIs)

3. True or False: SGTL2i are not beneficial for patients with heart failure without diabetes.

a. True
b. False

4. SGLT2i have been shown to decrease _____ in patients with heart failure.

a. Quality of life
b. Hospitalizations
c. Stroke
d. Diabetic ketoacidosis

5. Which of the following is an appropriate option to help assist patients with the cost of SGLT2i?

a. Do nothing because it is out of your scope of practice
b. Provide them with a copay card
c. Provide them with a sample
d. Recommend that they stop taking their SGLT2i because it is too expensive

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: SGLT2 Inhibitors for Heart Failure: To Diabetes and Beyond

Name: _____

Email: _____

NABP eProfile ID #: _____

Birthdate (MM/DD): _____

Completion Date: _____

Please circle: Pharmacist or Technician

UNIVERSAL ACTIVITY #: 0143-0000-23-012-H01-P /T | **CONTACT HOUR**: 1 .5| **EXPIRES**: 4/1/2026

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

PLEASE NOTE THAT PHARMACY TECHNICIANS ONLY HAVE 5 QUESTIONS

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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

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

KPhA Members Start Your Engines...

From fast cars to Nashville-bound music sensations, we are gearing up for a weekend of fun in Bowling Green, or according to Southern Living Magazine, one of "The South's Best Cities on the Rise 2022."

Whether you make it to the Welcome Mingle on Thursday at the Corvette Museum (dinner included with registration) or just in time for the keynote on Friday, we promise you'll feel the hype no matter your starting position at this year's Annual Meeting, June 8-11.
If any profession is familiar with teamwork, it's US!

It's time to **RevUp, GearUp, and TeamUp** because 2023 is the year pharmacists get a long overdue victory lap.

REGISTER TO "TAKE YOUR POSITION"

Member Registration:

Pharmacist: $350
Daily Rate: $200
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SCAN ME

SIGN UP AS AN RX TEAM MEMBER FOR A SPECIAL RATE!

It takes a whole pit crew to get from 0-60 mph in 2.8 seconds. For a **flat $1,000 fee,** send up to five pharmacists or technicians (ANY combo) from your "Rx Team" to the Annual Meeting. Celebrate your employees through team building and boost morale behind the bench.

KPhA Annual Meeting

Tentative Agenda at-a-glance

All times are CST – local time

Thursday, June 8

8:00-10:00 AM	KPERF Board Meeting
10:00 AM-3:00 PM	KPERF Golf Scramble
6:00-9:00 PM	Welcome and Mingle with Novo Nordisk at Corvette Museum Dinner at 7:00 PM

Friday, June 9

7:00 AM	Registration Opens
7:30-8:00 AM	Yoga on the Lawn
8:00 AM	Breakfast Sponsored by Walgreens
8:30 AM	Welcome: Ben Mudd, Executive Director KPhA and Misty Stutz, President KPhA
9:00 AM - CE	Opening Keynote: Do More with More Speaker: Kimber Booth
10:00 AM-2:30 PM	Travel Health Certificate (Registration and 6 hours of home study required prior to this in-person session)
10:15 -11:15 AM – CE	Topic: 1: Is Your Team Prepared for the Next Emergency? Speaker: Michele Pinkston + Panel Topic 2: The Early Adopters of Medical Billing Speakers: Panel Discussion on Engaging in Medical Billing
11:30 AM – 12:30 PM – CE	Topic 1: Documentation for Medical Billing Speaker: Kyle Bryan Topic 2: 340B -The Good, the Bad, and the Ugly Speaker: Ronnah Alexander
12:30 - 1:30 PM	Lunch
1:30 - 3:00 PM	Opening House of Delegates
3:00 - 4:00 PM - CE	Topic 1: Biologics Substitution Speaker: Trent Thiede Topic 2: Coding for Medical Billing Speaker: Kyle Bryan
4:00 - 6:00 PM	Exhibit Gallery (Exhibitors set-up 12:00-3:00 PM)
3:00 - 6:00 PM	Welcome Reception in the Exhibitor's Gallery
6:30 - 9:00 PM	Family Outing – Bowling Green Hot Rods Baseball Game

Saturday, June 10

7: 00 AM	Registration Open
7:30-8:00 AM	Yoga on the Lawn
8:00-9:00 AM	Breakfast and Conversation
9:00-10:00 AM - CE	Becoming a Person of Influence Speaker: Fatima Ghzala
10:00-11:00 AM - CE	Topic 1: Law Update Speaker: Dr. Ralph Bouvette Topic 2: Community Pharmacy Grand Rounds 10-minute presentations, 5 minutes of questions Topic 3: Nutritional Supplement Protocol Speaker: Dr. Shelley Roberts
11:10 AM-12:10 PM - CE	Topic 1: ADHD Speaker: Dr. Melinda Joyce Topic 2: Community Pharmacy Grand Rounds 10-minute presentations, 5 minutes of questions Topic 3: CRC Protocol Training Speaker: Dr. Emily Wilkerson
12:00-2:00 PM	Exhibitor Gallery and Poster Presentations *Please visit and engage with those presenting their research posters*
12:30-1:30 PM	Lunch
1:30-2:45 PM	Closing House of Delegates
3:00-4:00 PM - CE	Student OTC Competition Speaker: Jody Jaggers, PharmD
5:00-6:00 PM	President's Cocktail Reception
6:00-8:00 PM	Ray Wirth Awards Banquet

Sunday, June 11

8:00-9:00 AM	Breakfast
8:30-9:30 AM - CE	Topic: Leadership & Team Building Workshop Speaker: Fatima Ghzala
9:40-10:40 AM - CE	Topic: Opioid-Related CE for KY requirement Speaker: Martika Martin
10:50-11:50 AM - CE	Diabetes & Technology Speakers: Brooke Hudspeth & Blair Lykins
11:50 AM-Noon	Closing remarks & giveaways

KPhA Annual Meeting 2023:
RevUp. GearUp. TeamUp

MEET THE PRESENTERS

Dr. Kimber Boothe

Dr. Kyle Bryan

Dr. Fatima Ghzala

Dr. Brooke Hudspeth

Dr. Melynda Joyce

Dr. Martika Martin

Dr. Michele Pinkston

Trent Thiede

FILL YOUR TANK with CE

- Become a Person of Influence
- Medical Billing
- Emergency Preparedness
- Diabetes Technology
- Biologics Substitution
- CRC Protocol
- Team Building Workshop
- ADHD
- OPIOID CE Requirement
- Nutritional Supplements Protocol

Dr. Shelley Roberts

Dr. Emily Wilkerson

KPhA Annual Meeting

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Annual KPERF Golf Scramble

Thursday, June 8

CrossWinds Golf Course

Bowling Green, KY

Proceeds benefit education and research for the pharmacy profession

- **$125/ individual**
- **$500/team of four**
- **Lunch included**
- **Sponsor a Hole for $150**
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- **Voted Best Golf Course in Bowling Green**
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KPhA Annual Meeting

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UAN: 0143-0000-23-021-H03-P
Original Release Date: 5/1/2023
Planned Expiration Date: 4/30/2026

0.2 CEU for pharmacists

Review of Kentucky Controlled Substance Statutes and Regulations

Martika Martin, PharmD, MBA, BCGP

Pharmacist Objectives:

- Recall federal and state laws and regulations related to controlled substances.
- Define corresponding responsibility.
- List enforcers of the federal and Kentucky controlled substance acts.
- Review controlled substance prescribing authority of physicians, physician assistants, nurse practitioners, and other prescribers.
- List the exceptions to required electronic prescribing of controlled substances.
- Recall controlled substance record-keeping requirements.
- List requirements for a controlled substance prescription in Kentucky.
- Describe Kentucky regulations related to professional standards of prescribing buprenorphine for opioid use disorder and its recent changes.
- Summarize regulations regarding the sale of over-the-counter schedule listed chemical products.
- Describe SB 47 and the requirements created for the use and dispensing of medicinal cannabis.

Introduction:

The United States and other countries have attempted to regulate the availability of addictive substances since the early 20th century, complicated by the desire to curtail substance abuse while ensuring an adequate supply of medically necessary drugs[1]. In 1914, the Harrison Narcotics Act was passed, which required importers, manufacturers, and distributors of opium and cocaine to register with the Department of the Treasury, pay a tax on these drugs, and keep transaction records.[2] Prison sentences and other penalties for drug offenses resulted from the 1951 Boggs Act and the 1956 Narcotic Control Act[2]. In 1970, because of his "War on Drugs," President Nixon advocated for the passage of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Passed and signed by President Nixon, this Controlled Substance Act (CSA) replaced previous federal drug laws with a single comprehensive statute and created the framework by which the federal government regulates the manufacture, possession, and distribution of controlled substances.[2]

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Controlled Substance Schedules:

The CSA created the five schedules of controlled substances. Drugs are placed into the schedule based on their potential for abuse, the potential for dependence when abused, and the presence of a currently established medical use[3]. To determine the schedule of a new drug, the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) consider multiple factors, including:

- **Actual or potential for abuse**
- **Scientific evidence of pharmacological effects**
- **Current scientific knowledge of the substance**
- **History and significance of abuse**
- **Risk to public health**
- **Psychological or physiological dependence**
- **Whether the drug is an immediate precursor of an already scheduled substance[2]**

Schedule I substances are the most restrictive and include heroin, lysergic acid diethylamide (LSD), and marijuana. Schedule 1 substances are deemed to have a high potential for abuse or harm and no established medical purpose. Schedule 1 substances can only be obtained or used for research purposes with special registration and authorization from the DEA.[3]

Drugs in schedules II through V have established medical purposes and may be manufactured, prescribed, distributed, and administered by appropriately licensed and permitted individuals or organizations.

Schedule II substances have a high potential for abuse that may lead to severe psychological or physical dependence. This schedule includes stimulants such as amphetamine, methamphetamine, and methylphenidate. It also includes narcotic pain medications such as oxycodone, hydrocodone, methadone, and fentanyl.[3]

Schedule III controlled substances have less abuse potential than Schedule I or II substances and may cause moderate or low physical or high psychological dependence. Schedule III controlled substances include combination products with 90 milligrams or less of codeine per dosage unit, buprenorphine, ketamine, and testosterone.[3]

Table 1: Controlled Substance Schedules

Schedule	Definition	Examples
C-I	• High potential for abuse or harm • No established medical purpose	• Heroin • Lysergic acid diethylamide (LSD) • Marijuana
C-II	• High potential for abuse • Risk of severe psychological or physical dependence	• Hydrocodone • Oxycodone • Amphetamines

Schedule	Definition	Examples
C-III	• Less potential for abuse than C-I or C-II • Risk of moderate or low physical dependence or high psychological dependence	• Buprenorphine • Testosterone • Codeine 30mg-acetaminophen 300mg
C-IV	• Lower potential for abuse than C-III	• Alprazolam • Carisoprodol • Lorazepam
C-V	• Lowest abuse potential	• Promethazine with codeine syrup • Gabapentin • Tramadol • Pregabalin

Enforcement:

The United States Drug Enforcement Administration (DEA) operates under the Department of Justice. It is responsible for upholding federal laws related to the growing, manufacturing, or distribution of controlled substances, whether licit or illicit. Before the formal creation of the DEA by President Nixon in July 1973, enforcement of these laws fell to multiple federal agencies, including the Bureau of Internal Revenue (1915), the Bureau of Drug Abuse Control (1960s), and the Federal Bureau of Narcotics (1960s).[4]

Corresponding responsibility:

For a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose in the usual course of professional treatment. A pharmacist is responsible for ensuring that a prescription for a controlled substance meets those requirements. If a pharmacist knowingly dispenses a prescription for an invalid controlled substance, the pharmacist and the person issuing the prescription are subject to penalties under the CSA.[6]

According to the DEA, the pharmacist must use sound professional judgment and adhere to professional standards to determine the legitimacy of a controlled substance prescription and make that determination before the prescription is dispensed. A pharmacist is not required to dispense a doubtful, questionable, or suspicious prescription. Unlawful dispensing of a controlled substance is subject to criminal and civil penalties for the pharmacist and/or pharmacy.[6]

Table 2: Possible Red Flags for Prescription Diversion:

- Patient demands immediate attention
- Patient exaggerates medical condition
- Requests specific medication due to allergies
- Patients driving long distances to obtain their prescriptions
- Patients paying in cash
- Prescribers writing the same prescription strengths/combinations/quantities

Prescriber Limitations:

Kentucky has stricter limitations on what controlled substances non-physician prescribers can prescribe. The limitations are determined in statute by each profession's professional act. Nurse practitioner limitations are defined in KRS 314.011(8). Physician assistants statutes are found in KRS 311.858(5).[7]

Nurse practitioners may prescribe schedule II through V controlled substances. Class II controlled substances may only be prescribed for up to a three-day supply except for psychostimulants if the nurse practitioner is certified in psychiatric-mental health (limited to a 30-day supply) and hydrocodone combination products (limited to a 30-day supply). Class III controlled substances may only be prescribed for up to a 30-day supply. Class IV and V can be prescribed for up to a six-month supply. As of February 24, 2021, there is no longer a limitation on nurse practitioners prescribing carisoprodol, alprazolam, diazepam, clonazepam, and lorazepam to a 30-day supply with no refills.[7]

A physician assistant may not prescribe Class II controlled substances. They are limited to prescribing a 30-day supply with no refills of Class III controlled substances, Class IV benzodiazepines, and carisoprodol. All other Class IV and V controlled substances may be prescribed up to a six-month supply.

If treating acute pain with a Class II controlled substance, all prescribers are limited by KRS 218A:205 to a 72-hour supply unless:

- Professional judgment dictates that more than a three-day supply is warranted. This need must be documented.
- The provider is treating chronic pain.
- The provider is treating cancer pain.
- The patient is at the end of life or in Hospice.
- Patient is being treated for pain after major surgery or significant trauma as defined by the licensing Board of the Office of Drug Control Policy.
- The medication is administered directly to the patient in an inpatient setting.
- Other scenarios are authorized by the licensing board.[7]

Other than the 3-day limit for acute pain, there is no maximum quantity for Class II controlled substances in state or federal law for physicians, dentists/dental surgeons, veterinarians, or podiatrists. Optometrists are limited to a 72-hour supply of hydrocodone products but cannot prescribe any other Class II controlled substance.[7]

Table 3: Overview of Kentucky Prescriptive Authority

Kentucky Provider	Authority to Prescribe
Physician KRS 218A.010; 201 KAR 009:260	• Humans only • Limits: CII for acute pain, limited to a 3-day supply
Veterinarian KRS 321.181	• Animals only • No other limitations
Dentist KRS 313.035; 201 KAR 8:540	• Limited to conditions of the mouth and associated structures • Limits: CII for acute pain limited to a 3-day supply
Podiatrist KRS 218A.172; 201 KAR 025.090	• Limited to conditions of the feet and associated structures • Limits: CII for acute pain limited to a 30-day supply
Optometrist KRS218A.205; 201 KAR 005.130	• Limited to conditions of the eye or its appendages • Limits: Hydrocodone-combination products are limited to a 72-hour supply, not authorized to prescribe any other CII, limited to 72-hour supply with no refill of CIII-V

Advanced Practice Registered Nurse
KRS 218A.020(3); KRS 314.011(8)
	• Prescriptive authority defined by Collaborative Care Agreement
	• Limits:
	  ◦ CII- 72-hour supply
	  ◦ CII Hydrocodone combination product- 30-day supply (3 days for acute pain.
	  ◦ CII psychostimulant- Certified in psych-mental health may prescribe a 30-day supply
	  ◦ CIII- 30-day supply with no refill
	  ◦ CIV- original RX with refills not to exceed 6 months
	  ◦ CV- original RX with refills not to exceed 6 months

Physician Assistant
KRS 311.858(5)
	• Prescriptive authority delegated by supervising physician and defined by KBML applications.
	• Supervising physicians must be on the premise unless a KBML waiver has been granted and supervising physician is available via telecommunication.
	• Limits:
	  ◦ CII: not authorized
	  ◦ CIII: 30-day supply with no refill
	  ◦ CIV: All benzodiazepines and carisoprodol limited to 30-day supply with no refill

Prescription Requirements:

Prescriptions for controlled substances must have a written, facsimile, electronic, or oral prescription. Prescriptions for Class II controlled substances expire 60 days after the date of issue, while prescriptions for Class III through V expire six months after the date of issue. Prescribers must date and sign the prescription on the date of issue and cannot post-date prescriptions.[8]

There are limited circumstances in which a Class II controlled substance may be dispensed by a facsimile prescription, including:

- A prescription for a narcotic substance to be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.
- A prescription for a resident of a long-term care facility.
- A prescription for a hospice patient (prescription must note that the patient is in hospice care).

The facsimile prescription will serve as the original and must be stored in the same manner as an original Class II prescription.[8–9]

Class II controlled substances may only be dispensed by an oral prescription only for immediate administration to a patient enrolled in a hospice program or a resident in a long-term care facility. This does not include residents in a family care home or personal care home. The practitioner must determine that immediate administration is necessary, no alternative treatment is available, and it is not reasonably possible for the prescriber to provide a written or electronic prescription. The pharmacist must immediately reduce the oral prescription to writing and contain all the necessary information as any other written prescription, except for the prescriber's signature. If the prescriber is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered practitioner, including a callback to the prescriber's listed phone number or other good faith efforts. The prescriber must send a written or electronic prescription for the oral one within seven days of authorizing the oral prescription. It must contain the phrase "Authorization for Emergency Dispensing" and the date of the oral order. For an electronic prescription, the pharmacist must annotate the electronic prescription with the original authorization and date of the oral order. The written prescription shall be attached to the written version of the oral order. If the prescriber does not send a written or electronic prescription for the oral order, the pharmacist must notify the nearest DEA office[8].

All controlled substance prescriptions must include the patient's full name and address, drug name, strength, dosage form, quantity prescribed, directions for use, and the practitioner's name, address, and registration number. Written prescriptions must be written on an approved Kentucky Controlled Substance Security Blank as described in 902 KAR 55:105.[8]

As of January 1, 2021, all controlled substances must be prescribed electronically unless an exception is met.[8] Pharmacists are not required to verify that a written, oral, or faxed prescription for a controlled substance falls under one of the listed exceptions in Table 5 as long as the prescription is consistent with current laws and regulations.[8]

Table 4: Controlled Substance Prescription Blank Requirements[9]

Prescriber name, address, telephone number, and DEA number
Rx is 4 ¼ inches high and 5 ½ inches wide
Refill options on left side in order (NR, 1, 2, 3, 4, 5)
Six quantity check-off boxes (not location specific)
¾ inch opaque "RX" symbol that is 1/8 inch from the top and 5/16 inch from the right side that disappears if the prescription is lightened
Statement at bottom of blank saying, "Prescription is void if more than one (1) prescription is written per blank
A latent, repetitive "VOID" pattern at 5% in pantone green printed across the script. If copied, "VOID" appears in a pattern across the entire script."
Printed watermark on back of prescription blank: "Kentucky Security Prescription" only seen at 45º angle. Watermark appears horizontally in five step-and-repeat lines in a 12-point Helvetica Bold type

Table 5: Exceptions to Electronic Controlled Substance Mandate[8]

Prescription is issued by a veterinarian
Electronic prescribing is not available due to temporary technological or electrical failure
The practitioner is located out of the state
The prescriber and dispenser are the same entity
Prescription includes elements not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard
The prescription is for a drug that contains certain elements that cannot be incorporated as required by the FDA with electronic prescribing, including extemporaneous compounding
Prescribed a practitioner allowing for the dispensing of a nonpatient specific prescription under a standing order, approved protocol for drug therapy, or collaborative drug management or comprehensive medication management in response to a public health emergency
Prescribed by a practitioner prescribing under a research protocol
Prescribed by practitioners who have received a waiver or a renewal thereof from the requirement to use electronic prescribing due to economic hardship, technological limitations that are not reasonably within the practitioner's control, or other exceptional circumstances demonstrated by the practitioner. The initial waiver and subsequent renewal shall not exceed one year per waiver or waiver renewal.
Prescribed by a practitioner for an individual who receives hospice care
Prescribed by a practitioner for an individual who is a resident of a nursing facility

Record Keeping:

All pharmacies must keep complete and accurate records for each controlled substance received, sold, delivered, or otherwise disposed of. Controlled substance records must be kept for at least two years. Records involving Class II controlled substances, including inventories, must be kept separate from all other controlled substance records. The DEA requires that controlled substance records be readily retrievable for inspection and copying. Required records include:

- Executed official DEA Form 222 or the electronic equivalent
- Power of Attorney authorization to sign order forms.
- Receipts and/or invoices for schedules III, IV, and V controlled substances.
- All inventory records of controlled substances, including the initial and biennial inventories, dated at the beginning or close of business
- Records of controlled substances distributed (sales, returns, distributions to reverse distributors)
- Suspicious Orders Report System (SORS) accessed online.
- Records of controlled substances dispensed.
- Reports of theft of significant loss, DEA Form 106
- Registrant Record of Controlled Substance Destroyed, DEA Form 41, if applicable
- DEA registration certificate
- Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005.[6]

Pharmacists may store paper prescription records in two ways:

1. A file for Class II substances dispensed and a file for Class III through V substances dispensed
2. A file for all Class II substances dispensed and a file for all other drugs dispensed, controlled, and non-controlled.[6]

If a controlled substance prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be maintained electronically. Electronic records must also be maintained for at least two years and readily retrievable in an easily readable or easily rendered into a format that a person can read.[6]

An initial controlled substance inventory must be taken when issued a DEA registration. This is an actual count of all controlled substances in the pharmacy's possession. If no stocks of controlled substances are on hand, there must be a record of zero. An initial inventory must include:

- **Date of inventory**
- **Whether the inventory was taken at the beginning or close of business**
- **Name of each controlled substance inventoried**
- **Finished form of each of the substances**
- **Number of dosage units or volume of each finished form in the commercial container**
- **Number of commercial containers of each finished form**
- **Total count of the substance [6]**

The DEA recommends that registrants keep an inventory record that includes the name, address and DEA registration number of the registrant, and the signature of the person or persons taking the inventory.[6]

After an initial inventory, pharmacies are required to take a new inventory every two years. The requirements of the biennial inventory are the same as the initial inventory. Inventories do not have to be sent to the DEA but must be kept for two years.[6]

Reporting Robbery, Theft, or Missing Shipment:

Per 201 KAR 2:100, a pharmacy shall provide adequate security and control of its controlled substances.[10] The DEA states that a registrant must not employ a person in a position with access to controlled substances, who has been convicted of a felony relating to controlled substances, or who has had an application for a DEA registration denied, revoked, or surrendered for cause, unless the registrant has requested and had a waiver approved by the DEA.[6]

Immediately after a robbery or discovery of the theft of a controlled substance, a pharmacy must report the incident to the local law enforcement agency serving the pharmacy. If a pharmacy mails or ships a controlled substance and it does not arrive within three business days, the pharmacy must report the nonreceipt to the Department of Kentucky State Police and the United States Postal Inspection Service, if applicable.[9] Theft or significant loss of controlled substances must also be reported to the local DEA Diversion Field Office within one business day of discovering the theft or loss.[6]

All reports of robbery, theft, or missing shipments must contain the name, National Drug Code, and quantity of each controlled substance involved, a description of the circumstances of the loss, the names and contact information of any witnesses, and the names and description of any person suspected of committing the offense or causing the loss.[9]

Table 6: Factors for determining whether a loss is significant[6]
The actual quantity of controlled substances lost in relation to the type of business
The specific controlled substance lost
Whether the loss of controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances
A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses
Whether the specific controlled substances are likely candidates for diversion
Local trends and other indicators of the diversion potential of the missing controlled substances.

KASPER:

The Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) is the state's Prescription Drug Monitoring System (PDMP). All practitioners and pharmacies that dispense controlled substances to a patient in Kentucky must report the dispensing to KASPER unless:

1. The drug is administered to a patient in a hospital, a resident of a health care facility, a resident of a child-caring facility, or an individual in a jail, correctional facility, or juvenile detention facility.
2. A Class III through V controlled substance is dispensed by a facility licensed by the Cabinet for Health and Family Services in an amount to treat the patient for a maximum of 48 hours and is not dispensed by the emergency department of a hospital.
3. The drug is administered or dispensed to a research subject enrolled in a research protocol approved by an institutional review board that has an active federal-wide assurance number from the United States Department of Health and Human Services, Office for Human Research Protections, where the research involves blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.[8]

The reporting must be completed before the close of business on the business day immediately following the dispensing unless an extension has been granted.[9] Requests for a KASPER patient report are made electronically through the Kentucky Online Gateway. Corrections to KASPER reports should be made as soon as possible after identification. Corrections may also be made through the Kentucky Online Gateway Account. All pharmacists employed by an organization that dispenses controlled substances must have an active KASPER account and be able to access it.

Table 7: KASPER Patient Identification Number [8]

Patient's social security number (even if the patient is a minor, DO NOT USE A PARENT'S SOCIAL SECURITY NUMBER)
No social security number - use the patient's driver's license
If no social security number or driver's license number, use 000-00-0000 in the social security number field
If the patient is an animal, use the number 000-00-0000 in the social security number field.

Manufacturer limits:

The only quotas that the DEA formally sets are the Aggregate Production Quotas (APQ) for manufacturing Class I and Class II controlled substances. This quota process goes through the federal register and is open to public comment[11]. The APQ is the total amount of a controlled substance authorized to be manufactured in the United States. Each manufacturer applies for a portion of the APQ, its Individual Manufacturing Quota calculated based on the manufacturer's business activities and their justification to the DEA[11].

Pharmacies often face issues when dealing with wholesaler quotas or limitations on how much of a specific controlled substance or class of controlled substance a pharmacy can purchase. This is not set by the DEA, but by the wholesaler themselves. This is thought to be a direct result of the DEA's pressure on wholesalers to report suspicious orders. The DEA has stated that neither the CSA nor DEA regulations establish quantitative limits or thresholds on the amounts of controlled substances that DEA registrants may order or dispense. They also do not require registrants to set such limits[12].

Pharmacist Recovery Network:

The Pharmacist Recovery Network (PRN) is established in KRS 315.126. This network promotes early identification, intervention, treatment, and rehabilitation of pharmacists and pharmacist interns who may be impaired by illness, alcohol and drug abuse, or other physical or mental conditions. This is funded by a $10 assessment added to each licensure renewal application fee.[10]

If a pharmacist or pharmacy intern self-reports their impairment because of alcohol and drug abuse or if the Board of Pharmacy receives a complaint only reporting the impairment, the pharmacist or intern will not face disciplinary action if the individual:

- **Acknowledges the impairment problem.**
- **Voluntarily enrolls in an appropriate, approved treatment program.**
- **Voluntarily withdraws from practice or limits scope of practice as required by PRN, until the Pharmacist Recovery Network Committee is satisfied that the licensee has successfully completed an approved treatment program.**
- **Executes releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to PRN.[10]**

The Pharmacist Recovery Network Committee (PRNC) is made up of 11 members, including:

- **The President of the Board of Pharmacy**
- **The Chair of the PRNC**
- **The Executive Director of the Board of Pharmacy**
- **Eight other members, seven pharmacists, and one citizen member**

Buprenorphine

The regulations for prescribing buprenorphine for opioid use disorder are different for physicians/physician assistants and nurse practitioners. Physicians and physician assistants must adhere to the professional standards described in 201 KAR 9:270, while nurse practitioners must adhere to the professional standards defined in 201 KAR 20:065. The current versions of both regulations state that prescribers must have a waiver as issued by the DEA (X-waiver).

As of December 2022, the DEA is no longer providing X-waivers. Both the Kentucky Board of Medical Licensure and the Kentucky Board of Nursing have released statements that until the regulations can be reviewed and revised, all requirements in 201 KAR 9:270 and 201 KAR 20:065 are in effect except for the X-waiver requirement.[14–15] Providers are also no longer limited on the number of patients they may treat with buprenorphine. Only buprenorphine products that are FDA approved for opioid use disorder should be prescribed for opioid use disorder and those indicated for pain should not be used for opioid use disorder. Both regulations state that the buprenorphine-naloxone formulation should be prescribed unless the patient is pregnant or has a demonstrated hypersensitivity to naloxone. There is also an exception for patients transitioning from methadone to buprenorphine, where the buprenorphine mono-product may be prescribed for up to one week.

Patients on benzodiazepines, other sedative-hypnotics, stimulants, or other opioids may be prescribed buprenorphine products for opioid use disorder without consultation for up to 30 days. If the patient should be on these medications for greater than 30 days, a prescribing physician or physician assistant must consult with a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventative Medicine, the American Board of Medical Specialties in psychiatry, or an American Osteopathic Association certifying board in addiction medicine. A nurse practitioner must consult with a physician as described previously or with a nurse practitioner who is certified by the Addictions Nursing Certification Board, American Academy of Health Care Providers in the Addictive Disorders, or National Certification Commission for Addiction Professionals or a psychiatric-mental health nurse practitioner.

A patient prescribed buprenorphine for opioid use disorder must be seen by the prescriber at least ten days after induction, at least every ten days for the first month, and at least every 14 days for the second month after induction. If the patient demonstrates good progress after two months, the patient may be seen once a month for up to 2 years and then every three months if treatment is successful after two years. Physicians and physician assistants who prescribe buprenorphine for opioid use disorder can only prescribe buprenorphine to be taken once a day unless:

- **The patient is pregnant, buprenorphine may be taken up to twice daily.**
- **The patient is receiving less than 16mg per day, buprenorphine may be taken up to twice daily.**
- **The patient is also engaged in cancer treatment, hospice, or palliative care, buprenorphine may be taken twice or three times daily.**
- **The patient is undergoing major surgery or has suffered significant physical trauma, buprenorphine may be taken up to three times daily for up to 14 days.**

Nurse practitioners are not limited to the daily dosing frequency but are limited to prescribing an amount that does not exceed the FDA-approved dosage limit.

Neither of the buprenorphine prescribing regulations mandates a taper or that there is a time limit for treatment with buprenorphine. The prescriber may continue the patient on a maintenance dose of buprenorphine for as long as the patient needs.

Combat Methamphetamine

In March 2006, the Combat Methamphetamine Epidemic Act of 2005 (CMEA) was signed. This law lists requirements that regulated sellers must follow to sell over-the-counter products containing ephedrine, pseudoephedrine, and phenylpropanolamine (schedule listed chemical products- SLCP).[6] These products must be kept behind the counter or in locked cabinets, each sale must be logged, the logbook must be maintained for at least two years, all employees must be trained on the law and certify to the DEA that the training occurred, and places limits to the amount of List I chemicals that may be sold to a purchaser.[6] Only pharmacists, pharmacy interns, or pharmacy technicians in Kentucky may dispense, sell, or distribute an SLCP.[8]

A new addition to the 2022 DEA Pharmacist's Manual is the statement that "regulated sellers, including pharmacies, may not exceed this quantity limit of SLCP, even if state law mandates a prescription.

Multiple pharmacy associations have reached out to the DEA to clarify this statement, as patients who have needed more SLCP products than those allowed to purchase over-the-counter have obtained their medication through a prescription instead of over-the-counter.

Table 8: Federal Limitations on SLCP Purchase[6]
3.6 grams per day
9 grams per 30 days (DEA)
Kentucky Limitations on SLCP Purchase[8]
7.2 grams per 30 days (Kentucky)
24 grams per year
Maximum of 3 packages of any product per transaction

Medicinal Cannabis:

On the last day of the 2023 Regular Session of the General Assembly, Senate Bill 47 (SB 47) passed the Kentucky House of Representatives, legalizing medicinal cannabis in Kentucky by creating a new section of KRS 218A which outlines the requirements for medicinal cannabis in the state.[13]

Only physicians and nurse practitioners authorized to prescribe controlled substances in Kentucky may provide written certifications for medical marijuana. A written certification is a document signed and dated by the medicinal cannabis practitioner that states that in the practitioner's professional medical opinion, the patient may receive medical, therapeutic, or palliative benefit from the use of medicinal cannabis, specifies the qualifying medical condition or conditions that the patient has, and affirms that the practitioner has a bona fide practitioner-patient relationship with the patient.[13]

An initial written certification may only be provided during the course of an in-person visit. In contrast, subsequent written certifications may be provided electronically during a telehealth visit. A written certification for the purpose of applying for registry identification care is valid for up to 60 days. It may be renewed for up to 3 more periods of up to 60 days each, after which it can only be renewed after an in-person or telehealth examination. Medical cannabis practitioners cannot provide written certifications for their family members or themselves.[13]

There must be a "bona fide practitioner-patient relationship," which means that during the course of treatment with medical marijuana, the practitioner has completed an initial in-person exam and assessment of the patient's medical history and current medical conditions, consulted the patient on the possible medical, therapeutic, and palliative properties of medical cannabis, advised the patient on risks and side effects, including possible interactions, and established expected follow-up care that must be provided[13]. A bona fide practitioner-patient relationship cannot be established via telehealth[13].

Section 3 of SB 47 creates a Board of Physicians and Advisors, composed of seven physicians appointed by the Kentucky Board of Medical Licensure and two nurse practitioners appointed by the Kentucky Board of Nursing to review and recommend protocols for determining the amount of medicinal cannabis that constitutes a daily supply, an uninterrupted ten day supply, and an interrupted 30 day supply of medical cannabis for registered qualified patients; review and recommend protocols for evolving continuous quality improvement metrics and minimal performance standards for the biennial accreditation process for licensed cannabis businesses; review relevant peer-review, scientific data related to delta-9 tetrahydrocannabinol content limits, review relevant peer-reviewed, scientific data related to various methods of use and consumption of medicinal cannabis; review relevant peer-reviewed, scientific data related to the use of medicinal cannabis for medical, therapeutic, or palliative purposes.[13]

A patient must possess a registry identification card, issued by the Cabinet for Health and Family Services, identifying them as a registered qualified patient, visiting qualified patient, or provisional registration receipt to obtain medicinal cannabis. A patient may not have more than an uninterrupted thirty-day supply of medicinal cannabis in their residence and no more than an uninterrupted ten-day supply on their person unless transporting it to their residence. All medicinal cannabis in possession of a patient outside of their residence must be in the original container received from a dispensary. A patient may only purchase an uninterrupted 30-day supply of medicinal cannabis every 25 days. Medicinal cannabis is not to be smoked.

Physicians and nurse practitioners wanting to provide written certifications for the use of medicinal cannabis must apply to their licensing board for authorization. These applications will be denied if the practitioner has ownership or investment interest or a compensation agreement with a licensed cannabis business.

The Cabinet will create separate licenses, licensure application fees, initial licensure fees, and licensure renewal fees to allow persons to operate a cannabis business as a:

- **Tier I cannabis cultivator – indoor growth area up to 2,500 square feet**
- **Tier II cannabis cultivator- indoor growth area up to 10,000 square feet**
- **Tier III cannabis cultivator- indoor growth area up to 25,000 square feet**
- **Tier IV cannabis cultivator - indoor growth area up to 50,000 square feet**
- **Cannabis dispensary**
- **Cannabis processor**
- **Cannabis producer**
- **Cannabis safety compliance facility**

Each cannabis business location must have a separate license. Each license will be good for one year. All licensed cannabis businesses must conduct a criminal background check on the criminal history of all persons seeking to become a principal officer, board member, agent, volunteer, or employee before the person starts work. Each cannabis business must implement security measures to deter and prevent theft of medicinal cannabis or unauthorized entrance into areas containing medicinal cannabis.

Cannabis businesses may only acquire, cultivate, manufacture, deliver, transfer, transport, supply, or dispense medicinal cannabis for the purpose of distributing medicinal cannabis to registered cardholders from a licensed cannabis business. All licensed cannabis businesses are subject to inspections by the Cabinet.

A dispensary must maintain records of the amount of medicinal cannabis being dispensed to a cardholder and whether it was dispensed directly to the registered qualified patient or a caregiver. This data, including the date and time the medicinal cannabis was dispensed, is to be reported to the electronic monitoring system maintained by the Cabinet. Dispensaries may only dispense or sell medicinal cannabis that a safety compliance facility agent has checked for cannabinoid contents and contaminants. The of amount of medicinal cannabis being dispensed to a cardholder and whether it was dispensed directly to the registered qualified patient or a caregiver. This data, including the date and time the medicinal cannabis was dispensed, is to be reported to the electronic monitoring system maintained by the Cabinet. Dispensaries may only dispense or sell medicinal cannabis that a safety compliance facility agent has checked for cannabinoid contents and contaminants. The dispensary must verify the following:

- **The registry identification card**
- **That the person presenting the registry verification card is at least 18 years old and is the person identified on the registry identification card through examination of at least one other form of government-issued photo identification.**
- **The amount of medicinal cannabis the person is legally permitted to purchase by checking the electronic monitoring system.**

The dispensary cannot acquire, possess, sell, offer for sale, transfer, or transport any raw plant material with a delta-9 tetrahydrocannabinol content of more than 35%, medicinal cannabis products intended for oral consumption as an edible, oil, or tincture with more than 10mg of delta-9 tetrahydrocannabinol per serving, any medicinal cannabis product with a delta-9 tetrahydrocannabinol content of more than 70% or, a medicinal cannabis product that contains vitamin E acetate. Medicinal cannabis products intended for consumption by vaporizing cannot be sold or dispensed to a cardholder younger than 21 years old. A dispensary cannot rent office space to a medicinal cannabis practitioner. A dispensary may operate a delivery service for cardholders and may deliver medicinal cannabis, medicinal cannabis accessories, and educational material to cardholders at the address identified on the cardholder's registry identification.[13]

Table 9: Qualifying Medical Conditions for Medicinal Cannabis[13]
Any type or form of cancer, regardless of the stage
Chronic, severe, intractable, or debilitating pain
Epilepsy or any other intractable seizure disorder
Multiple sclerosis, muscle spasms, or spasticity
Chronic nausea or cyclical vomiting syndrome that has proven resistant to other conventional medical treatments
Post-traumatic stress disorder
Any other medical condition or disease for which the Kentucky Center for Cannabis, or its successor, determines that sufficient scientific data and evidence exists to demonstrate that an individual diagnosed with that condition or disease is likely to receive medical, therapeutic, or palliative benefits from the use of medicinal cannabis

Table 10: Practitioner Requirements for Providing a Written Certification[13]
Established a bona fide practitioner-patient relationship with the patient
Diagnosed the patient, or confirmed a diagnosis with a medical condition for which the medicinal cannabis practitioner believes that the patient may receive a therapeutic benefit or palliative benefit from the use of medicinal cannabis
Reviewed the KASPER report from the previous 12 months
Consulted with the patient or the patient's custodial parent or legal guardian, if the patient is a minor, on the possible risks and side effects associated with medicinal cannabis and any other drug or medication that the patient is taking at that time
Obtained the consent of the patient's custodial parent or legal guardian responsible for providing consent to treatment, if the patient is a minor

Summary

This summary of select federal and Kentucky controlled substance laws is not meant to be an exhaustive description or interpretation of all applicable federal and state laws. Pharmacists and pharmacy technicians are encouraged to review the laws and seek legal counsel if necessary.

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Questions for Pharmacists:

1. Under corresponding responsibility, a pharmacist:

a. Is not as responsible for ensuring the prescription is written for a legitimate medical purpose
b. Is responsible for ensuring a controlled substance prescription is written for a legitimate medical purpose in the usual course of professional treatment
c. Is responsible for only confirming the DEA number of the prescriber
d. Cannot question the prescriber's authority or reason for a controlled substance prescription

2. Which of the following entities enforces the Controlled Substance Act in Kentucky?

a. The Governor
b. The Attorney General
c. The Kentucky Supreme Court
d. The Cabinet for Health and Family Services Drug Enforcement and Professional Practices Branch

3. Which of the following would be appropriate to be prescribed by a nurse practitioner (APRN) in Kentucky?

a. Oxycodone/acetaminophen 30-day, no refills supply for chronic pain
b. Hydrocodone/acetaminophen 30-day supply, no refills for chronic pain
c. Hydrocodone/acetaminophen 30-day, no refills supply for acute pain
d. Testosterone cypionate 30-day supply, two refills for hypogonadism

4. Which of the following is an exception to the Electronic Controlled Substance Mandate?

a. Prescription is written by a physician
b. Prescription is written by a physician assistant
c. Prescription is written for a patient who lives in another state.
d. Prescription is written for a patient receiving hospice care

5. How long must a pharmacy keep and maintain controlled substance records?

a. Forever
b. Ten years
c. Two years
d. One year

6. Which of the following requires a controlled substance prescription blank in Kentucky?

a. The blank must be royal blue
b. The six quantity check boxes must be printed vertically on the right side of the blank
c. Refill options must be printed on the lower right side of the blank
d. An opaque "RX" symbol must be printed 1/8 inch from the top and 5/16 inch from the right side of the blank

7. Which of the following is required under the Kentucky regulations for the professional standards of prescribing buprenorphine for opioid use disorder by a physician?

a. A patient on buprenorphine for opioid use disorder with significant physical trauma may be prescribed buprenorphine up to 3 times a day
b. A patient must be weaned off buprenorphine for opioid use disorder after one year of treatment
c. A patient on buprenorphine may never be prescribed a stimulant
d. A physician must have a DEA X-waiver

8. What is the daily limit of an over-the-counter schedule listed chemical product allowed for an individual patient if prescribed?

a. 7.2g
b. four packages
c. 3.6g
d. There is no limit if the product is prescribed

9. What must be verified by a medicinal cannabis dispensary before selling to a patient?

a. The registry identification card
b. Government-issued photo identification of the person presenting the registry verification card
c. The amount of medicinal cannabis the person is legally permitted to purchase
d. All of the above

10. In which case may a prescription for a Class II controlled substance be dispensed by a facsimile prescription in Kentucky?

a. A CII prescription can only be prescribed electronically
b. A physician's electronic prescribing system is not functioning
c. The prescription is for a resident of a long-term care facility
d. There are no restrictions on facsimile CII prescriptions.

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: Review of Kentucky Controlled Substance Statutes and Regulations

Name: _____

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UNIVERSAL ACTIVITY #: 0143-0000-23-021-H03-P | **CONTACT HOURS**: 2 | **EXPIRES**: 4/30/2026

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

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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
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COMMERCIAL BIAS WAS PRESENT	__ YES __ NO

UNMET OBJECTIVES:

_____

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Alabama


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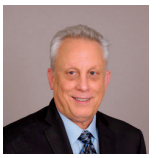
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Arizona


Brenda Dickerson McCrady
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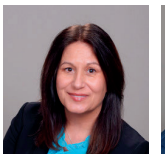
Maria Lopez
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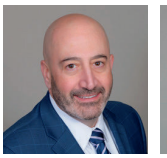
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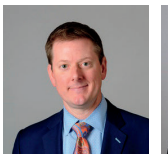
Sean M. Jeffery
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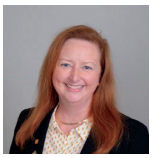
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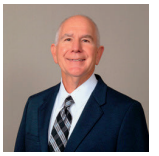
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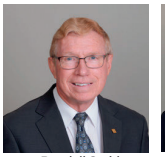
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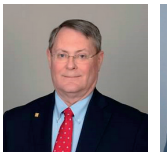
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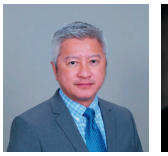
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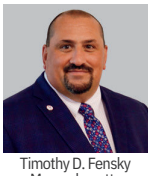
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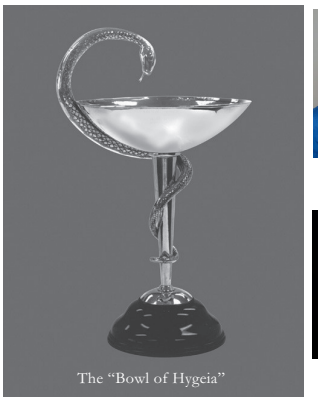
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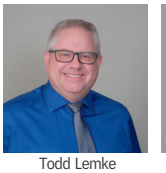
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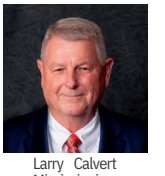
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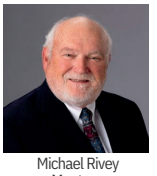
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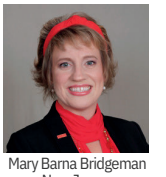
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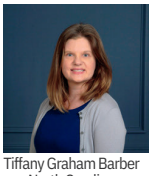
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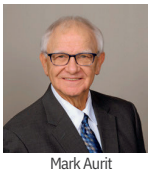
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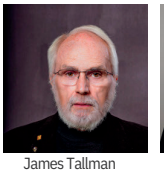
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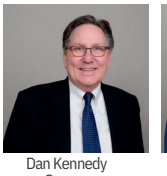
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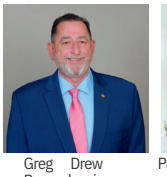
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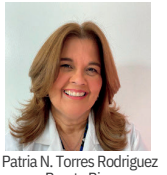
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Pharmacy Law Brief

FDA and the Law Applicable to Medical Devices

Author:
Joseph L. Fink III, BSPharm, JD, DSc (Hon), FAPhA, Professor Emeritus of Pharmacy Law and Policy, Department of Pharmacy Practice and Science, UK College of Pharmacy

Question:
I'm familiar from my time in pharmacy school with the FDA's drug product review, approval and classification rubric and framework. Is the same approach used for screening new medical devices for distribution in interstate commerce?

Response:
The Federal Food, Drug and Cosmetic Act confers on FDA the authority to regulate medical devices sold in the United States. Based on that grant of authority, the FDA has adopted regulations regarding classification, registration, premarket approval, product labeling requirements, and quality controls for medical devices. The legal definition of a medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory which is:

1] recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;

2] intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals; or

3] intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.[1]

Activities related to the regulation of medical devices have been assigned to the FDA's Center for Devices and Radiological Health. To discharge these responsibilities, the FDA has created a classification system that categorizes medical devices into three divisions. Designated Class I, Class II, and Class III, these categorizations are based on the level of risk associated with the use of the device. Those in Class I are associated with the lowest level of risk and, as a result, are the least regulated. At the other end of the spectrum, Class III medical devices are subject to the most stringent requirements and the highest level of controls related to safety and effectiveness. Class I medical devices present the least potential to cause harm. Accordingly, the FDA regulates these with only general controls, resulting in these products frequently being exempt from premarket notification requirements and good manufacturing practice standards. Many Class I devices would be considered common things for daily use that are unlikely to cause serious adverse effects if they were to malfunction. Typical examples of this category are bandages, dental floss, surgical masks, tongue depressors and non-powered wheelchairs.

Devices in Class II represent an intermediate level of risk. These are regulated with general controls and special controls, including performance standards and post-marketing surveillance. This is the largest classification in terms of number of products included. Examples in this category include powered wheelchairs and certain pregnancy tests.

Class III medical devices are so categorized because they represent the highest risk. Premarketing approval by the FDA is required before any marketing or sales of these products. Many products in this category are considered to be important in sustaining human life or preventing impairment of one's health status. Examples here would include cochlear implants, defibrillators, and implantable pacemakers.

As with medications, the FDA has created strict guidelines for the labeling and packaging of medical devices, including such important topics as intended uses of the device, preparatory steps required before use of the product, directions for proper use, along with when to use it and the duration or frequency of use. Labeling bearing the name and address of the manufacturer is also required. As with pharmaceuticals, the principal transgressions related to the production or distribution of medical devices are classified as either adulteration, focusing on the production and performance of the product, or misbranding, focusing on labeling of the item.[2–3]

FDA has a requirement that the manufacturer notify the agency if reports are received regarding serious injury or death.

Likewise, if a hospital or nursing home concludes that a device in use may have contributed to serious harm, they must notify both the FDA as well as the manufacturer.

If FDA concludes that a device represents a potential hazard to patients, i.e., serious health consequences or death, it can issue a Cease Distribution and Notification Order to the manufacturer or distributor.[4] The FDA also has authority to order a recall of devices it deems dangerous.[5] During 2021 and 2022 there was high profile activity like this related to respiratory devices for both institutional and home use manufactured by Phillips Respironics.

If a medical device is a "follow on" product (think of a generic version of a medication following a brand name innovator product) there is a special process to gain approval and access to the marketplace. Based on the section of the FDC Act that authorizes it, this is known as the 510(k) premarket notification to the FDA. Through this process a manufacturer can submit for review information establishing that the new device is substantially equivalent to a medical device already approved for marketing and distribution in the U.S. Such a submission to the FDA is also required if the manufacturer modifies the components or design of the device or its intended use.

A higher pre-marketing review standard is applied to a Class III device. Known as submission of a Premarket Approval Application, this is much more intense than the 510(k) process. It requires submission of clinical data and scientific evidence related to safety and effectiveness of the device.

Medical devices can make outstanding contributions to the health of patients. Thankfully, the FDA is on duty to safeguard the public health by regulatory activity in this arena.

References:
1] 21 U.S.C. §321(h).
2] 21 U.S.C. §351.
3] 21 U.S.C. §352.
4] 21 C.F.R. §810.10.
5] 21 C.F.R. §810.13.

Submit Questions: jfink@uky.edu

Pharmacy Policy Issues:

Improving Access to Care, Patient Outcomes, and Strengthening the Healthcare Team Through Collaborative Practice Agreements

Author: Jana R. Hostetler is a fourth-year pharmacy student at the University of Kentucky College of Pharmacy.

Introduction:

Collaborative practice agreements (CPAs) are a great way to improve access to patient care, improve patient outcomes, and strengthen the healthcare team. The U.S. Centers for Disease Control and Prevention defines a collaborative practice agreement as "a formal practice relationship between a pharmacist and prescriber" wherein the agreement "specifies what functions can be delegated to the pharmacist by the collaborating prescriber."[1] Common delegations in a collaborative practice agreement include ordering laboratory testing along with medication initiation, titration, discontinuation, as well as authorization of refills.

Improving Access to Care:

Compared to the entirety of the United States, Kentucky has a higher percentage of smokers, obesity, death by drug overdose, death from cancer, death from heart disease, and higher rates of infant mortality.[2] Some of this can be explained by a lack of access to healthcare. As a native of Eastern Kentucky, I know first-hand that rural areas of Kentucky have a disadvantage compared to other areas of the state when it comes to access to healthcare. In addition to long driving times to the nearest healthcare facility, many rural Kentuckians also experience long waiting times when they arrive due to the saturation of available institutions' resources.

Initiating collaborative practice agreements in these areas specifically may allow for streamlined patient care by minimizing the "back-and-forth" between pharmacists and providers while optimizing patients' medication regimens. This would potentially allow providers to see more patients, make patients more likely to access healthcare when needed and improve access to care in areas of Kentucky that desperately need it.

Improving Patient Outcomes

In addition to streamlining patient care, pharmacists are uniquely trained to consider issues related to insurance coverage, common adverse drug events, drug-drug interactions, patient social factors, etc., when optimizing a patient's medication regimen. These considerations improve patient adherence, patient cost savings, and long-term survival in chronic disease states. Implementing collaborative practice agreements across Kentucky, and expanding patient exposure to pharmacy services, would potentially be a step in the right direction to create a healthier Kentucky.

Strengthening the Healthcare Team

Trust and mutual respect in any healthcare team are of utmost importance. When these are impinged, the patient ultimately suffers. Collaborative practice agreements, at the core, are centered around these values. Collaborative practice agreements can potentially decrease the number of calls and messages between pharmacists and providers, saving time that can be used in face-to-face patient care. Ultimately, collaborative care agreements foster collaboration between pharmacists and providers while increasing pharmacist efficiency and provider satisfaction.[3]

During the COVID-19 pandemic with overworked healthcare providers and strained healthcare systems, we were able to see the value of streamlined patient care more clearly than ever before. Healthcare workers have been stretched to their limits physically and emotionally, and because of this, have learned to rely on one another. Pharmacists have been no exception. Implementing collaborative practice agreements will allow pharmacists to make even more meaningful contributions to the healthcare team, and, ultimately, improve patient outcomes.

Advancing the Profession

As we now know, collaborative practice agreements allow pharmacists to improve patient access to care, improve patient outcomes, and strengthen the healthcare team. Collaborative practice agreements also allow pharmacists to practice "at the top of their licenses," and apply their skills more readily to improve patient outcomes. Pharmacists should make every effort to build relationships with providers around them and ultimately aim to establish collaborative practice agreements. If establishing a collaborative practice agreement is not possible, everyone can advocate for legislation to increase pharmacist autonomy and patient access to care. Advocating for these things will help to propel the practice of pharmacy forward, and ultimately help create a healthier Kentucky.

References

1. Centers for Disease Control and Prevention. Advancing Team-Based Care Through Collaborative PracticeAgreements: A ResourceImplementation Guide for Adding Pharmacists to the Care Team. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017.
2. Foundation for a Healthy Kentucky. Kentucky Health Facts. Tracking Health Values. https://www.kentuckyhealthfacts.org/data/healthvalues/. Published July 1, 2021. Accessed October 28, 2022.
3. Wright AL, MattaSF, Kerr JR. Expansion of pharmacist practice in oral oncolytic therapy with a collaborative practice agreement. SAGE Publications Inc. https://us.sagepub.com/en-us/nam/journals. Published January 14, 2022.
Accessed October28, 2022.

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Learn more about the Drug Supply Chain Security Act (DSCSA) and how it helps pharmacists protect patients from counterfeit medicines.
safemedicines.org/pharmacists

College of Pharmacy

Campus Corner

Widely Available HPV Vaccines Help Prevent Many Types of Cancer

By Mya Desai and Lindsey Long,
doctoral students at the University of Kentucky College of Pharmacy

Humanpapilloma virus (HPV) is a sexually transmitted virus that can cause genital cancers and cancer of the throat, the base of the tongue, and tonsils. HPV vaccination is a safe and effective way to prevent more than 90% of cancers caused by HPV, including vaginal, cervical, and vulvar pre-cancers in women and anal cancer in both men and women.

Cervical cancer was once a leading cause of cancer-related deaths among women in the United States, but since the introduction of the HPV vaccine in 2006, the American Cancer Society has reported a 65% reduction in cervical cancer rates. Because the vaccine is most effective before exposure to HPV through sexual activity, it is recommended that boys and girls age 11-12 receive two doses six to 12 months apart. If the HPV series is not completed during that time, it is still recommended for all adults through age 26. Adults aged 27-45 who are not vaccinated against HPV should discuss the potential benefits of HPV vaccination with their pharmacist or another health care provider. You can request the vaccine at your next well visit with a primary care provider or at most retail pharmacies.

Operation Immunization, a service-oriented student group at the University of Kentucky College of Pharmacy (UKCOP), seeks to increase public knowledge of immunizations and raise the number of adults in Kentucky that receive recommended immunizations. Under the guidance of a faculty advisor, the student-led committee works with University Student Health and the Prevention, Outreach, and Wellness Education Resources Unit at the Get Yourself Tested (GYT) clinics.

The clinics provide HPV education and vaccinations at no cost to students. The group will expand these services to on-campus housing and other prominent locations on campus in the next academic year.

Although exposure to HPV is prevalent in the United States, there are several common myths surrounding HPV and the HPV vaccine. A common misconception is that the HPV vaccination only protects women. The vaccine protects both men and women and can still be received after age 12, even if the individual has already been sexually active. Another common myth is that an individual can skip cervical cancer screenings after receiving the HPV vaccine. The HPV vaccine is protective against the most common and high-risk forms of HPV but does not protect against all HPV strains. Maintaining regularly scheduled visits with your primary care physician or gynecologist to provide screening for cervical and other forms of cancer is essential.

The GYT clinic regularly holds dates throughout the academic year where the HPV vaccine will be available in the Prevention, Outreach, and Wellness Education Resources (POWER) suite of the Gatton Student Center.

Campus Corner

By Jenna Brophy, SUCOPHS Student Representative

Spring quarter is in full swing at Sullivan University College of Pharmacy and Health Sciences! The quarter started with a warm re-welcome of a Sullivan Alumni, Dr. Ibrahim Mattiche, to speak with students about their experiences at Sullivan, their professional journey, and general tips and tricks for new adventurers as they embark on their pharmacy careers. P1 students have started their institutional IPPE rotations and are finishing off their first year of pharmacy school. P2 students are finishing their last didactic quarter and anxiously awaiting the start of their APPE rotations, (and temporary absence of exams). Meanwhile, P3 students are rounding off their final APPE rotations in preparation for graduation and their first steps as pharmacists.

Sullivan's APhA-ASP chapter is happy to announce an ice cream social on May 12 from 4:00-6:00 pm at Sullivan, sponsored by KPhA. Sullivan will be inviting KPhA members, preceptors, and of course, students for mingling and refreshing ice cream!

To finish off the last quarter of the year, Sullivan pharmacy students are looking forward to another KPhA Annual Meeting. Students in attendance last year loved the ample post-CE networking opportunities with pharmacists from all over the state. Additionally, the ability to connect with pharmaceutical representatives was a unique opportunity to learn about the array of products and services available. Students were enthralled with open discussions about new drugs and opportunities for pharmacists blossoming in the state of Kentucky that are glossed over in typical classroom settings.

Last year, a group of four Sullivan students cleaned house at the Student OTC Competition with former board member Dr. Cassie Hobbs and newly inducted President of KPhA [Dean] Misty Stutz cheering them on from the back of the room. These students returned to Sullivan and have been hyping students up to repeat a Sullivan victory this upcoming conference.

KPhA continues to be supportive of its student membership and currently sponsoring a few rooms for students in Bowling Green and looking for sponsors to host more students!

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