Pharmacy Today
An official publication of the American Pharmacists Association
JANUARY 2024

AI'S POTENTIAL FOR PHARMACY

DIABETES
New testing recommendations

TELEHEALTH
DEA extends prescribing authorization

PATIENTS WITH HIV
New opportunistic infection guidelines

CONTINUING PHARMACY EDUCATION
CPE
Pharmacy law matters 2023

APhA

BulletinToday

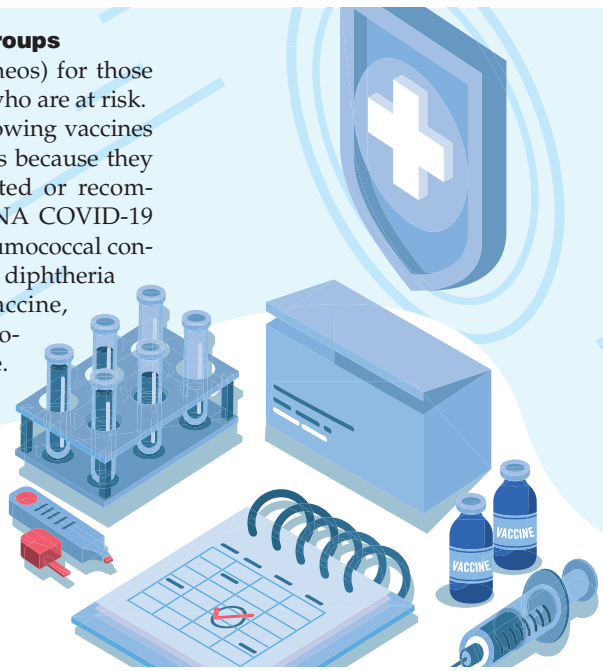
CDC releases 2024 immunization schedules for all age groups

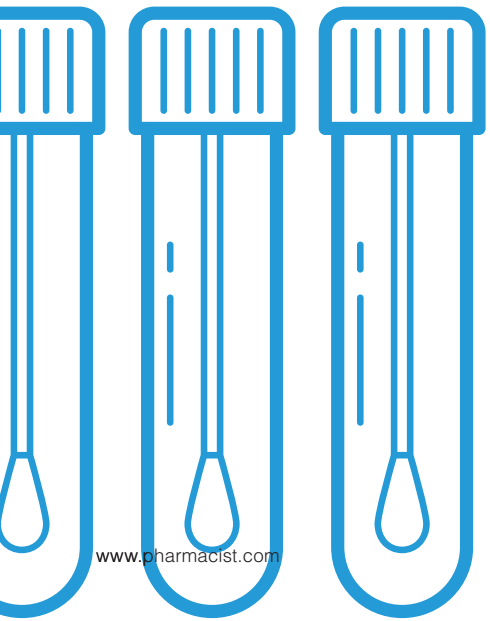
The official 2024 immunization schedules with new vaccine recommendations for children, adolescents, and adults are now available from CDC. The updated schedules were published in late 2023.

The 2024 immunization schedules contain several changes. Notably, CDC added vaccines for meningococcal disease and mpox to the immunization schedules following recommendations from ACIP. For meningococcal disease, CDC has included information about the use of the newly licensed MenACWY-TT/MenB-FHbp (Penbraya) vaccine. They also developed a resource to assist health care providers with shared clinical decision–making recommendations for this particular vaccination. Information was added for the mpox vaccine (Jynneos) for those aged 18 years or older who are at risk.

CDC deleted the following vaccines from the 2024 schedules because they are no longer distributed or recommended: bivalent mRNA COVID-19 vaccines, 13-valent pneumococcal conjugate vaccine (PCV13), diphtheria and tetanus toxoid vaccine, and Menactra meningococcal conjugate vaccine.

The schedules summarize final recommendations by CDC. Comprehensive details will be published in CDC's *Morbidity and Mortality Report* in early 2024. ■





FDA approves first OTC test for chlamydia and gonorrhea

FDA granted marketing approval to the first diagnostic test for chlamydia and gonorrhea with at-home sample collection.

Called the Simple 2 Test from LetsGetChecked, the test will be available OTC and is intended for use in individuals 18 years and older.

The Simple 2 Test is the first FDA-authorized test with at-home sample collection for any sexually transmitted disease other than HIV. The only previously cleared tests for either chlamydia or gonorrhea have required samples collected at the point of care, such as a doctor's office.

"This authorization marks an important public health milestone, giving patients more information about their health from the privacy of their own home," said Jeff Shuren, MD, JD, director of FDA's Center for Devices and Radiological Health, in a news release. "We are eager to continue supporting greater consumer access to diagnostic tests, which helps further our goal of bringing more health care into the home."

With the new test, samples are collected at home using either vaginal swabs or urine specimens, as appropriate, and are then submitted to a designated laboratory for testing. Results are provided online, with follow up from a health care provider in cases of positive or invalid test results. ■

CDC: Vaccine exemptions for kindergartners at highest level

Parents across the country are increasingly declining to vaccinate their children as they enter school, new CDC data reveal.

While all 50 states and the District of Columbia require school-age children to be protected against measles, polio, whooping cough, and other infectious diseases, exemptions for medical reasons are permitted, with some states offering religious and philosophical exemptions as well.

Based on mandatory reporting, CDC calculated a jump in the share of kindergartners with an exemption to a new high of 3% during the 2022 to 2023 school year, from 2.6% during the previous academic year.

"It is not clear whether this reflects a true increase in opposition to vaccination, or if parents are opting for nonmedical exemptions because of barriers to vaccination or out of convenience," the report noted.

Vaccine hesitancy and antivaccine sentiment have swelled during the pandemic, which also saw childhood vaccination rates dip for logistical reasons. Many parents have had trouble getting their child back on track in the aftermath of closed physicians' offices, scheduling problems, and other setbacks. ■

FDA warns of potential lethal reaction to certain seizure meds

On November 28, 2023, FDA issued an alert detailing potential harms tied to the use of brand-name and generic versions of certain antiseizure medications.

According to Medscape, nearly three dozen serious cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) linked to levetiracetam have been identified around the world, including three in the United States.

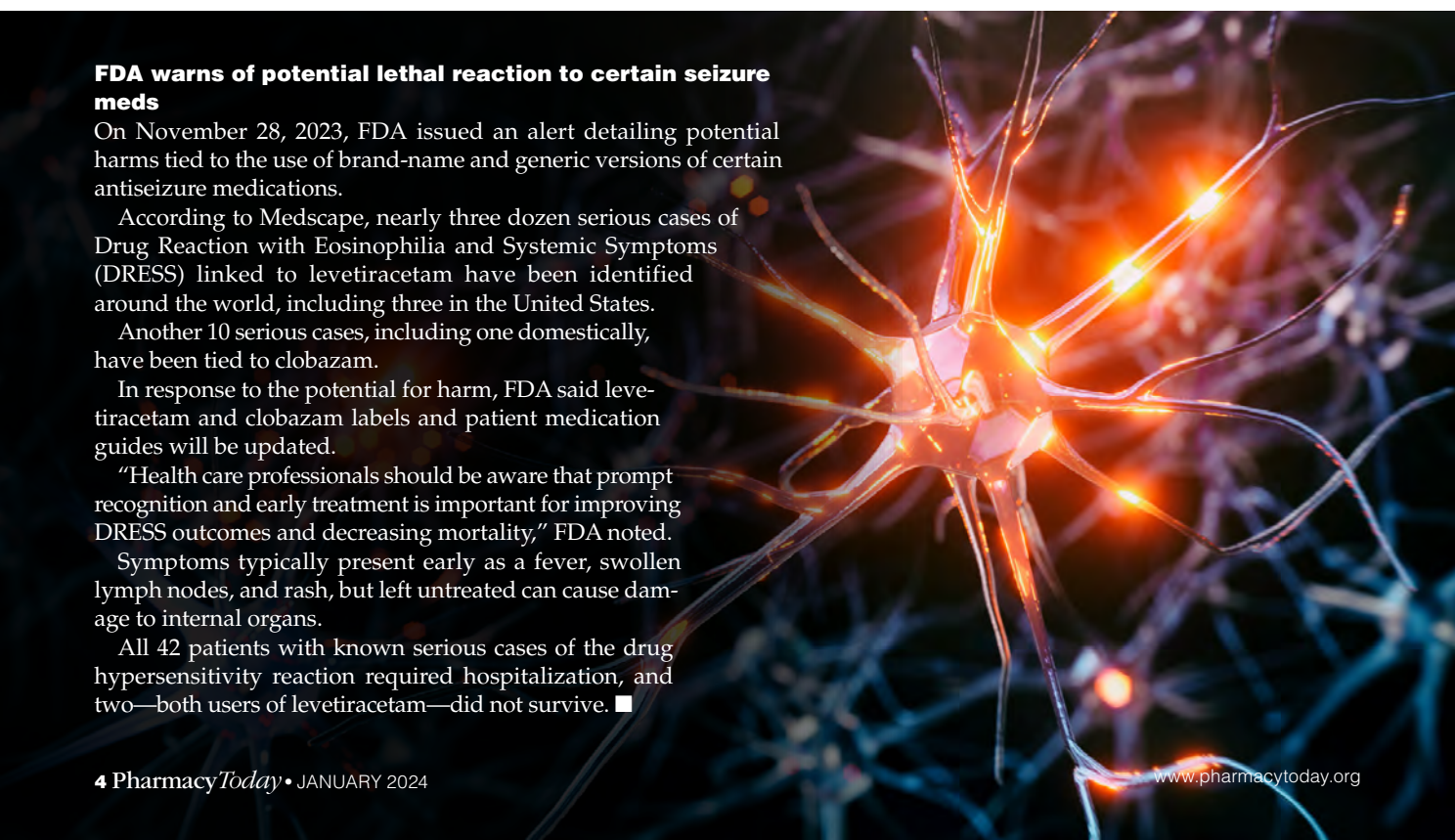
Another 10 serious cases, including one domestically, have been tied to clobazam.

In response to the potential for harm, FDA said levetiracetam and clobazam labels and patient medication guides will be updated.

"Health care professionals should be aware that prompt recognition and early treatment is important for improving DRESS outcomes and decreasing mortality," FDA noted.

Symptoms typically present early as a fever, swollen lymph nodes, and rash, but left untreated can cause damage to internal organs.

All 42 patients with known serious cases of the drug hypersensitivity reaction required hospitalization, and two—both users of levetiracetam—did not survive. ■



Pharmacists' role in BP control saves significant U.S. health care dollars

A new economic analysis published November 3, 2023, in *JAMA Network Open* found that with a pharmacist-led intervention, 15 million heart attacks could be prevented for Americans as well as over a trillion dollars saved for the health care system over 30 years.

The study, led by Virginia Commonwealth University (VCU) researchers, provides data on the economics of pharmacist prescribing to improve BP control. All 50 U.S. states has given pharmacists prescriptive authority in collaboration with physicians. However, even though the United States has all the tools and resources to put pharmacist prescribing interventions in place, there is still no reimbursement for pharmacists to be paid for their clinical services.

The $1.1 trillion in health care savings over 30 years, or a cost savings of $10,162 per patient, stems from preventive measures, such as pharmacists educating patients on high BP and prescribing antihypertensive medication, as well as from helping patients better manage their BP. The ability to offer these services could mean a reduction in CV emergencies, which is crucial given the increasing mortality rates around hypertension. Over 30 years, patients could regain more than 30 million "quality-adjusted life years," or years where their quality of life is significantly higher than it would have been if they were to have a health emergency.

Pharmacists' services could also close gaps in poor outcomes for racial and ethnic minority groups, said Dave Dixon, PharmD, lead author of the study. Black patients aged 35 years to64 years had the highest rates of death due to hypertension of any racial or ethnic group in the United States, according to a 2020 study in the journal *Hypertension.* "Pharmacist-led interventions have been shown to significantly improve BP control among Black individuals and individuals of racial and ethnic minoritized groups," wrote the *JAMA Network Open* study authors.

Researchers also found that if pharmacists had a larger role in prescribing medications to control BP, they could prevent more than 15 million heart attacks, nearly 8 million strokes, and more than 4 million cases each of angina and heart failure in the United States over 30 years.

"Being that hypertension affects so many Americans—we're talking about over 100 million people in the U.S.—I think the impact is tremendous because everybody knows somebody with high blood pressure," said Dixon in a news release. "It's one of the leading causes of heart disease and kidney failure in the world."

As the United States faces a shortage of primary care professionals, Dixon, who is chair of the Department of Pharmacotherapy & Outcomes Science at VCU School of Pharmacy, said pharmacists could bridge that gap.

"Pharmacists' role as health care providers tends to be underused in the community, and this is really about how pharmacists can provide for their communities in a way that improves access to care for hypertension," said Dixon, who also serves as an affiliate professor of internal medicine in the Division of Cardiology at the VCU School of Medicine.

According to CDC, patients visit their community pharmacist 12 times more frequently than their primary care provider. ■

Has generic imatinib reduced Medicare beneficiaries' cost for this expensive drug?

Imatinib is one of the most effective cancer drugs available, but many patients cannot afford the steep price.

In a cross-sectional study examining whether costs have come down for Medicare beneficiaries with the introduction of generic versions of the drug starting in 2016, researchers analyzed Medicare Part D plan, contract, and formulary records for each year from 2017 to 2022.

When they looked specifically at what pharmacies paid for generic imatinib and how much health plans, PBMs, and patients paid when filling prescriptions, they found that pharmacy acquisition costs declined dramatically to $59 per fill from $8,618. Despite lower prices, Medicare beneficiaries still faced out-of-pocket costs of $80 to $400 each time they filled a prescription.

"The gap between generic imatinib point-of-sale prices and average pharmacy acquisition costs supports […] efforts to evaluate spending across PBMs, health plans, and pharmacies to avoid overpayment for medications covered under Medicare Part D," wrote corresponding author Stacie B. Dusetzina, PhD, with Vanderbilt University School of Medicine.

The research was published in *JAMA Internal Medicine* on November 20, 2023. ■

JANUARY 2024 • VOLUME 30, NUMBER 1

PharmacyToday

An official publication of the **American Pharmacists Association**

CPE

PAGE 22

Take the Crossword Challenge

Page 60

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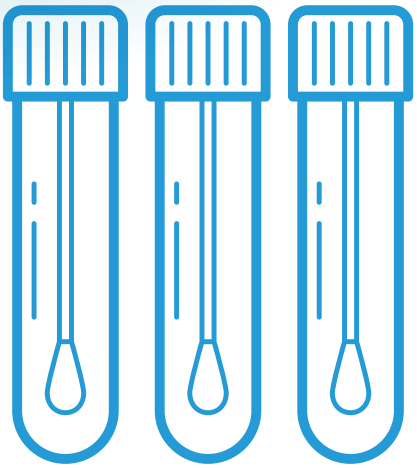

PAGE 3

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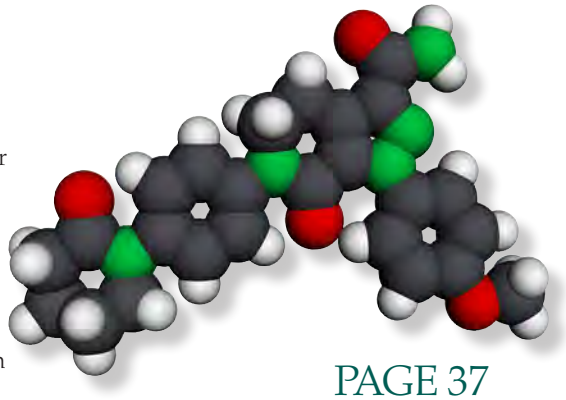
Drugs & Diseases

PAGE 19

PAGE 30

Practice & Trends

Health Systems



PAGE 37

AI will play an important role in the future of pharmacy

Artificial intelligence (AI) is the capacity of machines to perform tasks that would ordinarily require human intelligence, including sensing, thinking, learning, and decision-making. According to a recent study, although many pharmacists are willing to adopt AI, some are resistant to its use or cite barriers to implementation that would make mainstream use of AI in pharmacies highly unlikely. Skeptics are often concerned about the impact of AI on their job and their profession. However, a pharmacy landscape with increasing amounts of digitized data and processes that rely on AI is just around the corner.

This month's cover story in *Pharmacy Today* will help prepare you for what AI might look like in your pharmacy and highlight examples of how AI's ability to detect patterns or clusters in large datasets is being applied. For example, Andrea Sikora, PharmD, MSCR, at the University of Georgia College of Pharmacy is heading up the OPTIM study. In it, researchers compare traditional human methods to unsupervised machine learning to analyze the relationship between patient mortality in the ICU according to different factors, including the pharmacist's role. In this case, AI provides a way to identify barriers to care, including a pharmacist's workload while a patient is in the ICU. Among its many other applications described in this story, AI could ultimately be a tool that quantifies the value of a pharmacist's intervention.

This issue of *Today* also brings updated info on DHEA's effectiveness; provides data on the newest antidepressant, Exxua; and summarizes new guidelines on diagnosing, testing, and managing diabetes. You'll also learn how inaccurate a BP measurement can be when an inappropriate cuff size is used and you can stay up to date on your CPE with this month's article reviewing pharmacy law changes in 2023.

In our cover story, Adrian Wong, PharmD, MPH, FCCP, at Beth Israel Deaconess Medical Center in Boston, MA, makes a significant statement that we can keep in mind if fears of AI rear their ugly heads. According to Wong, "AI won't necessarily take away our jobs. It will just improve patient care." I am excited to learn more about AI's potential and watch it put into practice in order to do just that—improve patient care!

Have a great *Today!*

Kristin Wiisanen
PharmD, FAPhA, FCCP
***Pharmacy Today* editor in chief**

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Do something big for yourself!

We've all been running hard. We barely get a good night's sleep when it's time to get up, get to the pharmacy or hospital or office, and then the day is a blur.

Often, we face a workload that's backed up from the day before, and even before we see the first patient, we're solving other people's problems.

I wonder what the real number would be if we calculated how many problems a pharmacist solves in a single day? Dozens? I bet it's hundreds—big and small, and sometimes in ways that people didn't even know you solved the problem.

It's second nature in what pharmacists do and we don't usually even verbalize, "Hey, I just saved your life!" or "Doc, do you realize I just kept you from being sued?" Pharmacists are givers and helping is in our DNA. We give and give and give, but it can be exhausting to be a constant giver. Givers often don't take time for themselves.

The reality is that all of us need to recharge our batteries. When was the last time you did something for yourself? When was the last time you charged not only your professional batteries, but your soul? APhA's 2024 Annual Meeting & Exposition in Orlando is just that opportunity.

This pharmacy convention is not like your typical pharmacy meeting. Oh, don't get me wrong, there will be continuing education sessions and an exhibit hall just like all the others. However, what is different about APhA2024 is that you will be inspired. Your soul will be nourished.

APhA's meeting is different from all the others because you will be encouraged. The positivity and energy of the movers and shakers in pharmacy is electric.

I've found that APhA's annual meeting is the place where innovation and entrepreneurship abound, where student pharmacists can connect with lifelong mentors, where new practitioners and pharmacists looking for a career change can find their next big opportunity, where pharmacists who've been in practice for years can re-engage, get new ideas, find balance and hope, and build a network of supportive colleagues.

It's also a place where the most highly specialized in our profession can connect across the profession and gain perspective of the breadth of our profession. Scientists can share their innovations, and researchers looking to engage in implementation science and practice-based research can connect with pharmacists who are ready to partner. Pharmacy technicians can set a path for growth in their professional career.

So why not make a New Year's resolution to be in Orlando in March for APhA2024? Yes, the registration fee for a conference isn't cheap. Yes, you must travel and take time away from work. But isn't it time you did something big for yourself? When was the last time you did?

When you do something big for yourself, you'll feel energized and be a better caregiver. And you'll have started or expanded a professional network of colleagues who can be there for you when you need them. Joining us at APhA2024 may be the best decision you make this year.

I'd really like to meet you. As APhA's CEO I'm excited to meet you! I'd love to hear your story and gain your insights. Introduce yourself to me and say "Hey, I read your column! Let me tell you my story!"

For every pharmacist. For all of pharmacy. ■

NEW DRUGS

FRUQUINTINIB
(Fruzaqla—Takeda Pharmaceuticals)

Drug class: Fruzaqla is a kinase inhibitor.

Indication: Fruzaqla is indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) who have been previously treated with fluoropyrimidine, oxaliplatin, and irinotecan based chemotherapy, an anti-VEGF therapy, and, if RAS wild-type and medically appropriate, an anti-EGFR therapy.

Recommended dosage and administration: The recommended dose of Fruzaqla is 5 mg orally once daily with or without food for the first 21 days of each 28-day cycle.

Common adverse effects: The most common adverse reactions are hypertension, palmar-plantar erythrodysesthesia, proteinuria, dysphonia, abdominal pain, diarrhea, and asthenia.

Warnings and precautions: Control BP prior to treatment and monitor during treatment. Manage with antihypertensive medications and adjustment of the dose of Fruzaqla, if necessary. Withhold, reduce dosage, or permanently discontinue Fruzaqla based on severity of hypertension. Closely monitor patients who are at risk for bleeding, as hemorrhagic events may occur. Withhold, reduce dosage, or permanently discontinue Fruzaqla based on severity and persistence of hemorrhage. Monitor for infection during treatment and withhold Fruzaqla during active infections. Do not start Fruzaqla in patients with active infections. Periodically monitor for GI perforation. Permanently discontinue Fruzaqla in patients who develop GI perforation or fistula. Monitor liver laboratory tests prior to the start of Fruzaqla and periodically during treatment as hepatotoxicity can occur. Withhold, dose reduce, or permanently discontinue based on severity. Monitor urine protein. Discontinue Fruzaqla for nephrotic syndrome. Palmar-plantar erythrodysesthesia may occur. Withhold Fruzaqla based on severity. Immediately discontinue Fruzaqla if posterior reversible encephalopathy syndrome is suspected and confirmed via MRI. Fruzaqla can cause impaired wound healing. Withhold for 2 weeks before major surgery. Do not administer for at least 2 weeks following major surgery and until adequate wound healing. The safety of resumption of Fruzaqla after resolution of wound-healing complications has not been established. Initiation of Fruzaqla in patients with a recent history of thromboembolic events should be carefully considered. Discontinue Fruzaqla in patients who develop arterial thromboembolism. Fruzaqla contains FD&C Yellow No. 5 (tartrazine) and No. 6 (sunset yellow FCF) as color additives, which may cause allergic reactions, including bronchial asthma, in certain susceptible patients. Fetal harm may occur with use of Fruzaqla in pregnancy. Advise patients of reproductive potential of the potential risk to the fetus and to use effective contraception. Advise patients not to breastfeed. Avoid concomitant use with strong or moderate CYP3A inducers.

REPOTRECTINIB
(Augtyro—Bristol Myers Squibb)

Drug class: Augtyro is a kinase inhibitor.

Indication: Augtyro is indicated for the treatment of adult patients with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC).

Recommended dosage and administration: Select patients for the treatment of locally advanced or metastatic NSCLC based on the presence of ROS1 rearrangements in tumor specimens. The recommended dosage is 160 mg orally once daily for 14 days, then increase to 160 mg twice daily with or without food.

Common adverse effects: The most common adverse reactions were dizziness, dysgeusia, peripheral neuropathy, constipation, dyspnea, ataxia, fatigue, cognitive disorders, and muscular weakness.

Warnings and precautions: Augtyro can cause CNS adverse reactions including dizziness, ataxia, and cognitive impairment. Withhold and then resume at same or reduced dose upon improvement, or permanently discontinue Augtyro based on severity. Monitor patients for new or worsening pulmonary symptoms indicative of interstitial lung disease or pneumonitis. Immediately withhold in patients with suspected interstitial lung disease or pneumonitis and permanently discontinue if diagnosis is confirmed. Monitor liver function tests every 2 weeks during the first month of treatment, and as clinically indicated thereafter, as hepatotoxicity may occur. Based on severity, withhold and then resume at the same or a reduced dose, or permanently discontinue. Monitor serum creatine phosphokinase (CPK) levels during treatment in patients reporting unexplained muscle pain, tenderness, or weakness. Based on severity of myalgia with CPK elevation, withhold and resume Augtyro at same or reduced dose upon improvement. Monitor serum uric acid levels prior to initiating and periodically during treatment as hyperuricemia can occur. Initiate treatment with urate-lowering medications as clinically indicated. Withhold and resume at the same or a reduced dose, or permanently discontinue based on severity. Promptly evaluate patients with signs or symptoms of skeletal fractures such as pain, changes in mobility, or deformity. Augtyro can cause embryo-fetal toxicity. Advise patients of reproductive potential of the potential risk to a fetus and to use an effective nonhormonal method of contraception. Advise patients not to breastfeed. Avoid concomitant use with strong and moderate CYP3A inhbitors, P-gp inhibitors, strong and moderate CYP3A inducers, hormonal contraceptives, and certain CYP3A substrates where minimal concentration changes can cause reduced efficacy.

CAPIVASERTIB
(Truqap—Astrazeneca)

Drug class: Truqap is a kinase inhibitor.

Indication: Truqap is indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)–positive, human

epidermal growth factor receptor 2 (HER2)–negative, locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN alterations as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Recommended dosage and administration: Select patients for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer with Truqap based on the presence of one or more of the following genetic alterations in tumor tissue: PIK3CA/AKT1/PTEN. The recommended dosage is 400 mg orally twice daily with or without food for 4 days followed by 3 days off.

Common adverse effects: The most common adverse reactions are diarrhea, cutaneous adverse reactions, increased random glucose, decreased lymphocytes, decreased hemoglobin, increased fasting glucose, nausea, fatigue, decreased leukocytes, increased triglycerides, decreased neutrophils, increased creatinine, vomiting and stomatitis.

Warnings and precautions: Truqap is contraindicated in severe hypersensitivity to Truqap or any of its components. Hyperglycemia can occur. Evaluate blood glucose levels prior to starting and at regular intervals during treatment. Withhold, reduce dose, or permanently discontinue Truqap based on severity. Truqap caused diarrhea in most patients during clinical studies. Advise patients to increase oral fluids, start antidiarrheal treatment, and consult with a health care provider if diarrhea occurs while taking Truqap. Withhold, reduce dose, or permanently discontinue Truqap based on severity. Monitor for signs and symptoms of cutaneous adverse reactions. Withhold, reduce dosage of, or permanently discontinue Truqap based on severity. Truqap can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. Advise patients not to breastfeed during treatment. Avoid concomitant use of Truqap with strong CYP3A inhibitors. If concomitant use cannot be avoided, reduce the Truqap dose. Reduce Truqap dose if used concomitantly with moderate CYP3A inhibitors. Avoid concomitant use with strong and moderate CYP3A inducers.

NIROGACESTAT

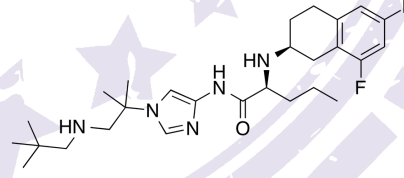
(Ogsiveo—Springworks Therapeutics)

Drug class: Ogsiveo is a gamma secretase inhibitor.

Indication: Ogsiveo is indicated for adult patients with progressing desmoid tumors who require systemic treatment.

Recommended dosage and administration: The recommended dosage of Ogsiveo is 150 mg orally twice daily until disease progression or unacceptable toxicity.

Common adverse effects: The most common adverse reactions are diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, dyspnea, decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.



Warnings and precautions: Severe diarrhea can occur. Monitor and dose modify for grade 3–4 diarrhea. Female reproductive function and fertility may be impaired. Advise patients of the potential risk prior to treatment and monitor routinely.

Elevated AST and ALT can occur. Monitor AST and ALT regularly and modify dose as recommended. Perform dermatologic examination prior to initiation of Ogsiveo and routinely during treatment as nonmelanoma skin cancers may occur. Monitor phosphate and potassium regularly and modify dose accordingly. Ogsiveo can cause fetal harm. Advise patients of the potential risk to a fetus and to use effective contraception. Advise patients not to breastfeed. Avoid concomitant use with strong or moderate CYP3A inhibitors and inducers. Avoid concomitant use with PPIs and H2-receptor antagonists. If concomitant use cannot be avoided, Ogsiveo administration can be staggered with antacids.

TAUROLIDINE AND HEPARIN

(Defencath—CorMedic Inc)

Drug class: Taurolidine is a thiadiazinane antimicrobial and heparin is an anticoagulant.

Indication: Defencath is indicated to reduce the incidence of catheter-related bloodstream infections in adult patients with kidney failure receiving chronic hemodialysis through a central venous catheter (CVC). The safety and effectiveness of Defencath have not been established for use in other populations.

Recommended dosage and administration: Defencath catheter lock solution is for instillation into CVCs only and is not intended for systemic administration. Do not use Defencath as a catheter flush product. Withdraw a sufficient volume of Defencath catheter lock solution from the vial using a sterile needle and syringe to fill the catheter lumens. Use 3 mL or 5 mL single-dose vials to instill Defencath into each catheter lumen at the conclusion of each hemodialysis session. Defencath must be aspirated from the catheter and discarded prior to the initiation of the next hemodialysis session. Discard any unused portion of Defencath remaining in the vial.

Common adverse effects: The most common adverse reactions are hemodialysis catheter malfunction, hemorrhage/bleeding, nausea, vomiting, dizziness, musculoskeletal chest pain, and thrombocytopenia.

Warnings and precautions: Defencath is contraindicated in known heparin-induced thrombocytopenia and known hypersensitivity to taurolidine, heparin, the citrate excipient, or pork products. If heparin-induced thrombocytopenia occurs, discontinue Defencath and institute appropriate supportive measures. If a hypersensitivity reaction occurs, discontinue Defencath and institute appropriate supportive measures. ■

Easing chest congestion with guaifenesin

Mary Warner

Colds and flu often result in chest congestion that can persist long after other symptoms have disappeared. An expectorant like guaifenesin can help thin mucus and phlegm and make it easier to cough up.

Guaifenesin (glyceryl guaiacolate) is the only FDA-approved expectorant for symptomatic relief of acute, ineffective cough. It works by loosening and thinning lower respiratory tract mucus and phlegm, making coughs more productive. It's not intended to treat chronic cough associated with chronic lower respiratory tract diseases such as asthma, COPD, or emphysema, or for smoker's cough. Guaifenesin may help control symptoms but does not treat the cause of symptoms or speed recovery.

Availability, dosage, and safety

Guaifenesin is available as tablets, capsules, extended-release tablets, dissolving granules, and liquids. Alcohol-, sucrose-, and dye-free formulations are also available.

As with all nonprescription cough and cold combination products, products that contain guaifenesin can cause serious adverse effects or death in young children. FDA-approved dosages of guaifenesin are 200 mg to 400 mg every 4 hours as needed for adults and children 12 years or older, 200 mg to 400 mg every 4 hours as needed for children aged 6 years to 12 years, and 50 mg to 100 mg every 4 hours as needed for children aged 2 years to 6 years. Guaifenesin is not FDA-approved for children younger than 2 years old.

Guaifenesin is often combined with antihistamines, cough suppressants, and decongestants, so it's important to carefully check the labels of any other nonprescription medications used at the same time to ensure that no more than the recommended dosage of guaifenesin is delivered. Products intended for adults should not be given to children.

Guaifenesin is generally well-tolerated, though adverse effects can include nausea, vomiting, dizziness, headache, rash, diarrhea, drowsiness, and stomach pain. Most reports of guaifenesin overdose involve combinations of medications and are difficult to assess. However, signs and symptoms of overdose appear to be extensions of guaifenesin's adverse effects.

What to tell your patients

Advise patients to drink plenty of water while taking guaifenesin and to continue their normal diet. Ensure that they understand that guaifenesin and other expectorants work best during the daytime since they will cause patients to cough more to clear congestion from the respiratory tract. Advise patients to see their primary care provider if their cough has not improved after 7 days or if they have a fever, skin rash, continuing headache, or sore throat with the cough.

For further information, please see APhA's *Handbook of Nonprescription Drugs*, available for purchase on pharmacist.com or in Pharmacy Library. ■

Examples of nonprescription medications that contain guaifenesin

Single ingredient products

- Adult Tussin®
- Air-Power®
- Bronchoril®
- Siltussin DAS®
- Siltussin SA®
- Topcare Mucus Relief®
- Topcare Tussin®
- Childrens Mucus Relief®
- Little Remedies Little Colds Mucus Relief Expectorant Melt Aways®
- Mucinex®
- Mucinex Childrens®
- Mucinex for Kids®
- Mucus Relief®
- Q-Tussin®
- Robitussin® Chest Congestion
- Scot-Tussin® Expectorant SF Cough
- Tussin®
- Up and Up Childrens Mucus Relief®
- Vicks® DayQuil®

Combination products

- Adult Tussin DM® (dextromethorphan, guaifenesin)
- Aldex® (guaifenesin, pseudoephedrine)
- Biocotron® (dextromethorphan, guaifenesin)
- Biospec® (dextromethorphan, guaifenesin)
- Childrens Mucus Relief® (dextromethorphan, guaifenesin)
- Chlo Tuss® (chlophedianol, guaifenesin)
- Codar® (codeine, guaifenesin)
- CVS Chest Congestion Relief® (dextromethorphan, guaifenesin)
- Mucinex Fast-Max® (dextromethorphan, guaifenesin)
- PediaCare Childrens Cough and Congestion® (dextromethorphan, guaifenesin)
- Primatene® (ephedrine, guaifenesin)
- Q-Tussin DM® (dextromethorphan, guaifenesin)
- RelCof-C® (codeine, guaifenesin)
- Robitussin Cough and Chest Congestion DM® (dextromethorphan, guaifenesin)
- Safetussin® (dextromethorphan, guaifenesin)
- Tussin DM® (dextromethorphan, guaifenesin)
- Vicks® DayQuil® (dextromethorphan, guaifenesin)
- Zicam® (acetaminophen and dextromethorphan, guaifenesin)

DHEA: The fountain of youth?

Mickie Cathers

DHEA supplements are advertised as an antidote to aging. Products on store shelves also purport that DHEA supports immune balance, metabolism, sexual health, mood, and bone and cardiovascular health. What is DHEA and what does it really do?

Background

DHEA (dehydroepiandrosterone) is an abundant steroid hormone in the human body, mainly synthesized in the adrenal glands and the liver. Several tissues, including the brain, liver, kidney, and gonads metabolize DHEA to biologically active steroids, such as testosterone and estrogen. More than 30% of total androgen in men and over 90% of estrogen in postmenopausal woman is derived from the conversion of DHEA in the body.

If DHEA is produced naturally in the body, why should anyone take it as a supplement? Though one of the most plentiful circulating hormones in the human body, DHEA does begin to decrease around age 30 years; diminishing by up to 80% throughout adulthood. Decreased levels of DHEA are associated with various pathophysiological conditions related to aging, such as lower bone density, as well as adrenal insufficiency, acute stress, and other severe systemic diseases. Low DHEA levels have also been associated with heart disease, depression, and mortality.

DHEA warrants further investigation to draw reliable conclusions for the physiological role, optimal dosage, and effects of these steroid hormones.

Is there a benefit?

Research shows that DHEA has a wide range of effects on numerous organs and organ systems and supports the use of DHEA in individuals with adrenal insufficiency as well as patients with depression and associated cognitive disorders. For those with adrenal insufficiency, in which the adrenal glands can't produce normal amounts of hormones, some research indicates DHEA may improve quality of life. DHEA may improve aspects of sexual function, including libido and fertility in women with benefits primarily seen in those with sexual disorders. Prescription DHEA is available to address vaginal tissue thinning.

Many preclinical studies have reported that DHEA has preventive and therapeutic efficacy against cancer, atherosclerosis, diabetes, obesity, and excess glucocorticoid exposure. However, few clinical trials clearly substantiate the beneficial effect of DHEA as a dietary supplement. Due to inadequate sample sizes and treatment durations, the safety and efficacy of DHEA warrants further investigation to draw reliable conclusions for the physiological role, optimal dosage, and effects of these steroid hormones.

Several studies have examined whether DHEA can improve bone density and body composition. A November 2020 meta-analysis by Wang and colleagues in *Steroids* reviewed 21 randomized clinical trials evaluating DHEA supplementation on body composition, including bone mineral density, lean body mass, and BP. Results revealed DHEA did not affect body weight or BP. While the researchers found DHEA supplementation may increase lean body mass and decrease fat mass, they wrote "there is not sufficient magnitude to recommend DHEA supplementation as a tool to improve body composition."

Dosage and availability

DHEA was previously marketed for weight loss and banned by FDA in 1985, only to again be widely available in health food stores and online as tablets and capsules ranging from 10 mg to 500 mg since the passage of the Dietary Supplement Health and Education Act of 1994. DHEA remains banned by the International Olympic Committee and the National Collegiate Athletic Association. The standard dosage in many clinical studies is 50 mg/day to 100 mg/day.

What to tell your patients

In general, young and healthy individuals produce DHEA naturally and supplementation is unnecessary. Older adults and those with certain adrenal, sexual, or fertility issues should talk with their health care providers before using DHEA. DHEA supplements have been safely used for up to two years in research studies in doses of 50 mg daily without severe adverse effects. Mild adverse effects have included upset stomach, acne, and increased hair growth in the armpits and pubic area. DHEA should not be taken by individuals with cancers affected by sex hormones, or those using medications changed by the liver, medications for depression, or anticoagulants. ■

FDA approves new ER antidepressant

Lauren Howell, PharmD

In September 2023, FDA approved Exxua (gepirone), a new extended-release antidepressant. When Exxua comes to the market in early 2024, it will mark a new treatment option for the estimated 21 million Americans who are affected by major depressive disorder (MDD) each year. Unlike most other antidepressants, Exxua doesn't carry a warning of weight gain or sexual dysfunction, suggesting that it may increase compliance for patients who experience these common adverse effects from other treatment options for depression.

Recommended dosage and administration

While the exact mechanism of action is not fully understood, it's thought that Exxua works by modulating the serotonergic activity in the central nervous system through selective agonist activity at the 5HT1A receptors. The recommended starting dose is 18.2 mg administered orally once daily with food at approximately the same time each day. Based on clinical response and tolerability, the dosage may be increased to 36.3 mg once daily on day 4, 54.5 once daily after day 7, and 72.6 mg after an additional week. Exxua is available in 18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg extended-release tablets.

In geriatric patients, patients with renal impairment (CrCl <50 mL/min), or patients with moderate hepatic impairment (Child-Pugh Class B), the recommended starting dosage is 18.2 mg once daily and can be increased to 36.3 mg after 7 days. The Exxua dose should be adjusted by 50% when a moderate CYP3A4 inhibitor is administered concomitantly.

Before treatment with Exxua is initiated, electrolyte abnormalities should be corrected. An ECG should be performed prior to initiating treatment, during dosage titration, and periodically during treatment. Exxua should not be started in individuals with a QTc interval of greater than 450 msec.

Adverse effects

Like many other antidepressants, Exxua carries a boxed warning for thoughts of suicide and suicidal behaviors. There is an increased risk of suicidal thinking and behavior in pediatric and young adult patients taking antidepressants. Patients should be closely monitored for worsening and emergence of suicidal thoughts and behaviors. Exxua is not approved for use in pediatric patients.

Exxua is contraindicated in known hypersensitivity to gepirone or components of Exxua, prolonged QTc interval of greater than 450 msec at baseline, congenital long QT syndrome, concomitant use of strong CYP3A4 inhibitors, severe hepatic impairment, or use with an MAOI or within 14 days of discontinuing one. The most common adverse reactions in patients taking Exxua include dizziness, nausea, insomnia, abdominal pain, and dyspepsia.

Exxua prolongs the QTc interval. Monitor ECGs more frequently when Exxua is used concomitantly with drugs known to prolong the QT interval, in patients who develop a QTc of greater than or equal to 450 msec during treatment, or patients who are at significant risk of developing torsade de pointes.

Do not escalate dosage if QTc is greater than 450 msec. There is an increased risk of serotonin syndrome when Exxua is coadministered with other serotonergic agents. If serotonin syndrome occurs, discontinue Exxua and initiate supportive measures. Patients should be screened for bipolar disorder as activation of mania or hypomania can occur. Avoid concomitant use with strong CYP3A4 inhibitors as they reduce Exxua exposure. Use during the third trimester of pregnancy may increase the risk for persistent pulmonary hypertension and symptoms of poor adaptation, such as respiratory distress, temperature instability, feeding difficulty, hypotonia, and irritability in the neonate.

Clinical trials

The efficacy of Exxua for the treatment of MDD in adults was evaluated in two 8-week randomized, double-blind, placebo-controlled, flexible-dose studies in adults between the ages of 18 years and 69 years that met the Diagnostic and Statistical Manual of Mental Disorders' criteria for MDD. In both studies, after an initial dosage of 18.2 mg daily, dosage was titrated based on clinical response.

While the exact mechanism of action is not fully understood, it's thought that Exxua works by modulating the serotonergic activity in the central nervous system through selective agonist activity at the 5HT1A receptors.

The primary efficacy measure was the change from baseline in the Hamilton Depression Rating Scale total score at week 8. Patients in the Exxua groups experienced statistically significantly greater improvement on the primary endpoint compared to patients in the placebo groups in both studies. ■

New guidelines for testing, diagnosing, and managing diabetes

Lauren Howell, PharmD

In July of 2023, the American Association for Clinical Chemistry and American Diabetes Association issued an update to the Guidelines and Recommendations for Laboratory Analysis in the Diagnosis and Management of Diabetes Mellitus, which were originally published in 2002. Using an evidence-based approach, the groups updated areas with new evidence that has developed since the last update to the guidelines in 2011.

The recommendations in these guidelines focus on the laboratory aspects of diabetes testing and management. They are not intended to replace or address recommendations that are made by the American Diabetes Association in relation to the clinical management of diabetes. While many of the recommendations made in these guidelines pertain to laboratory personnel, several recommendations are useful for pharmacists to know when counseling patients and determining monitoring parameters for treatment regimens. Here's what pharmacists need to know from the updated guidelines.

Monitoring blood glucose and A1C

The first set of recommendations that pharmacists should be aware of involve the diagnosis and management of diabetes based on blood glucose levels. The guidelines recommend that fasting glucose be measured in venous plasma when used for diagnosis of diabetes and that a value ≥7.0 mmol/L (≥126 mg/dL) is indicative of a positive diagnosis. Additionally, A1C screening, fasting plasma glucose (FPG), or a 2-hour oral glucose tolerance test is recommended for individuals who are at high risk of diabetes. If A1C is <5.7%, FPG is <5.6 mmol/L (<100 mg/dL), or the patient's 2-hour oral glucose is <7.8 mmol/L (<140 mg/dL), testing should be repeated every 3 years. Portable glucose meters should not be used to diagnose diabetes, including gestational diabetes.

Once a diabetes diagnosis has been established, the routine measurement of plasma glucose concentrations in a laboratory is not recommended as the primary method of monitoring therapy. Routine use of blood glucose monitoring in patients with T2D who are treated with diet or oral agents alone is not recommended. However, frequent blood glucose monitoring is recommended for all individuals with diabetes who are treated with intensive insulin regimens and are not using continuous glucose monitoring (CGM). Individuals who use insulin multiple times daily should be encouraged to perform blood glucose monitoring at a frequency that is appropriate for their insulin regimen, usually at least four times per day. Patients with diabetes should be instructed on how to use glucose meters correctly, including the proper technique for sample collection and use of quality control.

CGM

Real-time CGM should be used with insulin as a tool to lower A1C levels and to reduce hypoglycemia in teens and adults with T1D who are not meeting glycemic goals, have hypoglycemia unawareness, or episodes of hypoglycemia. Intermittently scanned CGM can also be considered in adult patients with T1D who are not meeting glycemic goals or experiencing hypoglycemia.

Real-time CGM should be considered to monitor A1C levels, time in range, and neonatal outcomes in pregnant women with T1D. Real-time or intermittently scanned CGM should be considered in adults with T2D who are using insulin and not meeting glycemic targets. In children with T1D, real-time or intermittently scanned CGM should be considered, based on regulatory approval, as a tool to improve glucose control and reduce the risk of hypoglycemia.

To help identify and address patterns of hyperglycemia and hypoglycemia in patients with T1D or T2D, consider using professional CGM data in addition to diabetes education strategies and medication dose adjustment. If a patient is using a CGM device that requires calibration, a blood glucose meter should be used to calibrate the device. This should be done when glucose levels are not rapidly increasing or decreasing. When CGM results are not available or seem to be inconsistent with the clinical state of the patient, a blood glucose meter should be used. Noninvasive glucose measurement systems should not be recommended as replacements for blood glucose monitoring or CGM technologies at this time.

Other recommendations

Other recommendations in the updated guidelines that may pertain to pharmacists include target glucose values for patients with gestational diabetes. Recommendations were also made for the timing of testing for gestational diabetes and how often pregnant patients with gestational diabetes should be tested for development of T2D after pregnancy. Some recommendations regarding the testing and treatment of diabetic ketoacidosis are also included. The complete guidelines can be found at apha.us/DiabetesLabGuidelines and are free to access. ■

Finding the right fit: Unveiling the effect of cuff size on BP measurement accuracy

Clarissa Chan, PharmD

A randomized crossover trial published in the October 2023 issue of *JAMA Internal Medicine* demonstrated that inappropriately sized BP cuffs significantly affected BP measurement accuracy.

Study overview and results

Researchers from Johns Hopkins University conducted the trial, which involved 195 community-dwelling adults in Baltimore, between March and October 2021.

The participants had varying mid-arm circumferences and a mean age of 54 years. Of these, 34% were male, 68% were Black, and 51% had hypertension. Study participants underwent four sets of triplicate BP measurements. The first three sets used an appropriate, too-small, or too-large cuff taken randomly, and the fourth set used an appropriately sized cuff.

Among individuals needing a small cuff, using a regular cuff resulted in a statistically significant lower BP reading (mean systolic BP difference of 3.6 mm Hg). In contrast, for those individuals requiring a large or extra-large cuff, using a regular cuff resulted in significantly higher BP readings (a mean systolic BP difference of 4.8 mm Hg and 19.5 mm Hg, respectively).

For participants requiring larger cuffs, BP differences were more pronounced with other cuff sizes. Findings were consistent across different systolic BP levels (≥130 mm Hg vs. <130 mm Hg) and BMI categories (≥30 kg/m^2 vs. <30 kg/m^2).

To guarantee precision, the study researchers followed clinical practice guidelines, using a validated BP device under specific conditions. These conditions included ensuring an empty bladder; abstaining from caffeine, tobacco, and exercise for 30 minutes before readings; providing support for the arm, back, and feet; maintaining a quiet room environment; using an appropriate cuff size; and averaging triplicate readings, according to Tammy Brady, MD, PhD, who was part of the study and is co-chair on the AMA Validated Device List (VDL) independent review committee.

Validating for accuracy

BP readings are difficult to study and report accurately," said Andy Lee, MD, from the University of California, Irvine School of Medicine. The benchmark, he said, is 24-hour ambulatory BP monitoring, which may be different from a single BP measurement done in a clinic.

Health care offices have medical-grade equipment that is independently verified and confirmed to be accurate. "The gold standard for comparison is a mercury sphygmomanometer, which is rare," said Lee.

Additionally, Brady said patients should note that sizes are not standardized when buying a home BP device. Patients should ensure that one of the included cuffs is appropriately sized.

"Cuffs may not compress the brachial artery properly, leading to imprecise artery oscillation detection," said Brady, an associate professor at Johns Hopkins University.

Individuals can check the U.S. National VDL at Validatebp.org to determine if cuffs are calibrated and validated for accuracy.

"Searching the cuff manufacturer's site for AAMI/ISO validation testing is also an option," said Brady. "Less than 20% of the devices on the market have ever been tested for accuracy."

FDA never "approves" BP devices; they "clear" devices, which does not mean that a cuff has been tested for accuracy. Sites advertising FDA approval are making a false claim, noted Brady.

Patients are encouraged to bring their home equipment to health care offices in order to verify that their home measurements correspond with verified devices, said Lee.

Advice for patients to accurately measure BP

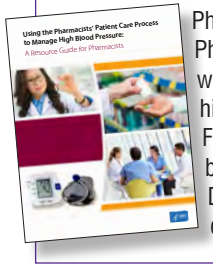
"Resting for 3 to 5 minutes prior to [BP] measurement is important for people with high BP to get the most accurate reading," said Brady.

Arm position and loud or busy environments can also affect BP readings, said Brady.

She recommends patients measure their mid-arm circumference with a tape measure to choose the right cuff. "All cuffs have markings to inform [individuals] what arm circumference size [are appropriate]," she said.

"If a cuff pops off while inflating, it is too small. And if a cuff covers the elbow, it may be too big," said Brady.

These implications are concerning for settings where a single regular BP cuff size is routinely used for all individuals. The researchers suggest a renewed emphasis on individualized BP cuff selection in clinical practice. ■



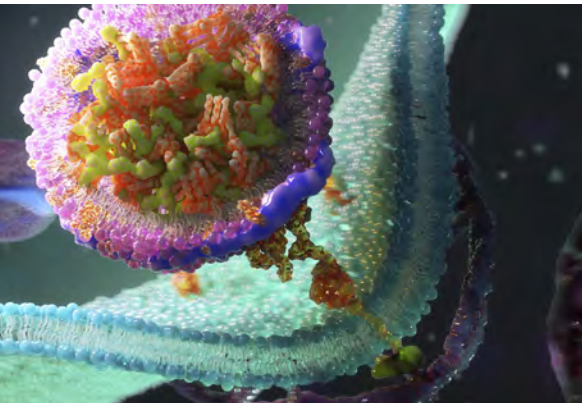
Pharmacists are also being encouraged to refer to CDC's Using Pharmacists' Patient Care Process to Manage High Blood Pressure, which incorporates a team-based care approach to prevent and manage high BP through five steps: Collect, Assess, Plan, Implement, and Follow-up: monitor and evaluate. The resource guide was co-developed by APhA and the American Medical Association along with CDC's Division for Heart Disease and Stroke Prevention. Visit www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf to review the guide. ■

Lipoprotein(a): A crucial influence on atherosclerotic risk

Olivia C. Welter, PharmD

When discussing cholesterol, most clinicians cite HDL and LDL as the primary cholesterol factors influencing atherosclerotic risk. Lipoprotein(a), also known as Lp(a), is another, less commonly discussed piece of the puzzle in determining risk for atherosclerotic CVD (ASCVD).

In a paper published in the October 2023 issue of the American College of Clinical Pharmacy's journal *Pharmacotherapy,* Dixon and colleagues examined Lp(a) as an independent risk factor for ASCVD. This is just one of many publications in recent years that attempt to bring more attention to Lp(a) and why clinicians should include it when assessing ASCVD risk.



FDA currently has no approved pharmacological treatments specifically for lowering Lp(a)-associated ASCVD risk.

The paper summarizes current therapies used to treat Lp(a) elevation and investigational drugs currently being developed to target it.

Lp(a) guidelines

Clinical guidelines vary in their acceptable Lp(a) concentration ranges, but the American College of Cardiology and the American Heart Association (ACC/AHA) advise in their guidelines that less than or equal to 50 mg/dL is an accepted target for individual patients. Any level higher than 50 mg/dL is considered a CV risk–enhancing factor in adults 40 to 75 years old, and warrants statin initiation based on the ACC/AHA guidelines. Overall, recent guidelines clearly demonstrate that Lp(a) must be considered an important factor when evaluating a patient for ASCVD risk.

Screening recommendations for Lp(a) are also variable. Guidelines range from some recommending that all individuals have Lp(a) measured at least once in their lifetime to others suggesting only those at increased risk of ASCVD need to be screened for elevated Lp(a).

In 2018, ACC published a multisociety guideline in the *Journal of the American College of Cardiology* on the management of blood cholesterol, which recommends screening individuals who have a family history of premature ASCVD.

Lipoprotein(a)

Lp(a) is essentially LDL with a glycoprotein apolipoprotein(a) addition. Although researchers have investigated Lp(a) extensively, its physiological function is still unclear.

A 2016 article published in *Journal of Lipid Research* by Schmidt and colleagues explored the heavy influence genetics, specifically the LPA gene, have on Lp(a), noting that concentrations can be two- to threefold higher in Africans than in Europeans and most Asian populations. Several studies show that quantitative Lp(a) is a highly heritable trait, with studies investigating twins, families, and siblings all demonstrating a heritability connection. Schmidt and colleagues noted that researchers have yet to discover an explanation as to why a high level of Lp(a) concentration variability exists among different populations.

Current therapies

FDA currently has no approved pharmacological treatments specifically for lowering Lp(a)-associated ASCVD risk. Based on the review conducted by Dixon and colleagues, several observations were noted regarding existing off-label therapies.

While statins are a first-line therapy for lowering LDL, similarly structured Lp(a) molecules react differently and Lp(a) concentrations can even increase when a patient is taking a statin. Ultimately, statin therapy likely does not change Lp(a)-associated ASCVD risk.

Ezetimibe was found to only moderately lower Lp(a) concentrations in one study, while no effect was observed in others.

PCSK9 inhibitors have demonstrated risk- and concentration-lowering effects, specifically in patients with Lp(a) levels elevated above baseline. Similarly, small interfering RNA (siRNA) therapies have also been associated with reduced Lp(a) levels.

Niacin can potentially decrease Lp(a) levels, but the risk of adverse effects in addition to its lack of mortality and morbidity benefit for patients at risk of CVD limits its use.

Investigational pipeline

Eight clinical trials in phases 2 and 3 are currently ongoing to investigate new therapies for lowering Lp(a) levels and their effect on CV risk.

Among these, mechanisms focus on siRNA-based approaches that target LPA gene transcription rate and antisense oligonucleotides, which affect gene translation. Only one investigational drug is taken orally, but most studies are exploring S.C. injections for delivering potential Lp(a)-reducing therapies. Some trials may be completed as early as 2024. ■

Researchers wield AI to address some of pharmacy's most serious problems

Sonya Collins

Artificial intelligence (AI) may have the capacity to extend its reach into virtually every industry and profession, and pharmacy is no exception. While professionals in many industries may envision ways in which the technology could make their jobs obsolete, there might be more reason for excitement than dread about the potential role for AI in pharmacy practice.

"As AI grows, pharmacists have a lot of expertise to help develop these models to make them more effective, especially given our expertise in medications," said Adrian Wong, PharmD, MPH, FCCP, a clinical pharmacy specialist in the medical intensive care unit at Beth Israel Deaconess Medical Center in Boston, MA. "Involving pharmacists from the beginning to help develop these models will be very helpful. AI won't necessarily take away our jobs. It will just improve patient care."

While most uses of AI in pharmacy practice remain theoretical, research underway examines AI as a tool to address some of the most serious issues affecting pharmacy practice and the patients in pharmacists' care.

AI to quantify the value of pharmacists' care

At a time when many hospitals are reporting shortages of clinical pharmacists in both the acute and ambulatory settings, the OPTIM study is engaging AI to quantify the effects of such a shortage.

The study, in which 20,000 patients are currently enrolled and which has a goal of 30,000 enrollees, will use traditional methods and unsupervised machine learning to analyze the relationship between patient mortality in the ICU, pharmacists' patient load, and many other components of ICU care. Unsupervised machine learning identifies distinctive clusters within a dataset, and researchers may then determine whether the clusters are meaningful.

"My hypothesis is that we're going to find a cluster of ICU patients who had the most ICU resources—the most physicians, pharmacists, nurse practitioners—are going to have the best outcomes," said Andrea Sikora, PharmD, MSCR, clinical associate professor of clinical and administrative pharmacy at University of Georgia College of Pharmacy in Augusta, GA, and the study's principal investigator. "The ability to figure out which resources, or which patterns, are associated with the best outcome would be an impossible study to do otherwise."

Sikora, along with her coinvestigators, expects OPTIM to be a landmark study for the pharmacy profession. "It's going to show for the first time that pharmacists' workload affects patient outcomes. If you overload your clinical pharmacists, they don't do as good of a job taking care of patients, and patients have worse outcomes."

"AI won't necessarily take away our jobs. It will just improve patient care."

Better allocation of pharmacists' time and expertise

In the face of an aging population and shortages across most all health professions, pharmacists practicing at the top of their licenses could fulfill many unmet health care needs. The COVID-19 pandemic demonstrated this. In fact, some state scope-of-practice laws would allow pharmacists to diagnose, prescribe, and treat many common health conditions. But basic pharmacy operations—many of which do not require a pharmacist's high level of training for execution—often keep pharmacists from providing more direct patient care. AI may offer solutions here as well.

AI platforms are already in use in some pharmacies to help predict times of day that get the most patient traffic or see the longest patient wait times so that pharmacies can plan, schedule, and allocate staff accordingly. Researchers in Taiwan taught machines to identify blister-packaged medications with greater than 90% accuracy, which freed up pharmacists for more clinical tasks.

AI's predictive abilities may help with drug shortages by heading them off at the pass, as well. Researchers at the University of North Carolina reported in the *American Journal of Health-System Pharmacy* that their machine learning model could predict drug shortages based on drug characteristics and manufacturer-related variables.

Planning ahead for drug shortages can save time and resources later.

AI and patient safety

Medical errors, including medication-related ones, are a leading cause of death. Since the advent of EHRs, medical errors have plummeted, but the digital medical records haven't eliminated the problem. Typically, pharmacists have had to check prescriptions against patient records for possible errors, and the most common triggers of these checks have been data about the patient or about the drug. AI may provide a means of reducing a different type of medication error substantially.

Researchers at New York University found that certain prescriber behaviors may predict risk for medication errors, too. When they used both machine learning and traditional methods to analyze the relationship between prescriber behavior and risk of error, machine learning outperformed other approaches. It found that multiple provider-specific factors, including prescriber experience and number of patient interactions in the hour before placing the medication order, predicted risk for errors.

In another study aimed at preventing medication errors, machines learned to link prescriptions for certain medications with diagnoses of corresponding GI disorders in the patients' medical records. Prescriptions that were ordered outside of diagnoses of these conditions were flagged for pharmacist intervention.

AI has also been used to mine social media for reports of adverse drug events, though this area needs more work, as humans must screen the data first for social media–specific phenomena, such as emojis, that machines cannot interpret.

Findings like these could power more effective clinical decision support tools that might flag potential errors for prescribers at the point of order entry and for pharmacists when they fill the prescription. The tool could streamline pharmacy operations by more accurately identifying prescriptions that require pharmacist intervention and save pharmacists from reviewing orders that are less likely to be erroneous.

AI approaches to more precise precision medicine

Increasing recognition that medications are not one-size-fits-all drives clinicians and scientists to search for tailored approaches that will have the best outcome for each individual patient based on their genes, comorbidities, lifestyle, environment, and disease state. AI may help hone these approaches.

For example, while canagliflozin has improved outcomes for many patients with T2D, a small subset of patients who take this drug face increased risk of lower-extremity amputation. Researchers at the University of Florida College of Pharmacy have used machine learning to determine who these patients might be. Their study found that those with a previous lower-extremity amputation and those on loop diuretics were at greater risk for this outcome.

"We can use the drug to protect the heart and kidney in most of the diabetes population but avoid using it in those for whom it could cause worse or life-threatening outcomes," said Serena Jingchuan Guo, MD, PhD, an assistant professor in the Department of Pharmaceutical Outcomes and Policy at the University of Florida College of Pharmacy in Gainesville.

In another study, Guo and colleagues used AI to home in on the reported protective effects of metformin against Alzheimer disease. The machine learning platform found that patients who didn't have neuropsychiatric disorders and those who didn't have long-term use of NSAIDs seemed most likely to receive the protective benefit of metformin.

"AI/machine learning helped us not only identify these subgroups, but also gave us more consistent results," Guo said. "Previous studies about this benefit of metformin had given weak signals or been inconsistent."

Similarly, researchers are using AI to improve warfarin dosing, which, Wong said, "is quite variable depending on the patient, and available guidance only explains approximately 60% of the dose variation by patient."

"This is where the design portion and the human brain piece comes in because the machine just sees the association and runs with it. AI is a tool and depends on how we use it."

Wong's recent narrative review in the November 2023 issue of the *Journal of the American College of Clinical Pharmacy*, which described the role of AI in multiple facets of pharmacy practice, highlighted two papers that used AI to tease out the remaining variables

in warfarin dosing. Both successfully employed various machine learning techniques to better predict warfarin dose in Black patients.

"This is an important area for AI research," Wong said. "These populations are not well represented in these models, so we don't have models that we can generalize to them."

An AI response to a public health crisis

Provisional data from CDC show that deaths due to opioid overdose topped 100,000 again in 2022, a projected slight increase over 2021. Researchers have begun to use AI to tackle this problem from multiple angles.

A study published in the *International Journal of Medical Informatics* used AI to screen EHRs for ICD-9 codes as well as natural language that might indicate risk of problem opioid use. Ten percent of the patients identified by the machine learning platform had been previously missed by more traditional means of flagging risk. In another study, machine learning identified some 50 factors, including concurrent medication use and laboratory data, that helped identify overdose risk with greater than 80% accuracy.

Researchers at the University of Florida College of Pharmacy have analyzed AI's potential to predict overdose risk among those receiving an opioid prescription. While the model proved highly accurate at quantifying overdose risk in many cases, the false negatives illustrated a common problem with AI.

"Sometimes AI/machine learning creates bias and can exacerbate existing health disparities," said Guo.

In this case, the false negatives—that is, those who were at risk of overdose but not captured by the AI model—were more likely to be Black patients than white patients. In fact, Black patients were twice as likely as their white counterparts to be classed as having low risk. One factor that raised a patient's risk for overdose was previous interaction with the health care system for overdose.

"We used claims data and most of the people who had sought medical attention for opioid overdose were white," Guo explained. "For many underlying reasons, Black people were less likely to pursue medical attention for opioid overdose."

Remember who's in control

The bias that AI introduced in the overdose risk study serves as an important reminder for pharmacists and any clinician who might lean on AI for support in clinical or other decisions.

"Before you do anything with the data, you need to understand the model that created it," said Almut Winterstein, RPh, PhD, distinguished professor and director for the Center for Drug Evaluation and Safety at the University of Florida College of Pharmacy.

She cites numerous examples of variables that AI might identify a causal relationship between but that human researchers would not. AI could suggest, for example, that people with diabetes have more depression than others, but that could be because they are more frequently seen by doctors and therefore more likely to be evaluated for depression than others. AI might suggest that if a patient stops statins, they are very likely to die in the near term, but a human clinical researcher would recognize that chronic therapies are typically discontinued close to death.

"These are the sorts of things we must be aware of," Winterstein said. "This is where the design portion and the human brain piece comes in because the machine just sees the association and runs with it. AI is a tool and depends on how we use it."

For these and other reasons, many potential clinical uses of AI are not yet ready for widspread adoption. AI models contain bias. Many populations are underrepresented in AI models. And there's a lack of thorough validation of AI technology. But as it gradually makes its way into the clinic, it's important for pharmacists to educate themselves on how the data were generated and the limitations of therein because it could eventually play a significant role in patient care and outcomes.

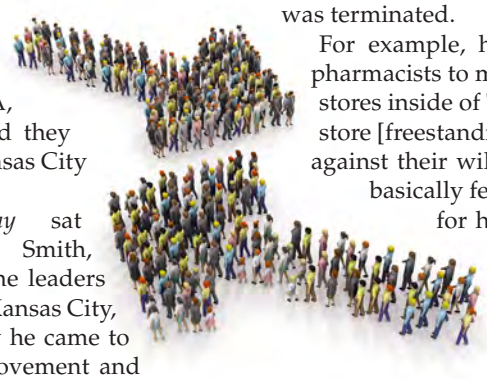
AI massively improving all of clinical pharmacy is still quite a ways away, Sikora said. "But I imagine it's eventually going to be providing clinical decision support that's just much smarter than what we have now." ■

Q&A with Ed Smith, leader of the Kansas City CVS Pharmacy walkouts

Loren Bonner

At the end of September, over 30 CVS pharmacists in the Kansas City metro area walked off the job. Their reason? Working conditions that put patients at risk.

Several pharmacy organizations released statements in support of the Kansas City pharmacists after news of the walkouts broke. The Kansas Pharmacists Association, APhA, and others all said they stand with the Kansas City pharmacists.



Pharmacy Today sat down with Ed Smith, PharmD, one of the leaders of the walkout in Kansas City, to hear about how he came to lead a national movement and get CVS to hear—and address—pharmacists' concerns.

Smith has been a staff pharmacist with CVS in the Kansas City area since 1998.

How would you describe your life as a pharmacist over the past year?

Honestly, it's been one of the most fulfilling years of my career—the lows so low and the highs so high.

Things have settled down now. The last thing we are fighting for with CVS—and continue to do so—is a pay raise for our technicians. The pharmacy technician role is by far the most important job in all of CVS, and they are extremely underpaid and deserve a livable wage. Their hourly rates are still at a prepandemic level, which is $16 an hour. A lot of people are frustrated.

How did you go from being a frustrated pharmacist to leading a movement of walkouts?

I had just transitioned to the Target store sector [CVS pharmacies inside of Target stores]. CVS terminated the district leader, whom everyone loved. He stood up for his pharmacists several times, and the consequence for protecting his people was that he was terminated.

For example, he didn't force pharmacists to move from their stores inside of Target to a core store [freestanding CVS stores] against their will. I felt that he basically fell on the sword for his people. This termination upset a lot of pharmacists within the district, and a lot of those pharmacists contacted me to discuss their frustration.

Then CVS adjusted the hours of operation for six pharmacies inside Target and closed them on the weekends to free up these pharmacists to fill in at core stores that CVS was struggling to staff. CVS was forcing these pharmacists into stores that were weeks behind—upward of 1,700 scripts behind.

Ed Smith, PharmD

This and the firing of the district leader were the catalysts for the September 20 and 21, 2023, walkouts.

The environments that the CVS-Target pharmacists were being forced into and that the core store pharmacists had to deal with on a daily basis compromised the safety of patients.

We discussed as a group what we could do to make a statement. After the covering district leader ignored the feedback I gave him regarding what was needed to settle things down, the only thing left to do was stage a walkout. It's extreme, but there needed to be some public shaming in order for CVS to listen to our concerns.

How have your actions resulted in changes for CVS?

CVS management agreed to eight goals we proposed for change. They include:

1. Leadership that is transparent, supportive, and not punitive.
2. Consistent pharmacy hours, as consistently changing store hours as a Band-Aid for your staffing needs negatively impacts both colleagues and patients.
3. Removal of extra, nonessential workflow tasks across the industry while working conditions stabilize, not over 120 vaccines with only one pharmacist on duty.
4. Increased hourly rates for technicians to be competitive in a post-pandemic market.
5. Consistent staffing levels to allow technicians to keep their benefits in all stores regardless of volume.
6. Reliable technology that allows staff to efficiently do their job without using the upgrade as an excuse to remove more pharmacist overlap and technician hours from stores.
7. Appropriate number of technician and pharmacist hours based on workflow demands to humanely and safely serve patients.
8. More competitive pay for pharmacy interns and a real-life training program that allows for proper training with the goal of developing the next leaders in this industry.

How do you hope to be involved with advancing the profession of pharmacy going forward?

Right now, my job is to hold CVS accountable for their past actions, but more importantly to the commitments they made to us in October 2023.

At press time, CVS management has addressed all except points four and eight, which involve pharmacy technicians. ■

Pharmacist-provided care may significantly help Hispanic patients lower A1C

Jonathan Little, PharmD

Research published in *JAMA* demonstrates the value that a pharmacist-led intervention provides to Hispanic patients with T2D.

Hispanic individuals with T2D are more likely than non-Hispanic white individuals to develop diabetes-related complications such as end-stage kidney disease and retinopathy. The study, published online on September 28, 2023, examined the impact that a pharmacist-led intervention can have on a patient's A1C and systolic BP.

Researchers found having at least one pharmacist visit was associated with a significant reduction in A1C and no significant change in systolic BP for patients participating in the study.

"The magnitude of the improvement in blood sugar level in this subgroup was consistent with what is seen with starting some diabetes medications," said lead author Kimberly Narain, MD, PhD, MPH, from the department of medicine at the University of California, Los Angeles (UCLA). The study involved patients of primary care clinics affiliated with UCLA who self-reported Hispanic ethnicity.

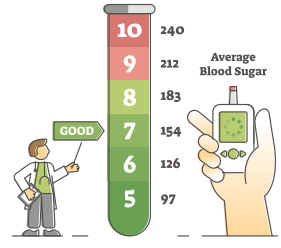
Improvement in blood glucose levels was particularly true for individuals with an English-language preference who were younger and had fewer comorbidities relative to individuals with a non-English preference.

"Consequently, it seems like there is a real opportunity for prevention of diabetes-related morbidity and mortality with this type of intervention," Narain said.

Clinical pharmacists

The UCMyRx initiative involved embedding clinical pharmacists trained in motivational interviewing into primary care practices to co-manage patients with complex care needs along with their primary care physicians.

In these settings, pharmacists meet with patients to review vital signs and laboratory results, order tests, perform medication reconciliation, assess medication adherence, and provide a personally tailored intervention to improve medication adherence. These assessments are communicated to the primary care provider who then reviews and documents agreement or disagreement with the pharmacist in the EHR. The pharmacist is then able to directly prescribe or discontinue medications and order lab tests as needed.



Researchers found having at least one pharmacist visit was associated with a significant reduction in A1C.

The researchers compared those patients who visited with a UCMyRx pharmacist to those who did not.

In addition to a reduction in A1C for participating patients, the researchers' analyses, based on visit frequency, suggested a negative association between A1C and UCMyRx exposure with a single UCMyRx pharmacist visit. Meaning, as little as one visit with a UCMyRx pharmacist may improve a patient's average blood glucose level.

Interventions for Hispanic patients

University of California researchers were prompted to look into the reasons Hispanic primary care patients had less favorable diabetes control relative to other racial and ethnic groups across their academic medical centers in the University of California Health System.

"Differences in medication adherence came up as a possible contributing factor," said Narain. "When we surveyed the literature for interventions to improve medication adherence among Hispanic patients with diabetes, we did not come across any interventions focused on Hispanic patients receiving care in academic medical centers. Instead, most interventions targeted Hispanic patients in safety net clinics and federally qualified health centers, which differ in important ways from the Hispanic patients served in UC Health."

Ultimately, they wanted to identify an intervention that had the potential to improve diabetes control for Hispanic patients receiving care in UC Health. This led them to UCMyRx, which has shown benefit among other subpopulations with diabetes at UCLA, according to Narain.

The authors noted that the reduction in A1C of 0.46%, as found in the study, is consistent with what other research has concluded for insulin initiation, and underscores the benefit that having a visit with a pharmacist may have for patients with diabetes.

In addition, the authors acknowledged that according to economic models, this 0.46% reduction in A1C may significantly reduce microvascular and macrovascular complications among patients with diabetes.

Recognizing the value that pharmacists can provide, Narain and coauthors said that a broader scope of practice for pharmacists is needed for wider dissemination of similar interventions.

UCMyRx pharmacists are authorized, per California state law, to bill for consultation services, which is a vital aspect of being able to provide these services for patients. ■

DEA extends telehealth authorities for controlled substances through 2024

Loren Bonner

In late 2023, DEA announced that it will continue to allow health care providers to use telemedicine to prescribe certain controlled substances through the end of 2024.

DEA said the temporary authorization is designed "to ensure a smooth transition for patients and practitioners that have come to rely on the availability of telemedicine for controlled medication prescriptions, as well as allowing adequate time for providers to come into compliance with any new standards or safeguards."

With providers able to continue prescribing controlled substances based on telehealth patient visits, Emily Leppien, PharmD, from Binghamton University School of Pharmacy and Pharmaceutical Sciences in New York, said this will significantly decrease access barriers, especially in more rural patient populations. Binghamton's hospital-affiliated outpatient pain clinic offers telehealth services for the treatment of chronic pain and SUD. As a pharmacist, Leppien holds telehealth appointments for patients who are referred to her for medication adjustment or management. Patients live anywhere from 5 minutes to 2 hours away from the facility.

"Many patients may experience challenges in securing time or transportation to in-person appointments," said Leppien. Not only do telehealth services allow for all patients to receive care regardless of location, but patients can also follow up with providers more quickly or frequently.

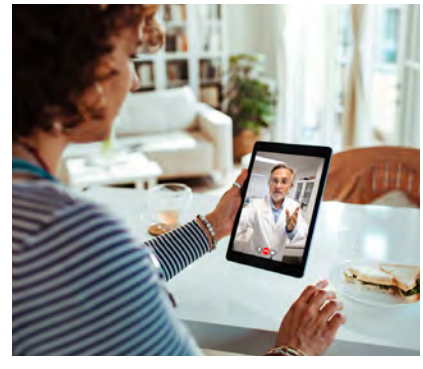
Controlled substances covered by the rule, which DEA released during the COVID-19 public health emergency, include not only medications for OUD, but also stimulant medications for ADHD and medications for anxiety.

Buprenorphine

In May 2023, just before the expiration of the public health emergency, DEA said it would temporarily extend telehealth flexibilities through November 11, 2023.

In September 2023, DEA hosted a listening session to hear from health care practitioners, experts, advocates, and patients who called on the agency to extend the more lenient rules and create a special registration pathway for remote prescribing.

Pharmacy groups, including the National Association of Boards of Pharmacy (NABP), said it's important for DEA to balance the need for access to care via telehealth with the risk of inappropriate access and diversion of particular medications.



"In regard to buprenorphine for treatment of opioid use disorder, NABP believes significant barriers to buprenorphine access persist and there are minimal risks of buprenorphine diversion," said Lemrey "Al" Carter, PharmD, NABP's executive director.

He said DEA should allow access to buprenorphine via telehealth.

A study published October 18, 2023, in *JAMA Network Open* found that when health care providers initiated buprenorphine for OUD via telehealth, it enhanced patients' likelihood of staying in treatment longer compared with starting treatment in a non-telehealth setting. The study was based on Medicaid data from 2019 to 2020 in Kentucky and Ohio. The researchers found that in Kentucky, 48% of those who started buprenorphine treatment through telehealth remained in treatment for 90 continuous days compared with 44% of those who started treatment in nontelehealth settings. In Ohio, 32% of those who used telehealth to start buprenorphine remained in treatment for 90 continuous days compared with 28% of those who started treatment in nontelehealth settings.

Other controlled substances

Carter said NABP's goal for other controlled substances besides buprenorphine is for DEA to set out clear requirements for pharmacists in its updated rules for telehealth prescribing.

"Pharmacists have a corresponding responsibility to ensure that prescriptions that they fill are valid, and receiving a prescription from a prescriber in a geographic area far from the pharmacy and with whom the pharmacist does not have a relationship has historically been a red flag," said Carter. "As telehealth models evolve and patients' access to care is expanded through telehealth, pharmacists need clarity in the rules of the road such that they can have confidence in the validity of prescriptions they receive that resulted from a telehealth visit."

Not only do telehealth services allow for all patients to receive care regardless of location, but patients can also follow up with providers more quickly or frequently.

DEA received over 38,000 public comments, including comments from NABP, to their proposed rules back in March 2023, the majority of which were concerned about restricted access to care. DEA said it hopes to draft new regulations by fall of 2024. ■

Pharmacists poised to fill gaps amid primary care shortage

Elizabeth Briand

Across the country, patients are finding it increasingly difficult to access the services of a primary care physician (PCP)—a situation that likely will not improve anytime soon. In fact, the Association of American Medical Colleges projects that by 2034 there will be a nationwide shortage of between 17,800 and 48,000 PCPs.

Fortunately, pharmacists are being empowered to help mitigate this shortage by increasingly taking on prescribing duties, based on state scope of practice laws, that are traditionally held by PCPs.

Bridging the gap

A recent data brief published by Surescripts examined growth in e-prescribers on the Surescripts network and found that while primary care prescribers—defined as physicians, nurse practitioners, and physician assistants working in family practice, internal medicine, and pediatrics—increased by an average of just 0.6% a year between 2018 and 2022, prescribers outside of primary care increased by an average of 12.1%.

That increase was driven in large part by pharmacists. Between 2019 and 2022, there was a 47% increase in the number of e-prescriptions issued by pharmacists. Currently, the majority of those prescriptions were for patients with chronic conditions such as diabetes, high cholesterol, and hypertension.

"The stark difference in growth was very surprising," said Shannon Reidt, director of medication research and analytics at Surescripts. "It shows that our PCPs are maxed out. They cannot prescribe anymore."

In recent years, more and more states have changed laws to welcome more direct intervention by pharmacists on behalf of patients. "Over the past several years, states both have broadened their collaborative practice agreement laws and expanded independent prescribing laws for pharmacists," said Allie Jo Shipman, PharmD, who served as senior director of policy and professional affairs at the National Alliance of State Pharmacy Associations. "This trend seems to be growing exponentially, so I do see pharmacists continuing to get more involved in prescribing."

The increase in prescribing by pharmacists offers benefits for patients and physicians alike, providing expedited service for individuals in need of medication and relief from time-consuming duties for PCPs.

"Community pharmacists are the most accessible health care provider, especially in small towns and rural areas," said Shipman. "Also, since pharmacists are medication experts, utilizing them to manage chronic conditions makes sense because it frees up time for other primary care providers."

In addition, said Shipman, "more patients get access to care, and patients also get more dedicated time with a medication expert who can answer their questions and concerns."

For anyone who has ever faced confusion over a new prescription or had questions on behalf of a loved one, that added time with an expert pharmacist can be a difference maker.

Looking ahead at a growing trend

This rise in prescribing reflects a growing trend that welcomes pharmacists as partners on the care team, with many even joining clinic staffs. A recent survey by Surescripts found that 89% of prescribers and 97% of pharmacists felt it was important for health care to move toward a more team-based approach to care.

"Everyone on a health care team has a role," said Reidt. "And whether we're talking about PCP shortages or not, the pharmacist should have a role. All of their training is about medications and how they can support patients to make sure those medications work for them."

Once they are part of the care team, pharmacists demonstrate their collective ability to improve outcomes and reduce costs. These benefits, alongside changing policies and attitudes, are fueling this new era in care management.

Reidt believes that pharmacists will become even more involved as the physician shortages continue. "Long ago, you wouldn't have thought to get your vaccines from pharmacists," she said. Now, the pharmacy is the first stop for the annual flu shot. Soon, "you'll go to a clinic and expect to see a pharmacist there. For transitions of care pathways, we'll see more patients referred to pharmacists. It's all happening now." ■

Pediatrics and women's health

There are many options to treat most bothersome symptoms for children. For some women, nonprescription drugs are first-line options to treat uncomplicated vaginal infections, and patient preference is preferred in product selection. Women are able to self-treat for common menstrual issues and the pharmacist can support optimal self-care management.

Pediatrics

Children's allergic reaction treatments

Children's Benadryl....1
Children's Zyrtec....2

Children's cold relief

Children's Dimetap....1
Children's Tylenol....2
Children's Robitussin....3
Mucinex Children's....3

Children's cough relief

Children's Delsym....1
Children's Robitussin....1
Mucinex Children's....2

Children's cough/cold multisymptom relief

Children's Dimetapp....1
Children's Robitussin....1
Mucinex Children's....2
Children's Tylenol....3

Children's earache relief

Similasan....1
Hyland's Naturals....2
Children's Tylenol....3

Children's multivitamin

Flintstones....1
Centrum Kids....2

Children's seasonal allergies

Children's Claritin....1
Children's Zyrtec....1

Women's health

Menstrual relief

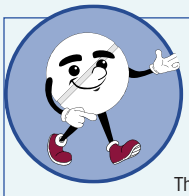
Midol....1
Pamprin....2
Advil....3

Vaginal lubricant

K-Y....1
ASTROGLIDE....2
Replens....2

Yeast infection treatment

Monistat....1



Self-care survey redux

This section of *Pharmacy Today*'s Self-Care Product Survey is reprinted from the full survey results published in the August 2023 issue of the magazine and available online at pharmacytoday.org.

The current survey was conducted by BrandSpark/Newsweek International using scientifically valid methodology, and lists those nonprescription products most often recommended by pharmacists in the United States to consumers.

The winners were selected based on a survey of 1,716 pharmacists practicing in the United States who gave their unaided write-in opinions on which brands they'd recommend to patients in 86 categories. The highest share of citations as most trusted in the category determined the winner. If the margin of citation share between the leading brands did not exceed the estimate of sampling error at 90% statistical confidence, a tie was declared.

Please also see APhA's *Handbook of Nonprescription Drugs*, the definitive source of professional information about OTC products. The *Handbook* is available in print on pharmacist.com and online at PharmacyLibrary.com.

Court considers pharmacist liability in opioid-related case

David B. Brushwood, BSPharm, JD

Judicial rulings in the large volume of opioid-related lawsuits continue to clarify pharmacists' legal responsibilities that are broadly applicable beyond opioid litigation. A recent case from New Jersey addresses a novel approach to pharmacist liability. Rather than alleging that the defendant pharmacies were liable for causing a patient to become addicted to dispensed opioids, this recent case contended that the defendants' pharmacists knew, or should have known, that the patient was already addicted to opioids and that their negligent dispensing of opioids exacerbated the patient's pre-existing condition.

Background

The plaintiff was the estate of a deceased patient. The estate sued four pharmacies that had dispensed oxycodone to the patient, sometimes in combination with alprazolam. The patient allegedly died as the result of the defendants' negligence. The prescriber of the controlled substances was also sued, but that lawsuit was separated from the pharmacy litigation.

The lawsuit against the defendant pharmacies alleged that pharmacists honored prescriptions for the patient "that they knew or should have known were negligently, carelessly, and or recklessly prescribed, given their amount and frequency." The lawsuit alleged that the pharmacists "engaged in professional malpractice by not noticing that the amount and frequency of the prescriptions were for addictive medications outside reasonable practice, and by not refusing to fill those prescriptions."

The pharmacies moved to dismiss the lawsuit based on the learned intermediary doctrine, contending that it is the physician, and not the pharmacist, who has a duty to warn the patient. The pharmacies also contended that the lawsuit did not properly allege proximate cause, because it was the patient's underlying condition that caused her death, and not any action or inaction by the pharmacists.

Pharmacists may have a legal duty to know a patient's underlying condition and to refuse pharmaceutical products or services that exacerbate the underlying condition.

The trial court granted the pharmacies motion to dismiss the lawsuit, and the plaintiff appealed.

Rationale

On appeal, the court first considered the defendants' defense based on the learned intermediary doctrine. The court recognized that the doctrine applies to pharmacists who accurately process prescriptions "issued in amounts and at frequencies within reasonable medical standards." According to the doctrine, it is the prescriber, and not the pharmacist, who is the learned intermediary and who has the duty to warn the patient of medication-related risks. However, the plaintiff's lawsuit did not allege the breach of a duty to warn the patient of risks. The lawsuit alleged the breach of a duty to refuse the improperly issued prescriptions. Therefore, the learned intermediary doctrine was ruled to be inapplicable.

The appellate court also disagreed with applicability of the defendants' proximate causation defense. The court noted that a plaintiff need not allege that a defendant's conduct was the only cause of the plaintiff's injury. Rather, "a plaintiff may recover if he establishes that professional negligence increased the risk of harm posed by a preexisting condition and the increased risk was a substantial factor in producing the harm."

The dismissal of the lawsuit was reversed on appeal and the case was remanded to the trial court for further proceedings.

Takeaways

This case illustrates a variation of the legal principle known as the "eggshell plaintiff" doctrine. Under that doctrine, an allegedly negligent defendant must accept the plaintiff's condition when the plaintiff was presented to the defendant, even if that condition is as fragile or as delicate as an eggshell. The defendant cannot escape liability by arguing that the action taken by the defendant toward the plaintiff would have been harmless if the plaintiff had not been so susceptible to the harm.

The significance of this case is that pharmacists may have a legal duty to know a patient's underlying condition, and to refuse pharmaceutical products or services that exacerbate the underlying condition. Pharmacists can know of an underlying condition based on a patient's medication history or information contained in the medication record. Suspicions about a patient's underlying condition that arise due to a pattern of medication use can be investigated by consulting with the patient or with the prescriber. ■

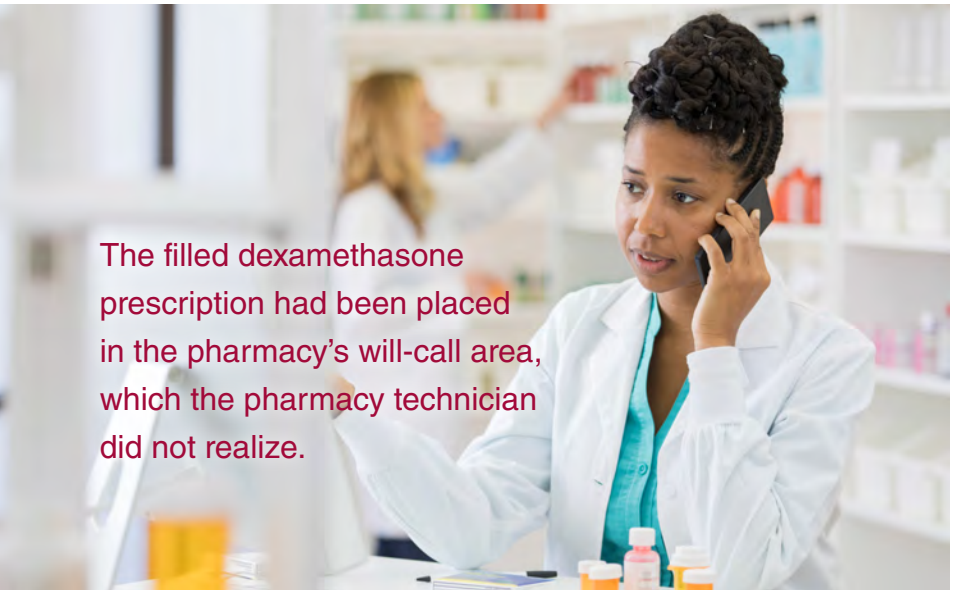
Medication omitted from delivery due to vulnerabilities in workflow

Institute for Safe Medication Practices, Horsham, PA

Recently, an error occurred at a health system specialty pharmacy that delivers prescriptions to onsite clinics when patients come in to meet with providers.

The program includes providing medications to patients with complex medical conditions and medications that require extra steps before they can be dispensed, such as medications with REMS requirements.

In this case, a patient with multiple myeloma was scheduled to come into the clinic to pick up Revlimid (lenalidomide) and dexamethasone. Because of the REMS requirements, prescriptions for Revlimid cannot be refilled; patients need to obtain a new prescription every month, which for this patient coincides with their clinic visits.



The filled dexamethasone prescription had been placed in the pharmacy's will-call area, which the pharmacy technician did not realize.

What happened

The patient in this case presented to the clinic, and a new prescription for Revlimid was sent to the pharmacy. The pharmacy filled the Revlimid prescription and delivered it to the patient.

However, the pharmacy technician did not deliver the patient's dexamethasone (a nonspecialty medication) that the pharmacy had filled earlier in anticipation of the patient coming into the clinic. The filled dexamethasone prescription had been placed in the pharmacy's will-call area, which the pharmacy technician did not realize.

When the pharmacist identified this, they called the patient at home multiple times before reaching them. Fortunately, the patient had one extra week of dexamethasone supply so they did not have a lapse in therapy.

The pharmacy's findings

When the pharmacy investigated this event, several contributing factors were identified.

First, the pharmacy staff were focused on meeting the REMS program requirements for Revlimid and thus were less focused on the dexamethasone prescription.

Second, when prescriptions for the same patient are filled at separate times or on separate days, they may be assigned to different electronic will-call bins, which happened in this case, rather than merged into a single bin and storage location in will-call. This increases the risk that pharmacy staff miss medications placed in separate bins.

Finally, staff had developed an alternate point-of-sale (POS) workflow when delivering prescriptions to patients in clinics. The standard procedure was to scan all prescriptions at the POS to mark the prescriptions as "sold" before releasing them to the patient.

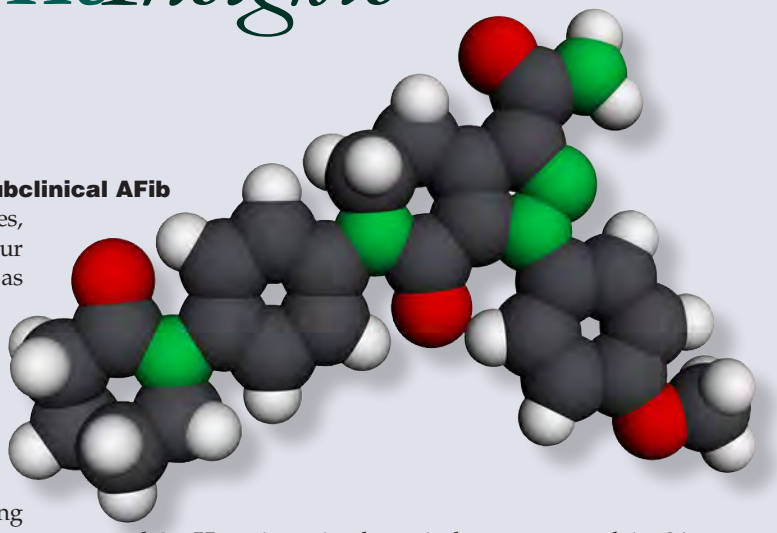
However, when delivering medications to patients in the clinic, staff did not conduct the barcode scanning step. Instead, they manually updated the system to "sold" after they delivered the prescriptions to the patient.

Staff adopted this alternate workflow because patients were not always present in the clinic when delivering the medications. If the medication must be returned to the pharmacy, it is a lengthy process to reverse the prescription from "sold" back to "ready" because, in part, the pharmacy computer system required the prescription(s) to go through the entire dispensing workflow again.

Risk-reduction strategies

- Develop a standard prescription delivery process that incorporates scanning all prescriptions (e.g., at the POS) using barcode scanning technology, including prescriptions delivered as part of Meds-to-Beds programs.
- Investigate the use of handheld technologies that can be brought to the clinic and enable completion of the POS transaction at the bedside.
- Establish a system to verify with the clinic, before the patient leaves the pharmacy, that the patient is there to receive the medications.
- Standardize processes and investigate pharmacy computer system upgrades to ensure all prescriptions for one patient are combined into one will-call bin.
- Incorporate system alerts to notify staff when multiple bins contain prescriptions for the same patient. ■

Inpatient*Insights*



Apixaban may prevent strokes in patients with subclinical AFib

Subclinical AFib, also known as atrial heart rhythm episodes, is a nonsymptomatic repetitive tachyarrhythmia that can occur most often in patients with electronic cardiac devices such as pacemakers or defibrillators. Subclinical AFib is associated with an increased risk of stroke, but treatment with oral anticoagulants is of uncertain benefit. A global group of researchers sought to determine whether apixaban would result in a lower risk of stroke or systemic embolism than aspirin among patients with subclinical AFib detected by a pacemaker, defibrillator, or implantable cardiac monitor.

The ARTESIA investigators conducted a trial involving patients with subclinical AFib lasting 6 minutes to 24 hours. Patients were randomly assigned in a double-blind, double-dummy design to receive 5 mg apixaban, a direct-acting oral anticoagulant that has been useful for stroke prevention among patients with clinical AFib, twice daily or 81 mg aspirin daily. The trial medication was discontinued, and anticoagulation started, if subclinical AFib lasting more than 24 hours or clinical AFib developed.

The results of the study, which were published online in *NEJM* on November 12, 2023, indicated that after a mean follow-up of 3.5 ± 1.8 years, stroke or systemic embolism occurred in 55 patients in the apixaban group and in 86 patients in the aspirin group. In the on-treatment population, the rate of major bleeding was 1.71% per patient-year in the apixaban group and 0.94% per patient-year in the aspirin group. Fatal bleeding occurred in five patients in the apixaban group and eight patients in the aspirin group.

The authors concluded that apixaban resulted in a lower risk of stroke or systemic embolism among patients with subclinical AFib. Apixaban resulted in a lower risk of stroke or systemic embolism than aspirin but a higher risk of major bleeding. ■

Does aspirin reduce bleeding risk for patients with an LVAD?

Although left ventricular assist devices (LVADs) greatly enhance the quality of life for patients with advanced heart failure, nonsurgical bleeding is an inherent risk factor and is the leading cause of death in this population.

To address this risk, aspirin as an antiplatelet agent is mandated along with vitamin K antagonists as antithrombotic therapy. Researchers participating in the ARIES-HM3 trial found that antithrombotic therapy without aspirin is safe and associated with a reduction of bleeding events.

The trial, a randomized, double-blind, placebo-controlled study of vitamin K antagonist therapy with and without aspirin (100 mg/day), was conducted across 51 centers in 9 countries and included 628 patients with advanced heart failure implanted with a fully magnetically levitated LVAD. The study enrolled patients from July 2020 to September 2022 with median follow-up of 14 months. The primary outcome was survival free of a major nonsurgical hemocompatibility-related adverse event (i.e., stroke, pump thrombosis, major bleeding, or arterial peripheral thromboembolism) at 12 months.

Results of the study, published online in *JAMA* on November 11, 2023, showed that 68.1% of patients who received aspirin reached the primary outcome, compared with 74.2% of patients who did not receive aspirin. The authors concluded that avoidance of aspirin as part of an antithrombotic regimen that included a vitamin K antagonist in patients supported with an LVAD resulted in a significant decrease (34%) in major nonsurgical bleeding events and no significant increase in thromboembolic risk. ■

Pharmacotherapy can help those with alcohol use disorder

According to the results from the 2021 National Survey on Drug Use and Health published by SAMHSA, only 265,000 (0.9%) of the approximately 29.5 million people who reported an alcohol use disorder in 2021 received pharmacotherapy. Researchers from RTI International, Kaiser Permanente, and The Ohio State University conducted a systematic review and meta-analysis to determine which pharmacotherapies are associated with improved outcomes for people with alcohol use disorder.

The study, published in the November 7, 2023, issue of *JAMA*, included 118 clinical trials and 20,976 participants pulled from PubMed, the Cochrane Library, the Cochrane Central Trials Registry, PsycINFO, CINAHL, and EMBASE from November 2012 to September 9, 2022, with additional relevant articles added until August 14, 2023. For evaluating efficacy outcomes, randomized clinical trials of at least 12 weeks' duration were included, while for evaluating adverse effects, randomized clinical trials and prospective cohort studies that compared drug therapies and reported health outcomes or harms were included.

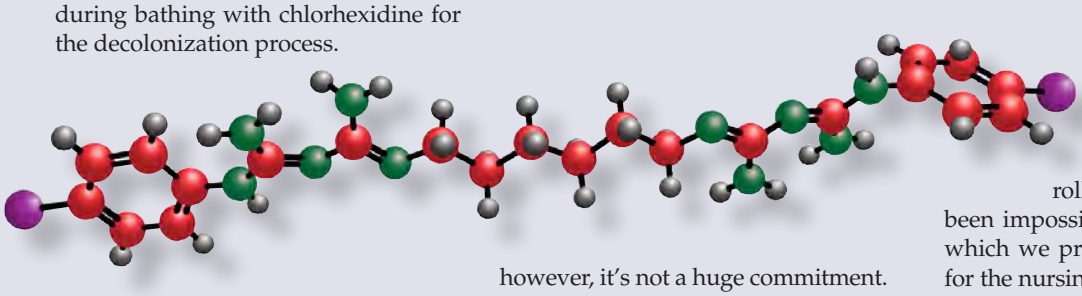
The meta-analysis showed that 50 mg/day of oral naltrexone and acamprosate were each associated with significantly improved alcohol consumption–related outcomes compared with placebo. Adverse effects included higher GI distress for acamprosate and naltrexone compared with placebo. The authors suggested that these findings support the use of oral naltrexone and acamprosate, in conjunction with psychosocial interventions, as first-line pharmacotherapies for alcohol use disorder. ■

Simple, effective decolonization measure in nursing homes a "no-brainer"

Loren Bonner

An estimated 1.6 million to 3.8 million nursing home residents acquire a health care–associated infection each year. It's one of the most common reasons for hospitalization and even death in this patient population. Decolonization, a type of pathogen reduction that eliminates colonizing pathogens specifically on the skin and mucosal surfaces, has already been shown to reduce infections for patients in hospital ICUs or before surgical procedures. But what about nursing home residents—a vulnerable group at high risk for serious illness?

For the first time, researchers conducted a large scale prevention study in residents of nursing homes where soap and water were swapped out during bathing with chlorhexidine for the decolonization process.



Results showed that for a typical 100-bed nursing home, the decolonization process would prevent 1.9 infection-related hospitalizations per month.

"This is a dramatic drop for such a relatively straightforward and inexpensive intervention," said lead author Loren Miller, MD, MPH, a professor of medicine at the David Geffen School of Medicine at UCLA and chief of the division of infectious diseases at Harbor-UCLA Medical Center.

Chlorhexidine is a topical skin disinfectant, relatively inexpensive and available over the counter. "Most of the nursing homes randomized to switch to chlorhexidine could implement the decolonization protocol since basically they weren't bathing residents any more or less frequently than they were already doing. They were just swapping the skin cleanser," said Miller.

The decolonization process also involved the administration of nasal povidone-iodine twice daily for the first 5 days after admission and then twice daily for 5 days every other week.

"Implementing the nasal iodophor decolonization was trickier since this adds a process that staff weren't already doing," said Miller. In the big picture, however, it's not a huge commitment.

"Our results really argue that nursing homes can do decolonization," said Miller.

Adherence to chlorhexidine use was 85% to 95% from the participating nursing homes, according to the findings.

"Implementing this intervention takes training, takes initiative from nursing home leadership, but it can be done and incorporated into daily workflow with minimal disruption," Miller said.

Trial details

Given that the study was a cluster randomized trial in which the research team randomized nursing homes—not residents or patients—Miller said the effect of decolonization was striking: decolonizing 10 residents prevented one infection-related hospitalization, according to the findings.

Researchers obtained their data from 28 nursing homes, all in Southern California, with a total of 28,956 residents participating. The trial took place from September 2015 through December 2018. All the nursing homes provided skilled nursing care.

At the time of trial randomization, none of the sites routinely used topical chlorhexidine or performed nasal decolonization. The nursing homes that were assigned to the routine-care group continued their usual bathing practices. Those in the decolonization group put the decolonization protocol into practice with 10% nasal povidone-iodine and chlorhexidine for bathing.

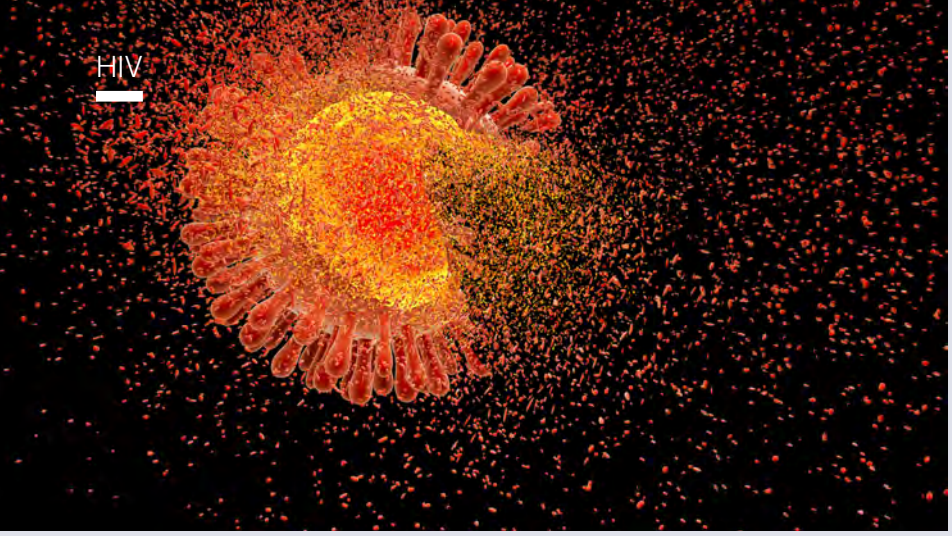
The findings showed that transfers to hospitals for infections in the intervention nursing homes decreased compared to those nursing homes that continued their standard of care bathing routine.

What's next?

Miller noted that without the nursing home leadership support they had for this study, rolling this out would have been impossible. "Even in our trial in which we provided logistical support for the nursing homes, 4 of the 28 nursing homes withdrew from the study," he said. He attributes some of that to leadership transitions. Nursing home administration leadership turnover is common.

The effect of decolonization was striking: decolonizing 10 residents prevented one infection-related hospitalization, according to the findings.

"Based on the trial's results, I'm really hoping that local and state health departments now start to advocate that decolonization should be the standard for nursing home residents," Miller said. "Again, nursing home residents are our loved ones, and advocating for their safety through such a simple intervention, in my mind, is a no-brainer." ■



Experts release 6-month update for HIV opportunistic infection treatment

Corey Diamond, PharmD

In the dynamic landscape of HIV prevention and treatment, the U.S. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV are at the forefront.

Through a collaboration with NIH, CDC, and the HIV Medicine Association of the Infectious Diseases Society of America, the guidelines are continuously evolving to incorporate the latest advancements in prevention and treatment recommendations. The document undergoes regular updates, ensuring it remains a reliable resource in the ongoing battle against HIV, including some major revisions made within the past 6 months.

Mpox

The mpox chapter update to the NIH HIV guideline, which was previously under development, has been added as of July 24, 2023, as a response to the 2022 outbreak. Specifically, the new chapter guideline adds epidemiologic, diagnostic, prevention, and treatment considerations for people living with HIV.

Mpox is a rare viral disease that belongs to the same family of viruses as smallpox. The virus is primarily found in the regions of Central and West Africa. However, the large outbreak in May 2022 raised concerns for future outbreaks. Although mortality as a result of mpox infection is less than 1% in the general population, the death rate is higher for individuals with advanced HIV.

In terms of preventing mpox infection in HIV individuals, the guideline states that all people with HIV who have a potential for mpox exposure should be vaccinated. The JYNNEOS vaccine is the preferred vaccine and is administered in two doses 28 days apart. Additionally, the vaccine is recommended up to 14 days after mpox exposure as it may still provide some protection.

According to the guideline, individuals with HIV who have a contraindication to vaccination or advanced immunosuppression may be considered for two alternative PEP treatments: oral tecorvirmat 600 mg every 8 to 12 hours (based on weight) for 14 days, or a single dose of vaccinia immune globulin I.V. (VIGIV) 6000 to 9000 units/kg.

In terms of treating mpox infection in HIV individuals, the guideline authors recommend, foremost, that antiretroviral therapy be initiated as soon as possible. Additionally, several treatment modalities are available for severe mpox disease or for individuals at risk for severe disease (not virologically suppressed or who have CD4 counts <350 cells/mm^3).

The NIH guideline recommends tecovirimat 600 mg by mouth every 12 hours (<120 kg) or every 8 hours (≥120 kg) for 14 days. Alternatively, tecovirimat 200 mg I.V. every 12 hours for 14 days (<120 kg) or 300 mg I.V. every 12 hours (≥120 kg) may be considered if concern exists regarding altered GI absorption capacity, the inability to take by mouth, or the extent of organ systems affected by mpox. Adjunctive therapy for severe mpox disease includes cidofovir, brincidofovir, and VIGIV.

Chagas disease

Chagas disease, also known as American trypanosomiasis, is a tropical parasitic infection caused by the protozoan parasite *Trypanosoma cruzi*. The disease is primarily found in Latin America, where it is transmitted to humans through the bite of infected triatomine bugs, also known as "kissing bugs."

In the case of individuals with HIV, the immune system is less able to control the initial infection and prevent the progression of the disease to its chronic phase, which can lead to more severe complications over a lifetime.

Benznidazole and nifurtimox are two of the main antiparasitic drugs used to treat Chagas disease. The June 14, 2023, update of the NIH HIV guideline changes the recommended dosing for nifurtimox. Whereas previously the guideline recommended 8 mg/kg/day to 10 mg/kg/day, administered for 90 to 120 days as an alternative to benznidazole, the guideline now recommends administering nifurtimox 8 mg/kg/day to 10 mg/kg/day in three divided doses with food for 60 days.

Syphilis

Syphilis, which is caused by the bacterium *Treponema pallidum*, is linked to a higher likelihood of acquiring and transmitting HIV through sexual activity. The NIH guideline has added a section as of September 25, 2023, for post-exposure syphilis prophylaxis based on data from recent clinical trials in individuals with HIV.

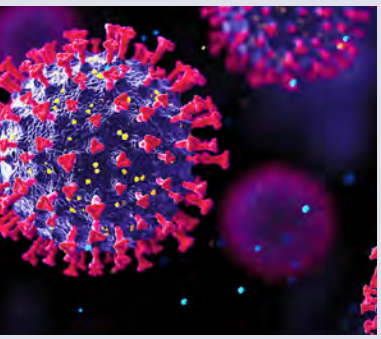
In general, doxycycline 200 mg after unprotected sex in men and transgender women was associated with a 73% reduction in syphilis incidence rates. The evidence, however, is not robust at this point. The NIH guideline notes that other studies are underway regarding the use of doxycycline for the indication of PEP. ■

What pharmacists should know about DDIs for patients with COVID-19

Loren Bonner

For clinicians who work in acute care settings, some practical guidance pertaining to drug–drug interactions (DDIs) for the treatment of patients with COVID-19 is finally available.

In an article published October 1, 2023, in the *American Journal of Health-System Pharmacy (AJHP)*, researchers addressed DDIs for patients being treated for COVID-19, as some of these medications used for COVID-19 treatment are started prior to hospitalization and may have continuing effects in terms of drug interactions after hospital admission.



A key issue is that even if the drug is stopped when the patient is admitted to the hospital, the drug interaction effect can be pertinent for several days.

"The most striking part of this article pertains to ritonavir-boosted nirmatrevir," said lead author Asad Patanwala, PharmD, MPH, chair of clinical pharmacy at the University of Sydney School of Pharmacy in Australia. "There are a lot of drug interactions with this agent, and [it] has important clinical implications for patients who may be admitted to the hospital after being prescribed this drug in the community."

Patanwala said a key issue is that even if the drug is stopped when the patient is admitted to the hospital, the drug interaction effect can be pertinent for several days. "This is something that clinicians may not commonly consider," he noted.

Handy guide

After reviewing the published literature on the topic and summarizing what is known to date, researchers put together the guide for clinicians to refer to and read as practical advice.

Not only do the authors provide key pharmacological concepts underlying DDIs, including a discussion of the gastric environment, the CYP450 isozyme system, transporters, and pharmacodynamics in relation to DDIs, but they also provide a decision-making framework for clinicians.

They also include important DDIs pertaining to contemporary acute care clinical practice related to COVID-19.

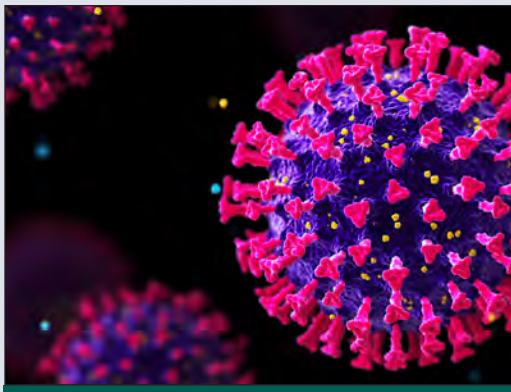
"We think that table will be particularly useful as clinicians can visualize all the pertinent issues that may apply to each drug," said Patanwala. "It is possible that as new drugs are approved for COVID-19, there will be additional interactions to consider, which we have not discussed."

Tables as well as the decision-making framework can be found in the article (see sidebar for link).

Continuous evaluation

Because the information is applicable to every patient with COVID-19 who presents to the hospital, Patanwala said it could affect many patients as the country experiences waves of COVID-19 each year. "It also applies to the entire spectrum of patients with mild acute illness and to those who are critically ill," he said.

"We hope that clinicians will use the framework and the summary table we have created to guide their decisions," Patanwala said. "As more patients are admitted to hospitals with COVID-19, these drug interactions should be evaluated and when appropriate, alternative therapies should be used for concurrent medical problems." ■



COVID-19 therapies to consider for DDIs

Below are current COVID-19 therapies recommended by NIH and most likely seen in clinical practice.

Specific mechanisms for DDIs for each COVID-19 drug can be found in the table in the *AJHP* article at apha.us/COVIDandDDIs

Monoclonal antibodies
Bebtelovimab
Tixagevimab/cilgavimab
Corticosteroids
Dexamethasone
IL-6 inhibitors
Tocilizumab
Sarilumab
JAK inhibitors
Baricitinib
Tofacitinib
Antivirals
Ritonavir-boosted nirmatrelvir
Molnupiravir
Remdesivir

A minute with ...

Douglas Tam, PharmD, BCPS, OR clinical staff pharmacist, UF Health Shands Hospital, Gainesville, FL
Member since 2015

"As a member of APhA, I have had an abundance of opportunities opened up to me. Whether it was a leadership experience or networking with colleagues from across the nation, APhA has consistently helped me grow personally and professionally as a practitioner. This growth has translated to confidence in my leadership at work and has helped me to develop effective communication skills with anesthetists, surgeons, and nurses in my area of practice."

How has APhA helped you establish meaningful connections?
Over the years, APhA has helped me foster friendships and connections across the United States.

When I travel to any major city, I know that there's a high likelihood that I know a student pharmacist or pharmacist who I could reconnect with or who could show me around! These ongoing connections allow for a broad understanding of what challenges pharmacists are facing outside of my state of practice.

How does APhA help you thrive in your everyday practice?
APhA often provides valuable information on the impact of pharmacists across country. From updates on COVID-19 treatment and response to the legal push for provider status and information on vaccine schedules, APhA gives me confidence that I can be knowledgeable when talking to providers who have questions on a variety of topics.

What excites you about the profession of pharmacy?
Pharmacy is always changing and growing, with new opportunities to practice at the top of our licenses and abilities and with growing recognition by providers as crucial members of the health care team. I'm also excited to see how pharmacy adapts and supports patient care as digital health and artificial intelligence continues to intersect with health care.

Can you share a meaningful story about a time you interacted with a patient? Perhaps a time you felt like you really made a difference for them?
During a holiday weekend, I had the opportunity to help coordinate supply of a unique liquid formulation medication prior to a patient's discharge.

Due to issues with insurance coverage dependent on prescription processing and timing of pharmacy hours during the holiday, I was able to effectively discuss options and hospital supply of the medication with the ordering physician and expedited the discharge process so the patient could safely return home quickly. ■

Did you know?

APhA and the American Society of Consultant Pharmacists are collaborating to offer board prep and recertification education for the geriatric credential. APhA's offerings will include a monthly clinical case study where learners are given the opportunity to practice identifying medication-related problems and making recommendations to help keep older adults safe. Additionally, APhA will offer sessions at APhA's 2024 Annual Meeting & Exposition, a literature and podcast series, and full certificate training program on deprescribing that will launch later this year.

Visit www.pharmacist.com/Education/Board-Prep-Recertification/Geriatric for more information. ■

Get involved

The primary purpose of the APhA Preceptor Special Interest Group (SIG) is to serve as an interactive community in which pharmacists who precept student pharmacists and residents can communicate and receive feedback on precepting strategies, precepting challenges and solutions, and opportunities for preceptor growth and development. This community also serves as a conduit for APhA to identify practice-based teaching models that support the advancement of patient-care services and address training and development needs of preceptor pharmacists in order to continually improve the quality of experiential teaching within the profession of pharmacy.

Members of the SIG can choose to be further involved in either the communications or education committee, where they will work to identify resource needs and develop valuable toolkits and resources for learning.

Interested in getting involved in the Preceptor SIG? Please visit pharmacist.com/Membership/Get-Involved/Special-Interest-Groups/Preceptor-SIG to learn more. ■

APhA2024

Join us in Orlando, FL, March 22–25, 2024, at our Annual Meeting & Exposition! APhA2024 is hosting some of the industry's top innovators and experts representing every practice area and covering the key hot topics that have surfaced over the past few years as they present trends, real-world case studies, recent legislature, and more. Don't miss our dynamic presentations!

The theme of this year's meeting—Unleashing the Power of Pharmacy—acknowledges the pivotal role pharmacists play in health care and seeks to amplify their voice and impact. It calls on pharmacists to think beyond traditional boundaries, embrace new opportunities, and champion initiatives that enhance patient care, optimize medication management, and improve overall health outcomes.

Visit aphameeting.pharmacist.com/Education to learn more! ■

APhA pharmacy law matters: A year in review

The legislative, regulatory, societal, and economic issues impacting the pharmacy community in 2023 resulted in some wins, some losses, and some continuing challenges that will carry into 2024. While a new normal has swept across the country as many COVID-19 pandemic measures came to a close, advocacy efforts focused on, among other things, maintaining the authorities permitted during the PHE, ensuring appropriate payment for pharmacists' patient care services, fixing the broken pharmacy reimbursement system, and stocking adequate supplies of essential medicines.

Addressing many of the issues is still a work in progress, but there have been advancements providing new opportunities for pharmacists to provide innovative, meaningful, and important patient care.

Spotlighted issues

Pharmacists' recognition as patient care providers

Recognizing pharmacists as eligible providers under Medicare Part B (medical services) continues to be a top priority in advancing the profession of pharmacy. Several bills have been introduced over the years that would add pharmacists as eligible Medicare providers. The 118th Congress, introduced two bills: the Pharmacy and Medically Underserved Areas Enhancement Act of 2023 (S. 1491), introduced by Senator Chuck Grassley (R-IA), and the Equitable Community Access to Pharmacists Services Act (ECAPS, H.R. 1770, S. 2477) introduced in the House by Representative Adrian Smith (R-NE) and the Senate by Senator John Thune (R-SD).[1,2] While both bills aim to provide reimbursement for pharmacists' services under Medicare Part B in the outpatient setting, there are slight differences between the two:

- The Pharmacy and Medically Underserved Areas Enhancement Act provides Part B reimbursement for all pharmacist services under state scope of practice for beneficiaries in underserved or rural areas.
- ECAPS provides Part B reimbursement for testing, treating, and immunization of upper respiratory illnesses such as COVID-19, flu, pneumonia, respiratory syncytial virus (RSV), and group A streptococcus (strep) as allowed under state scope of practice. ECAPS is not limited to Medicare beneficiaries in rural or underserved areas.

At the time of this writing, both bills sit in committee. The Senate version of ECAPS and the Pharmacy and Medically Underserved Act sit in the Senate Finance Committee, while the ECAPS House bill sits in the Ways and Means and Energy and Commerce Committees.

All three bills have broad bipartisan support (94 and 13 cosponsors for ECAPS in the House and the Senate, respectively, and 13 for the Pharmacy and Medically Underserved Act at the time of writing this article) and are led by key members of Congress who sit on major committees of jurisdiction. One of the original leads on ECAPS is Representative Larry Bucshon (R-IN), who is a physician, which is notable because of opposition from parts of the physician community.

Increased momentum for federal legislation is attributable to the Future of Pharmacy Care Coalition, which was cofounded by APhA.[3] The coalition brought together all the different facets of the pharmacy community to help draft the ECAPS legislation, which capitalizes on the care and access that pharmacists have been providing during the pandemic and recognizes pharmacists as Medicare providers. Pharmacists and pharmacy personnel demonstrated their essential role on the health care team throughout the pandemic by administering 300+ million vaccines, conducting 42+ million point-of-care tests, and contributing to billions of dollars in savings in avoidable hospitalizations.[4]

An important step for a bill to become law is to receive a "score" from the Congressional Budget Office (CBO). A CBO score is a cost estimate that predicts the impact of legislation on the federal budget and other outcomes. The CBO

Learning objectives

At the end of this activity, participants will be able to

- Discuss government action (legislative and regulatory) to advance pharmacists' practices.
- Describe the latest federal regulations related to the practice of pharmacy.
- List examples of state advocacy (e.g., payment for pharmacists' services, expansion in scope of practice, PBM reform).

Preassessment questions

Before participating in this activity, test your knowledge by answering the following questions. These questions will also be part of the CPE assessment.

1. **What federal legislation would recognize pharmacists as providers under Medicare for testing, treatment, and immunization services?**
   a. H.R. 1770, S. 2477, the Equitable Community Access to Pharmacist Services Act
   b. H.R. 1000, S. 3200, the Lower Costs, More Transparency Act
   c. H.R. 6000, S. 4101, the Allied Health Workforce Act
   d. H.R. 1550, S. 497, the More Pharmacists in Underserved Areas Act

2. **When does the DSCSA stabilization period end?**
   a. December 31, 2023
   b. January 1, 2024
   c. February 14, 2027
   d. November 27, 2024

3. **How long is the current DEA extension for telehealth prescribing flexibilities without an in-person visit?**
   a. November 11, 2023
   b. February 14, 2024
   c. December 31, 2024
   d. August 13, 2025

score is important as Congress has been reluctant to support any piece of legislation that would be too costly to implement for the federal government.

The CBO score for ECAPS was requested by the House Ways and Means Committee Majority staff and several senators; Senator Grassley has requested a CBO score for the Pharmacy and Medically Underserved Areas Act.

While the CBO has yet to release any scores, an independent analysis compiled for the Future of Pharmacy Care Coalition suggests ECAPS would cost $1.3 billion over 10 years, after incorporating $22 million in savings from improved health outcomes.[5]

Outlook

There has been continued momentum to advance legislation recognizing pharmacists as patient care providers during this Congress with the help of state pharmacists, pharmacy associations, and the Future of Pharmacy Care Coalition.

At the time of this writing, both House and Senate leaders have considered ways to incorporate ECAPS into a broader package at the end of the year.

However, with the recent developments that a continuing resolution will be passed, one of the larger legislative vehicles in the form of an omnibus (a large funding bill) is off the table. There still may be an opportunity for the legislation to be included in a Medicare extenders package, but that may prove to be more difficult than a broad appropriations/funding package. Regardless of whether ECAPS language is included in a legislative package this year, enough momentum and support from congressional leaders has been gained for the legislation to be considered in early 2024.

State efforts

Aligning pharmacists' scope of practice with their education and training has also continued to be a top priority for the profession through the updating of state laws and regulations.

Policymakers in many states continue to look to our nation's pharmacists as providers of preventive health care services. These services include, but are not limited to, pharmacists' ability to test and treat acute ailments, prescribe hormonal contraceptives and HIV PrEP/PEP, and give immunizations.

Significant progress has been achieved over the past year to update pharmacists' state scope of practice by codifying the temporary expansions granted during the COVID-19 pandemic under the federal PREP Act. These declarations expanded pharmacists', pharmacy interns', and pharmacy technicians' COVID-19 and influenza vaccination authority and pharmacists' ability to test for COVID-19 and furnish I.M., S.C., and oral treatments for COVID-19.[6]

As a result of some of these authorities ending in May 2023—and the remaining authorities expected to end in December 2024—states have focused on codifying these temporary authorities to ensure that patients maintain access to these services.[7]

At the time of this writing, examples of states that signed into law, or implemented, expanded scope of practice laws or regulations include the following.

Alaska

HB 112 expands pharmacists' prescriptive authority by allowing pharmacists to independently prescribe epinephrine autoinjectors.[8]

Arizona
Regulations codified pharmacy technician authority to administer immunizations under the supervision of a pharmacist.[9]

Arkansas
HB 1007 expands pharmacists' authority to prescribe HIV PrEP/PEP via a statewide protocol.[10]

Colorado
SB 162 expands pharmacy technicians' scope of practice to perform point-of-care tests under the supervision of a pharmacist and provides reimbursement options by the state Medicaid program for pharmacists for the administration of vaccinations to patients under the age of 19 years old.[11]

Connecticut
SB 1102 expands pharmacists' authority to administer vaccinations and codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist. Additionally, the law expands pharmacists' authority to administer point-of-care tests and prescribe and dispense HIV PrEP/PEP.[12]

HB 6768 allows pharmacists to prescribe and dispense hormonal contraceptives.[13]

Delaware
SB 165 allows pharmacists to enter into collaborative practice agreements (CPAs) for pharmacist-provided services.[14] Pharmacists can now provide services to a patient via a CPA in all 50 states.

District of Columbia
DC adopted regulations allowing pharmacists to administer ACIP-recommended vaccinations to patients 3 years to 18 years old. Additionally, the regulations allow pharmacy interns and pharmacy technicians to administer COVID-19 and influenza vaccinations to patients who are 18 years or older under the supervision of a pharmacist.[15]

Georgia
HB 416 codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[16]

HB 440 expands pharmacists' authority to dispense glucagon pursuant to a prescriber protocol.[17]

Illinois
HB 559 authorizes pharmacists to test and treat for COVID-19 and to test for influenza and other emerging and existing public health threats.[18] It also provides coverage for these services by health plans in the state.[18] Additionally, the law expands pharmacists' authority to administer COVID-19 and influenza vaccinations to patients 7 years and older.[18]

Indiana
HB 1568 allows pharmacists to prescribe and dispense hormonal contraceptives under a standing order and provides coverage for these services by the state's Medicaid program.[19]

Maine
LD 351/SP 158 allows pharmacists to prescribe and dispense hormonal contraceptives to patients who previously have been issued a prescription for hormonal contraceptives.[20]

LD 899/HP 555 codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[21]

LD 1151/SP 478 expands pharmacists' authority to administer vaccinations to patients 3 years old and older.[22]

LD 1728/SP 692 updates state law to allow pharmacists to provide increased access to opioid antagonists other than naloxone.[23]

Maryland
HB 693/SB 647 expands pharmacy technicians' authority to administer certain vaccinations under the supervision of a pharmacist.[24,25]

Massachusetts
H 4040 expands pharmacists' authority to prescribe and dispense hormonal contraceptives.[26]

Michigan
SB 219 authorizes pharmacists to test and treat for COVID-19 and influenza as well as test for influenza and other respiratory viruses.[27]

Montana
SB 112 authorizes pharmacists to prescribe medications for conditions that do not require a new diagnosis, are minor and generally self-limiting, and can be diagnosed with a Clinical Laboratory Improvement Amendments–waived test or are patient emergencies.[28]

HB 710 codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[29]

Nebraska
LB 227 codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[30]

Nevada
AB 156 expands pharmacists' authority to assess, prescribe, and dispense medications for OUD.[31]

New Hampshire
SB 35 expands the vaccinations pharmacists can administer to include immunizations for RSV.[32]

New Jersey
SB 275 authorizes pharmacists to prescribe self-administered hormonal contraception under a standing order in accordance with protocols established by the New Jersey Board of Pharmacy and the State Board of Medical Examiners.[33]

New Mexico
SB 92 authorizes pharmacists to test and treat for influenza, group A streptococcus, COVID-19, UTIs, and other emerging public health threats via a statewide protocol.[34] Additionally, pharmacists are authorized to prescribe HIV PrEP and PEP via a statewide protocol.[34]

New York
A 1060 allows pharmacists to dispense hormonal contraceptives under an order that is not patient-specific written by a physician or a certified nurse practitioner.[35]

Ohio

New regulations codified pharmacy technician authority to administer immunizations under the supervision of a pharmacist.[36]

Oregon

HB 2278 expands pharmacists' authority to administer immunizations by allowing pharmacists to administer influenza vaccinations to patients 6 months old and older.[37]

HB 2395 expands pharmacists' authority to prescribe all short-acting opioid antagonists.[38]

HB 2486 codifies pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[39]

Rhode Island

S 103 and S 563 allow pharmacists to prescribe hormonal contraceptives and HIV PrEP/PEP.[40,41] Importantly, both bills include provisions that expand opportunities for pharmacists to be paid for these patient care services.[40,41]

Vermont

S 37 allows pharmacists to prescribe emergency contraceptives pursuant to a state protocol.[42]

H 305 makes updates to specify pharmacists' authority to test and treat for acute ailments and pharmacy technicians' authority to administer vaccinations under the supervision of a pharmacist.[43]

Virginia

SB 948/HB 2274 authorizes pharmacists to test and treat for group A streptococcus, influenza, COVID-19, and UTIs via a statewide protocol.[44,45]

Outlook

The future of expanding the scope of practice for pharmacists' services at the state level continues to grow every year. As a result of the end of all PREP Act authorities in December 2024, states only have 1 year left to codify authorities before patients lose access to services they have grown accustomed to receiving from their pharmacists, which is expected to be a primary focus of state lawmakers in 2024. Additionally, there have been significant discussions on the role of pharmacists in increasing access to HIV PrEP/PEP from federal agencies and patient advocacy organizations, which may translate to expanded state legislative efforts focusing on pharmacist-prescribed HIV PrEP/PEP.[46]

Payment for services

A key achievement in 2023 has been the continued expansion of the recognition of pharmacists as medical providers by state Medicaid programs and commercial insurance plans as well as the coverage of pharmacists' patient care services. These programs commonly recognize the individual pharmacist as a provider and reimburse them for their services under the medical benefit using billing codes commonly used by other health care professionals who are providing comparable services.

At the time of this writing, examples of states that signed laws, or implemented payment for services laws or regulations include the following

Medicaid Other Licensed Practitioners approval

The Illinois Department of Healthcare and Family Services received approval from CMS to allow pharmacists to bill for services associated with the prescribing of HIV PrEP/PEP.[47]

The Indiana Office of Medicaid Policy and Planning recently received approval from CMS to allow pharmacists to bill for services associated with the prescribing of hormonal contraceptives.[48]

CMS approved Kansas and New York Medicaid's request to add pharmacists to its list of "Other Licensed Practitioners."[49,50]

CMS approved North Carolina Medicaid's request to add pharmacists' services related to prescribing COVID-19 therapeutics.[51] These services are covered beginning February 1, 2023, through at least 12 months after the end of the public health emergency.[51]

CMS approved Oklahoma Medicaid's request to add pharmacists to its list of "Other Licensed Practitioners."[52] This allows pharmacists to be reimbursed for "any and all services within their scope of practice pursuant to state law."[52]

CMS approved Utah Medicaid's request to add pharmacists to its list of "Other Licensed Practitioners."[53] This allows pharmacists to be reimbursed for "cognitive services such as [medication therapy management] MTM services and contraceptive prescribing."[53]

California

AB 317 requires a health care service plan to pay or reimburse the cost of services performed by a pharmacist at an in-network pharmacy or by a pharmacist at an out-of-network pharmacy if the health care service plan or insurer has an out-of-network pharmacy benefit.[54]

Maryland

HB 1151/SB 678 allows for the reimbursement by private and public health plans in the state for services provided by pharmacists practicing within their scope of practice.[55,56]

Nevada

SB 161 expands coverage by health plans of pharmacist-prescribed hormonal contraceptives.[57]

North Dakota

HB 1095 allows for the reimbursement by health plans in the state for comprehensive medication management provided by pharmacists.[58]

Virginia

SB 1538 recognizes pharmacists as providers within the state Medicaid program and requires Medicaid to cover pharmacists' patient care services.[59]

Wisconsin

The Wisconsin Division of Medicaid Services announced that pharmacists can begin enrolling as medical providers in the state and billing for their patient care services.[60] This comes as the result of the signing of SB 255 in 2021.[61]

Wyoming

SF 9 recognizes pharmacists as health care providers within the state's Medicaid program and establishes a pathway for pharmacists to be reimbursed

for their patient care services by the state's Medicaid program.[62]

Outlook

Recognition of pharmacists as providers by state Medicaid and commercial health plans has continued to expand throughout 2023 and is expected to continue throughout 2024.

PBM reform

Pharmacists continue to stress to policymakers that increased oversight of the PBMs' business practices is needed to keep health care costs down, lower the cost of rising prescription drug prices, and keep pharmacy doors open.

For example, PBMs' use of "clawbacks," or DIR fees that are not reflected at the point of sale for pharmacies participating in Medicare Part D networks, increases costs to patients at the pharmacy counter. DIR fees are imposed on pharmacies by PBMs based on pharmacies' performance—or lack thereof—on certain measures. In addition, pharmacies are being hit with a financial loss because they are forced to dispense drugs below their acquisition costs. As a result of PBMs' business practices, health care costs have increased across the board.[63]

To address these issues, pharmacists have engaged with policymakers by providing data and insight on the impact PBMs have had on pharmacies, pharmacists, and patients. These engagements included face-to-face meetings, congressional staff briefings on PBM reforms, and expert testimony during congressional hearings.[64,65]

One PBM issue that is a priority for pharmacists is for policymakers to address the "DIR cliff," which refers to the situation starting on January 1, 2024, when pharmacies are expected to still face DIR fee clawback payments to PBMs for DIR fees from calendar year 2023 and lower point-of-sale reimbursement for dispensing Part D medications that begins in 2024. To address this issue, pharmacists have met with policymakers to offer both legislative and regulatory fixes. Among the solutions under consideration are a delay of 2023 pharmacy DIR payments to the PBMs and establishing payment plans and/or loan forgiveness plans for 2024.

In 2023, Congress has illustrated that PBM reform has become a top priority on both sides of the aisle. PBM reform legislation has been introduced and/or passed in key committees of both the House and Senate with jurisdiction over health care, including the House Ways and Means and Energy and Commerce committees as well as the Senate Finance and Health, Education, Labor, and Pensions committees.

Recently, these efforts advanced with the Senate Finance Committee's passage of the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act, which includes several major PBM reforms supported by the pharmacy community.[66] This legislation, combined with earlier legislation passed by the committee in July, the Modernizing and Ensuring PBM Accountability Act (MEPA), will begin to address the opaque business practices of PBMs.[67]

One notable provision in the Senate legislation will require that an "essential" independent community pharmacy cannot be reimbursed by PBMs or health plans lower than the average National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee. NADAC is the approximate invoice price pharmacies pay for medications in the United States. The provision is designed to create a national benchmark that is reflective of the prices paid by community pharmacies to acquire prescription drugs. However, this provision would only take effect after CMS issues a request for information in 2025 with implementation beginning in 2028. State and national pharmacist organizations have provided data to both Congress and CMS showing that many rural pharmacies will not likely be open in 2028.[68]

MEPA provisions include[67]

- Delinking PBM compensation from Medicare Part D drug prices and increasing PBM transparency
- Requiring PBMs to provide pharmacies with information on all components to price a Medicare Part D claim
- Requiring HHS to establish standardized pharmacy quality and performance measures under Medicare Part D
- Prohibiting PBM spread pricing in Medicaid and Medicaid managed care plans (in which PBMs overcharge a state Medicaid program and underpay network pharmacies and keep the spread)
- Including NADAC as a floor for future Medicaid pharmacy payments

Pharmacist organizations were also successful in securing the following key amendments during the committee's consideration of this legislation:[69]

- Ensuring pharmacy reimbursements include professional dispensing fees
- Expanding the definition of essential independent pharmacies
- Increasing the number of reasonable and relevant contract term violations that pharmacists can report to CMS
- Ensuring pharmacies are not underpaid for dispensing certain discount-eligible drugs under net prices
- Increasing congressional oversight of CMS' implementation of the final rule on Medicare Part D reimbursements and DIR fees (e.g., the DIR cliff)

Outlook

As of the writing of this article, the next step for federal PBM legislation is a vote in the full Senate. The House of Representatives also has several PBM reform bills and plans to incorporate many of the Senate's provisions through its committees in the next few weeks. With broad bipartisan support, PBM reform should be passed into law by the end of 2023 or early 2024.

PBM reform in the states

Comprehensive PBM reform legislation continues to be a goal for states across the country. Many states continue to focus on increasing oversight of PBMs as well as creating a system of enforcement to ensure compliance with laws and regulations that have previously been adopted. As pharmacy reimbursement rates continue to decline and reports of pharmacies clos-

ing grow, there has been an increased focus in the states on establishing sustainable reimbursement rates for pharmacies and payment methodologies that can adjust for reimbursement as the price of medications or the cost of dispensing increases.

The following are examples (this list is not intended to represent a comprehensive listing) of state policy changes impacting PBMs in 2023.

At the time of this writing, examples of states that implemented PBM laws or regulations include the following.

Arizona
SB 1382 requires PBMs to obtain certification in the state and increase oversight and enforcement measures to ensure PBMs are complying with state laws and regulations.[70]

Arkansas
SB 94 expands the insurance commissioner's authority to provide oversight of PBMs and enforce state laws.[71]

Colorado
HB 1227 expands the power of the insurance commissioner to enforce state laws and regulations that prohibit various PBM actions that can negatively affect patients and pharmacies.[72]

Florida
SB 1550 enacts comprehensive efforts to certain business practices of PBMs.[73]

Idaho
H 215 and H 291 grants the director of the Department of Insurance the power to enforce current PBM laws and establishes a PBM appeals process for pharmacies.[74,75]

Illinois
HB 3631 expands protections for pharmacies, including prohibiting PBMs from retaliating against a pharmacist or pharmacy for disclosing information to a government or law enforcement agency.[76]

Iowa
HF 423 creates protections from PBMs for contract pharmacies and covered entities in the 340B program.[77]

Louisiana
HB 548 creates protections from PBMs for contract pharmacies and covered entities in the 340B program.[78]

Maryland
HB 374/SB 565 establishes requirements for PBMs when conducting audits of pharmacies or pharmacists and requires the Maryland secretary of health to promulgate regulations on PBM audit practices.[79,80]

Montana
HB 379 maintains protections for contract pharmacies and covered entities in the 340B program from PBMs.[81]

Nevada
AB 434 establishes protections for contract pharmacies and covered entities in the 340B program from discriminatory practices by PBMs.[82]

New Jersey
A 536 establishes greater oversight over PBMs in the state and prohibits specific actions by PBMs, including mandating patients use mail-order pharmacies and prohibiting the inclusion of pharmacist gag clauses in contracts.[83]

North Dakota
SB 2378 prohibits mandates for white bagging (when insurers require certain prescribed drugs be dispensed from a specific specialty pharmacy and shipped directly to a practice, hospital, or clinic for patient administration) and brown bagging (when a specialty pharmacy ships a medication prescribed by a health care practitioner directly to the patient, who then brings the medication to the site of care for the health care practitioner to administer it) by health plans and PBMs related to clinician-administered drugs.[84]

Oregon
SB 192 and HB 2725 require PBMs to submit annual reports to the Oregon Department of Consumer and Business Services about certain rebates, fees, price protection payments, and other payments received from pharmaceutical manufacturers.[85,86] Additionally, the resulting law prohibits PBMs from retroactively denying or reducing payment on claim after adjudication, unless it is agreed that the payment was made in error.[85,86]

SB 608 requires that the state Medicaid program conduct a survey every 3 years to determine the cost of dispensing and update dispensing fees based off the results of the survey.[87]

South Carolina
S 520 makes numerous changes to state law to reform PBMs, including expanding oversight of PBMs during audits of pharmacies, and prohibiting certain patient steering activities by PBMs.[88]

South Dakota
HB 1135 expands PBM licensure requirements, sets reporting requirements for PBMs, increases oversight of PBMs by allowing health plans to audit PBMs, and bans PBMs from charging pharmacists and pharmacies various fees.[89]

Texas
HB 1647 prohibits white-bagging mandates by health plans and PBMs related to clinician-administered drugs.[90]

Utah
SB 193 prohibits a health insurer from requiring a pharmacy to dispense a clinician-administered drug to a patient with the intention that the patient will transport the drug to a health care provider for administration.[91]

Outlook
States will continue to pursue legislation that increases oversight of PBMs and provides for greater transparency of the price of medications and PBM practices. However, it is anticipated that increased state PBM oversight will also result in legal challenges by PBMs and related trade organizations. It is also uncertain if the outcome of recent court cases will have an impact on state PBM reform efforts.[92]

In the courts

As a result of the U.S. Supreme Court's 2020 decision in the *Rutledge v PCMA* case, the door was opened for states

to pass PBM laws and regulations.[93] Before the Supreme Court ruling, federal courts generally had ruled against states' efforts to regulate PBM activities.[94] As demonstrated above, many states have passed—or are attempting to pass—legislation providing greater oversight, transparency, and regulation of PBMs.

However, this year the Tenth Circuit Court of Appeals recently ruled that parts of federal laws, specifically those governing employer-sponsored plans and Medicare, preempted an Oklahoma state law regulating PBMs which may have broader impacts on the ability of states to regulate PBMs' business practices.[95]

Outlook

The Tenth Circuit's decision is inconsistent with what other federal courts have decided and will lead to additional litigation from PBMs of state laws and regulations that currently provide oversight of PBM business practices. The federal ruling also creates greater confusion rather than providing much-needed clarity for pharmacists regarding their interactions (contracts, claim payments, etc.) with the PBMs.

Drug shortages

Drug shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Manufacturers are required to notify FDA of a permanent discontinuance or temporary interruption in manufacturing that is likely to lead to a meaningful disruption in the supply of a drug or biologic in the United States.[96] FDA works closely with hospitals, pharmacists, Congress, and others to prevent or reduce the impact of drug shortages.

For example, on August 1, 2023, FDA and DEA released a rare joint public letter to provide an update on the recent ADHD drug shortage.[97] The two agencies announced they were working with multiple manufacturers, agencies, and others in the supply chain to reduce the impact of these shortages and asked drug manufacturers to increase production.[97] FDA is also taking steps to support alternative treatment options while there is a shortage and recommends the use of nonstimulant medications.[97] FDA and DEA also stated that some drug manufacturers have allotted production quota they have not fully used and are on track to fall below their allocated quota by 1 billion doses.[97] Both agencies are asking for unused product quota to be reallocated to manufacturers who could produce these drugs.[97]

On November 1, 2023, DEA announced changes to its quota allocation process to be more flexible and resilient in allocation management.[98]

A variety of legislation has also been introduced in the U.S. Congress to address drug shortages that would require earlier notifications from drug manufacturers, increase supply chain resiliency, and incentivize domestic manufacturing. Pharmacist compounding could also play a role (see the compounding section later). Most recently, the chair of the Energy and Commerce Committee, which has jurisdiction over this issue, released draft legislation for comments on several legislative proposals to address drug shortages.[99] Forthcoming legislation is also expected from the Senate Finance Committee.

Outlook

On October 31, 2023, DEA released a proposed rule to adjust the 2023 aggregate production quotas for several controlled substances in Schedules I and II of the Controlled Substances Act and accepted comments until November 30, 2023.[100]

It is unlikely that Congress will be able to reach a consensus on federal legislation to address drug shortages this year.

End of the PHE

The PREP Act provided flexibilities for pharmacists and pharmacy teams to provide critical COVID-19 countermeasures including vaccines, tests, and treatments. While the federal PHE officially ended on May 11, 2023, that alone does not automatically terminate federal PREP Act coverage for a number of these countermeasures provided by pharmacy teams.[101]

Following advocacy by pharmacists and pharmacy organizations, the HHS Secretary issued an 11th amendment to the declaration under the PREP Act in May 2023 that ensures certain pharmacy-provided COVID-19 vaccines and related health care services will continue through December 2024.[102]

PREP Act coverage extended until December 2024 includes

- Coverage for COVID-19 vaccines, seasonal influenza vaccines, and COVID-19 tests.
- PREP Act immunity from liability for pharmacists, pharmacy interns, and pharmacy technicians to administer COVID-19 and seasonal influenza vaccines (to those individuals 3 years and older, consistent with other requirements.)
- COVID-19 tests, regardless of any U.S. government (USG) agreement or emergency declaration.
- Coverage for COVID-19 countermeasures that are provided based on a federal agreement (including the vaccines and oral antiviral treatments purchased and provided by the USG, or directly conducted by the USG, including by federal employees, contractors, or volunteers).
- Coverage for products under an EUA to prevent or treat COVID-19.

In addition, PREP Act coverage that ended on May 11, 2023, (i.e., the end of the PHE) included

- COVID-19 vaccination by nontraditional providers (e.g., recently retired providers and students)
- COVID-19 vaccinations across state lines by licensed providers, pharmacists, and pharmacy interns
- Coverage for routine childhood vaccinations (non–COVID-19)

Outlook

While many of the temporary PREP Act authorities were extended until 2024, Congress needs to pass ECAPS or other federal legislation to establish a permanent payment pathway to preserve patient access to these pharmacist-provided patient care services.

In addition, many of the covered

countermeasures (e.g., oral antiviral treatments) are transitioning to the private sector and commercially available products will no longer be covered under the federal PREP Act.[103]

Federal agency activity

FDA

DSCSA implementation

The Drug Supply Chain Security Act (DSCSA), also known as the "track and trace law," outlines the implementation of certain requirements for enhanced drug distribution security. DSCSA creates an electronic, interoperable exchange of information that identifies and traces certain prescription drugs through the supply chain down to the package level. DSCSA requires pharmacies, referred to as "dispensers" in the law, to have systems and processes in place to comply with the law.

DSCSA established a stepwise implementation plan for different requirements over 10 years. The final requirements were expected to go into effect on November 27, 2023. Much of the supply chain, including dispensers, was not ready to comply with the requirements by that date. As a result, on August 25, 2023, FDA announced a 1-year "stabilization period" of these final requirements to provide additional time to work with trading partners to establish interoperable connections for compliance with the law and avoid supply chain disruptions.

Outlook

FDA's 1-year stabilization period of the final DSCSA requirements will allow all sectors of the pharmaceutical supply chain time to stabilize the complex systems and processes necessary for efficient transactions. FDA has advised trading partners not to delay their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements by November 27, 2024.

Prescription-to-OTC switches

In 2023, there were two notable switches of drugs from prescription to OTC. First, on March 29, 2023, FDA approved a 4 mg naloxone hydrochloride nasal spray for OTC use, the first naloxone product approved for use without a prescription.[104] In the fall of 2023, the OTC version of Narcan nasal spray became available in pharmacies and other retailers in a two-dose package with a 3-year shelf life.[105] Second, on July 13, 2023, FDA approved the Opill (norgestrel) tablet for nonprescription use to prevent pregnancy, which is the first daily oral contraceptive approved for use without a prescription.[106]

Concerns have been raised that patient counseling services could assist patients and caregivers in understanding how to correctly use OTC naloxone and whether OTC norgestrel is right for them.

Outlook

Pharmacists have expressed concerns regarding how moving medications to OTC status will affect the affordability of these drug products and services if health plans no longer cover them. Some naloxone products remain available with a prescription, and initiatives such as standing orders issued by health officials (e.g., allowing prescription dispensing absent a patient-specific prescription) represent potential avenues for patients to continue accessing prescription naloxone in an affordable way.[107]

The timeline for the availability of OTC norgestrel has not yet been announced. The manufacturer will determine both the cost and availability of this nonhormonal nonprescription birth control.

On October 4, 2023, the Departments of the Treasury, Labor, and HHS issued a request for information to seek input regarding potential benefits and costs of requiring nongrandfathered group health plans and health insurance issuers offering nongrandfathered group or individual health insurance coverage to cover OTC preventive items and services, such as OTC birth control, naloxone, and others, without cost-sharing and without a prescription by a health care provider and any potential challenges associated with providing this type of coverage.[108] The comment period for this request for information closed in December 2023 and it is unknown what future actions may be taken based on the comments received.

Mifepristone

On January 3, 2023, FDA updated the REMS for mifepristone to remove the in-person dispensing requirement and added a new pharmacy certification process, which enabled retail pharmacies that meet certain qualifications to dispense mifepristone directly to patients who have a prescription from a certified prescriber. All other previous mifepristone REMS requirements remained in effect, including the need for prescriber certification and completion of prescriber and patient agreement forms.[109]

Significant legal challenges have called into question the approval and marketing of mifepristone. On April 7, 2023, the U.S. District Court for the Northern District of Texas suspended FDA's approval of mifepristone.[110] In addition, on April 21, 2023, the U.S. Supreme Court announced a stay on this suspension to hear the case.[111]

Outlook

Although most pharmacies have not applied to be certified to provide mifepristone, a few pharmacies have become certified in states where the legal and regulatory conditions are clear.[112]

Petitions are expected to be submitted to the U.S. Supreme Court in early December 2023, and the case is tentatively scheduled to be set for briefing and arguments in April 2024. The Supreme Court ruling on this case could be as early as June 2024.

Compounding

FDA defines compounding as "a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[113] Compounding can also play a role in addressing drug shortages when FDA declares a shortage

and uses enforcement discretion of current laws, as was recently experienced during the PHE.[114] FDA has since announced this flexibility is no longer in effect at the end of the PHE.

Ibuprofen and acetaminophen

In 2023, compounding pharmacist organizations requested temporary guidance from FDA to allow for the compounding by 503A pharmacies of ibuprofen and acetaminophen oral suspensions for pediatric populations until sufficient supply was available across the country.

FDA did not issue 503A-specific guidance. However, FDA did issue guidance for how 503B outsourcing facilities could compound ibuprofen suspension for use in hospitals that was later revised to create a pathway for 503B outsourcing facilities to provide ibuprofen suspension to other 503A facilities, including community pharmacies.[115]

FDA did address 503A pharmacies' ability to compound these drugs in a Q&A document outlining that 503As could produce copies of manufactured drugs as long as the compounding is not done "regularly or in inordinate amounts."[116] However, FDA's guidance on essential copies for 503A facilities provides enforcement discretion for only up to four compounds per month.[117] Without FDA listing ibuprofen suspension on their drug shortage list, 503A pharmacies continue to be very limited in the number of patients for whom they could compound an ibuprofen suspension.

H.R. 167, the Patient Access to Urgent-Use Pharmacy Compounding Act, has also been introduced.[118] This legislation would create a permanent path allowing 503A pharmacies to compound certain medications that are in shortage when those drugs cannot be acquired from manufacturers or 503B outsourcing facilities.[118]

Semaglutide

Recently, the compounding of semaglutide, the active pharmaceutical ingredient (API) in weight loss medications, has been a focus of state boards of pharmacy, which have primary oversight over traditional compounding pharmacies. FDA-approved semaglutide drugs are listed as "currently in shortage" on the FDA drug shortage list. If a drug is listed as "currently in shortage" it may be compounded. However, FDA received reports that some compounding pharmacies may be compounding semaglutide using semaglutide sodium.[119] Semaglutide sodium is not listed as the API in the product labeling of the FDA-approved drug products, does not have a USP monograph, and does not appear on the FDA 503A Bulks List. FDA issued guidance stating they are "not aware of any basis for compounding a drug using these semaglutide salts that would meet federal law requirements."[120]

Outlook

Legislation creating a permanent path to allow 503A pharmacies to compound certain medications in shortage was introduced in the U.S. Congress in 2023 and may gain traction as additional drug shortages continue to go unaddressed, in particular for hospitals and pediatric populations.

DEA

COVID–19 telemedicine flexibilities for prescribing of controlled medications including buprenorphine

On May 20, 2023, DEA announced an extension of the COVID-19 telehealth prescribing flexibilities for controlled substances, including buprenorphine. Under the May 2023 temporary rule, DEA allowed Schedule II–V controlled substances to be prescribed via telehealth without an in-person visit until November 11, 2023.[121] On October 10, 2023, DEA announced a second extension of these telehealth flexibilities for Schedule II–V controlled substances, including buprenorphine to be prescribed via telehealth without an in-person visit until December 31, 2024.

Additionally, prescribing will no longer be limited to patients with an established patient-practitioner relationship until November 11, 2023, which was required under the initial May 2023 temporary rule.[122]

Outlook

DEA is considering nearly 38,000 comments on their temporary rule to extend the COVID-19 telehealth prescribing flexibilities for controlled substance prescribing, including buprenorphine. DEA plans to finalize a rule on telehealth prescribing of controlled substances, including buprenorphine, before the end of 2024. Additionally, DEA is working on a proposal for pill presses and encapsulating machines. Current federal law requires a seller to file a report of the transaction to DEA via DEA Form 452 within 15 calendar days after the order has been shipped by the seller. DEA intends to propose that sellers notify the agency of these transitions 15 days prior to being shipped by a seller to combat counterfeiting drugs.

Pharmacist training and prescribing of buprenorphine

With the HHS Secretary's renewal of a nationwide opioid PHE, legislation that addresses OUD treatment remains crucial.[123] Last year, President Biden signed into law the Consolidated Appropriations Act for 2023, which includes the Mainstreaming Addiction Treatment Act provision, which removed federal barriers to accessing medications for OUD by eliminating the X-waiver that was preventing many health care providers, including pharmacists, from prescribing buprenorphine for OUD. The passage of this legislation signaled a significant step toward removing barriers that prevented pharmacists and other providers from prescribing medication-assisted treatments, which is critical to the prevention of OUD.

Currently, 11 states allow pharmacists to prescribe controlled substances such as buprenorphine for patients with OUD pursuant to varying CPAs and practice settings within each state.[124]

Outlook

Under the Medication Access and Training Expansion Act, in order to prescribe buprenorphine for OUD, specific training is required. However, no pharmacy organization was spe-

cifically listed to provide the required training for health care professionals. Efforts currently are underway to include APhA and ACPE as providers of this training in legislation for pharmacists.

Suspicious orders

Research in North Carolina and Kentucky has found that many pharmacists are concerned that ordering buprenorphine from their wholesaler will trigger a DEA investigation.[125,126] DEA does not specify thresholds for controlled substances, but it requires wholesalers to flag suspicious orders. In turn, wholesalers typically limit how much a pharmacy can buy or use algorithms to detect orders that exceed projected need.

Wholesalers impose these limits, in part, as a result of opioid litigation settlements and DEA's enforcement actions. As a result, because pharmacies are not typically privy to the limits or algorithms, they often order small amounts of buprenorphine out of caution. The result is what the researchers in Kentucky call a "prescribing cliff," in which physicians may prescribe buprenorphine to more patients, but pharmacies only order enough for their patient base. The research finds that, once the pharmacy hits its self-established quota, newly prescribed patients may not be able to locate a pharmacy that has the supply to fill their prescriptions.

This higher level of scrutiny is not limited to buprenorphine, as many pharmacies are finding that their controlled substance purchasing suddenly may be cut off by their wholesaler with little explanation.

Outlook

Pharmacists are engaging with wholesalers and DEA to ensure legitimate access to buprenorphine to treat patients with OUD. Currently, many pharmacies are not incentivized to order larger quantities of buprenorphine due to DEA's aggressive enforcement toward pharmacies trying to dispense additional medication where DEA can revoke a pharmacy's registration to dispense controlled substances.

2022 Pharmacist Manual change for prescription SLCPs, including pseudoepherine

DEA's 2022 edition of the Pharmacist's Manual indicated that the federal daily sales quantity limit of 3.6 g and the 9 g monthly limit would apply when a pharmacist dispenses a scheduled listed chemical product (SLCP), including pseudoephedrine pursuant to a prescription.[127] DEA's 2022 update was a reversal of its previous policy and would cause access issues by limiting a patient from receiving needed medication pursuant to a prescription by hitting quantity limits not previously imposed on prescription SLCPs.

Outlook

On July 11, 2023, DEA announced an "interim remedy" that the federal 3.6-gram daily sales limit and logbook requirements will not apply for SLCPs, including pseudoephedrine, if they are issued by prescription in accordance with state laws. However, DEA is planning to issue a formal Q&A document in 2024, which is currently under formal review with the Department of Justice and may or may not align with this interim policy.

CMS

As the largest federal government payer for medications dispensed and services provided to our nation's seniors, CMS policies have a major impact on access and availability for Medicare patients to get care at pharmacies across the country. These policies and how they are carried out by Part D plans and PBMs threaten the ability of pharmacies to stay open and make health care services available, particularly in rural and underserved areas, and areas with pharmacy deserts.[128]

DIR cliff

Under the Medicare Part D program, beginning January 1, 2024, all price concessions (including retroactive DIR fees) are moved into the "negotiated price" at the pharmacy counter. This provides consistency for Part D plans and transparency for patients' co-share amount. However, CMS has also allowed PBMs' unrestricted use of DIR fees until then, which increased in PBMs' 2023 contracts with pharmacies. CMS is also implementing a floor for pharmacy payment at the "lowest possible reimbursement," in 2024 which sets up the DIR cliff mentioned above.

APhA recently met with the CMS Administrator to discuss this issue and secured a CMS memorandum to all Part D plans strongly encouraging Part D plan sponsors to provide payment plans or alternate payment arrangements to pharmacies in advance of the January 1, 2024, effective date to address the DIR cliff. CMS also stated the agency will "closely monitor plan compliance with pharmacy access standards" and "ensure that all Medicare Part D beneficiaries continue to have access to pharmacies and medications." However, Part D plans have yet to announce the availability of any such payment plans for pharmacies' 2023 DIR fees.

Under current law and CMS regulations, Part D plans have "[t]o agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy."[129] Despite issuing guidance in 2015, CMS has been lax to enforce the "any willing pharmacy" law intended to prevent the exclusion of pharmacies from Part D plan networks.[130]

Medicare drug negotiations

CMS announced the first 10 drugs covered under Medicare Part D selected for negotiation.[131] The negotiations with participating drug companies will continue into 2024, and any negotiated prices will become effective beginning in 2026. The number of drugs subject to Medicare's drug negotiation will increase to 20 drugs (including Part B drugs) by 2029, with stiff penalties for manufacturers that do not negotiate. However, CMS will delay negotiation for biologics if a biosimilar is highly likely to be licensed within 2 years of the biologic drug becoming eligible for negotiation.

Outlook

Pharmacist organizations continue to urge CMS to use its current regulatory authority to require "reasonable and relevant" Part D contracts to delay collection of 2023 pharmacy price concessions/DIR fees to allow vulnerable pharmacies time to address continuing cash flow issues in 2024.

For Medicare drug negotiation, pharmacists continue to express concerns that lower government-negotiated prices may not cover the full costs of drugs, dispensing, and any associated pharmacist services. Reimbursements for pharmacies may also be lower under the new price negotiation framework, as any difference between the "negotiated price" and the new "discounted price" may be subject to remuneration (clawbacks and/or DIR) by PBMs. Clarification by Congress and CMS is needed to ensure that these new Part D negotiated rates will not reduce payments to our nation's pharmacies.

Conclusion

Legislative and regulatory activity at the state and federal levels continues to impact, for better and for worse, pharmacists and pharmacy teams' ability to practice at the top of their training and experience, as well as keep pharmacy in business and doors open. Pharmacists should continue to work with their state and national pharmacy associations and reach out to state and federal legislators, pharmacy boards, and regulators to make the case for ensuring access to pharmacists' patient care services for testing, immunizing, treating, and more. The barriers to advancing the profession and addressing harmful actions by corporate or government entities continue to be challenging. APhA and our partners have proven that when pharmacy joins together, we can achieve great advancements for the practice of pharmacy.

APhA offers regular comprehensive reviews of legislative and regulatory issues and provides numerous tools and resources for pharmacists who choose to advocate on behalf of their profession. APhA's advocacy efforts include legal, legislative, and regulatory actions on behalf of pharmacists and the patients who rely on our care. APhA will continue to drive change and keep our members, including pharmacists, student pharmacists, pharmacy technicians, pharmaceutical scientist members, and other relevant parties, up to date and engaged in a variety of important ongoing national developments to keep moving the pharmacy profession forward.

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Accreditation information

Provider: APhA
Target audience: Pharmacists
Release date: January 1, 2024
Expiration date: January 1, 2027
Learning level: 2
ACPE Universal Activity Number: 0202-0000-24-002-H03-P
CPE credit: 1 hour (0.1 CEU)
Fee: There is no fee associated with this activity for APhA members. There is a $25 fee for nonmembers.

APhA is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). The ACPE Universal Activity Number assigned to this activity by the accredited provider is 0202-0000-24-002-H03-P.

CPE Assessment

This assessment must be taken online; please see "CPE information" in the sidebar below for further instructions. The online system will present these questions in random order to help reinforce the learning opportunity. There is only one correct answer to each question.

1. **What federal legislation would recognize pharmacists as providers under Medicare for testing, treatment, and immunization services?**
   a. H.R. 1770, S. 2477, the Equitable Community Access to Pharmacist Services Act
   b. H.R. 1000, S. 3200, the Lower Costs, More Transparency Act
   c. H.R. 6000, S. 4101, the Allied Health Workforce Act
   d. H.R. 1550, S. 497, the More Pharmacists in Underserved Areas Act

2. **When does the DSCSA stabilization period end?**
   a. December 31, 2023
   b. January 1, 2024
   c. February 14, 2027
   d. November 27, 2024

3. **How long is the current DEA extension for telehealth prescribing flexibilities without an in-person visit?**
   a. November 11, 2023
   b. February 14, 2024
   c. December 31, 2024
   d. August 13, 2025

4. **In how many states can a pharmacist provide services to a patient via a CPA?**
   a. 13
   b. 26
   c. 49
   d. 50

5. **The "track and trace law" refers to which piece of legislation?**
   a. Mainstreaming Addiction Treatment Act
   b. SUPPORT Act
   c. Drug Supply Chain Security Act
   d. Medication Access and Training Expansion Act

6. **Which bill in 2023 expands the insurance commissioner's authority to provide oversight of PBMs in Arkansas?**
   a. SB 94
   b. HB 1227
   c. SB 1550
   d. H 215

7. **On which day did the public health emergency officially end?**
   a. May 11, 2023
   b. November 1, 2023
   c. March 23, 2023
   d. January 1, 2023

8. **What is the estimated cost of ECAPS according to an independent study?**
   a. $2.1 billion over 10 years
   b. $1.8 billion over 10 years
   c. $2.5 billion over 10 years
   d. $1.3 billion over 10 years

9. **How many first Part D drugs covered under Medicare Part D has CMS selected for negotiation?**
   a. 20
   b. 10
   c. 60
   d. 35

10. **How many states allow pharmacists to prescribe controlled substances such as buprenorphine for patients with OUD?**
    a. 50
    b. 24
    c. 11
    d. 30

CPE information

To obtain 1 hour of CPE credit for this activity, complete the CPE exam and submit it online at www.pharmacist.com/education. A Statement of Credit will be awarded for a passing grade of 70% or better. You have two opportunities to successfully complete the CPE exam. Pharmacists and technicians who successfully complete this activity before January 1, 2027, can receive credit. Your Statement of Credit will be available online immediately upon successful completion of the CPE exam.

This policy is intended to maintain the integrity of the CPE activity. Learners who successfully complete this activity by the expiration date can receive CPE credit. Please visit CPE Monitor for your statement of credit/transcript.

To claim credit
1. Go to http://apha.us/CPE0124.
2. Log in to your APhA account, or register as a new user.
3. Select "Enroll Now" or "Add to Cart" (click "View Cart" and "Check Out").
4. Complete the assessment and evaluation.
5. Click "Claim Credit." You will need to provide your NABP e-profile ID number to obtain and print your statement of credit.

Assistance is available Monday through Friday from 8:30 am to 5:00 pm ET at APhA InfoCenter by calling 800-237-APhA (2742) or by e-mailing infocenter@aphanet.org.

Across

8 Used in Moderna and Pfizer COVID-19 vaccines
9 H1-receptor antagonist used to treat nausea during pregnancy
10 Enzyme that catalyzes phosphorylation
11 A previously prescription-only NSAID that is now available over the counter
12 Green fruit high in vitamin C
13 Irregular heartbeat
17 A _____ from a rabid animal requires treatment
18 Containing element 53
19 Part of a molecule
20 Antidepressant that some patients take once weekly
22 Hydrated magnesium silicate powder
23 Opioid antagonist medication used to reverse an overdose
27 Food containing probiotics
28 Fungal bloodstream infection
29 One billionth (prefix)

Down

1 With "intelligence," subject of this month's cover story
2 Lotion used for itching caused by poison ivy
3 Epinephrine
4 Impulse transmitter
5 Gymnast's feat
6 Type of muscle
7 Joint that connects the femur and the tibia
14 Multiple forearm bones
15 Noisy blather
16 Inhalation anesthetic
19 Causes of immune responses
21 Eggs, e.g.
24 Berry often used in smoothies
25 Probabilities
26 Loveable red *Sesame Street* character

Solution is available online at pharmacytoday.org.