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QUARTERLY PUBLICATION OF THE MISSISSIPPI PHARMACISTS ASSOCIATION

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WINTER 2023

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Mississippi Pharmacist

VOL XLVIII, No. 4 | Winter 2023 | Growing Stronger Together at MPhA

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This emblem designates *Mississippi Pharmacist* is a member of the State Pharmaceutical Editorial Association, recognizing its high journalistic standards in endeavoring to keep its members well informed on all developments relative to the pharmaceutical profession.

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PRESIDENT'S MESSAGE



Members of MPhA,

We are in the midst of the holiday season. It brings both joy and challenges. It is a busy time of the year with lots of competition for our attention. However, we should take the opportunity to appreciate our blessings. Enjoy the time, though often limited, you get to spend with your family and friends. We often do not appreciate how precious this time together is until it is no longer available.

As we plan for 2024, we can make certain predictions with expected accuracy. We will continue to write 2023 on dated documents for a few weeks. Community pharmacy customers will insist, "Oh no, I don't have a deductible." We will need to learn the new lists of formulary preferred medications. There are many other examples specific to our particular practice sites as well.

However, there are also areas of uncertainty. What workplace mandates await us in the new year? What is the future of utilizing technicians in immunization efforts? How expensive can newly approved medications become? We must find ways to adapt to the changing landscape.

As one year ends and another begins, one's thoughts turns toward the future. Sometimes we plan for the immediate future and what lies ahead in the new year or even just this month. However we must also maintain a vision for the longer term. Along with everything happening in close proximity to us relative to both time and location, we should continue to be mindful of the upcoming legislative session.

The recent statewide election resulted in two pharmacists serving in the Mississippi House, John Read (District 112) and Andy Stepp (District 23). While this can be helpful, we, as a profession, need to remain attuned to activities at the Capitol. We need to present ourselves with a unified front. This is an area where MPhA can provide value. We utilize a lobbyist to help present accurate information, as well as our point of view to the legislators. We have a Government Affairs Committee, chaired by Cliff Kelly, charged with watching for legislative proposals with the potential to impact the profession of pharmacy. We have PAC funds to help provide access to have our voice heard.

When you are renewing your pharmacy license, remember to also renew you MPhA membership at <https://www.mspharm.org/membership>.

This membership renewal process also provides an opportunity to financially support the PAC. I would like to encourage you to seriously consider a PAC donation. It can make a difference.

I also encourage you to visit the Secretary of State website at <https://myelectionday.sos.state.ms.us/VoterOutreach/Pages/VODashboard.aspx>.

This will allow you see who is representing you in the Legislature. Enter your address on the website and look for the "View My Office Holders" icon. This information can be quite valuable when there is a need to contact your State Representative or Senator. The points of view of constituents are quite impactful when they are deciding how to vote on issues.

Speaking for the Executive Committee of MPhA, I want to re-emphasize how highly we regard our commitment to the profession of Pharmacy in the State of Mississippi. We seek your input. We are able to better attend to your values and concerns when we know what they are. Fasten your seat belts and hang on – we do not know the ride awaiting us when the legislature convenes for 2024.

Thanks for all that you do,

A handwritten signature in black ink, appearing to read "Richard L. Ogletree, Jr.", written in a cursive style.

Richard L. "Buddy" Ogletree, Jr., PharmD, RPh

MPhA President



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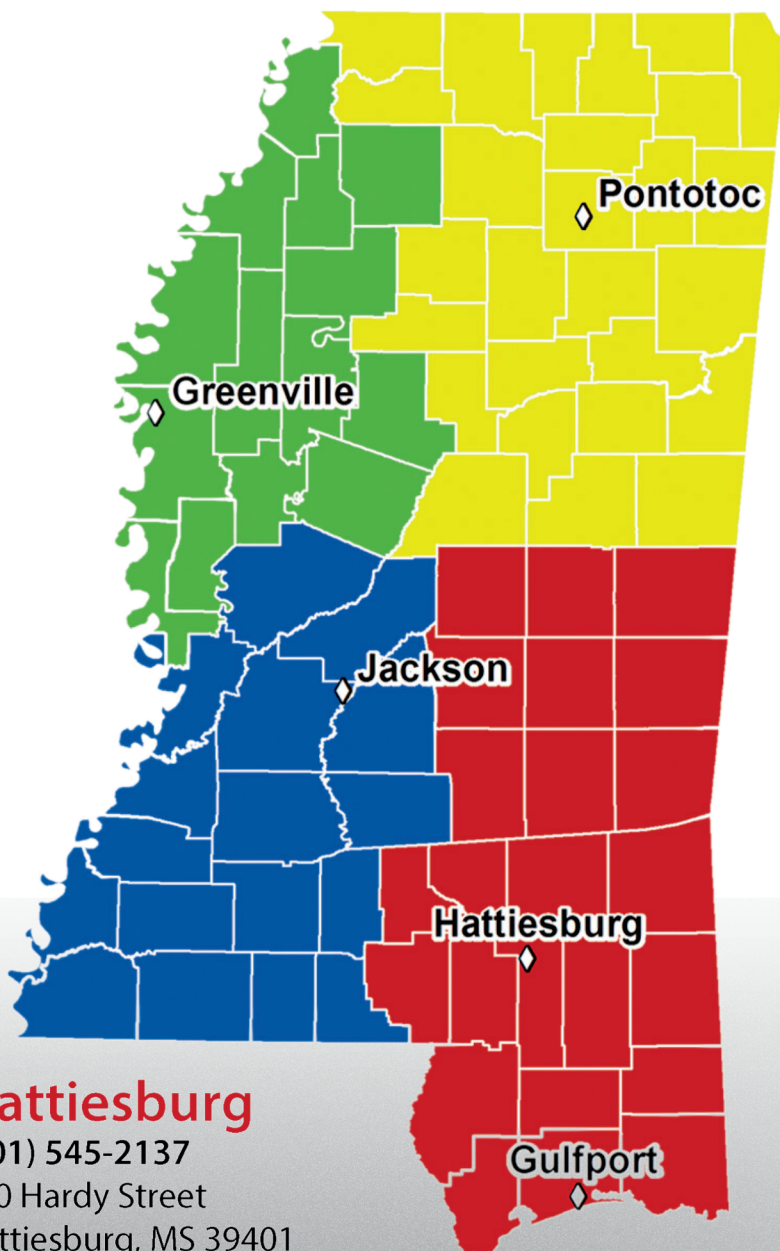
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EXECUTIVE DIRECTOR'S LETTER



Our journal theme is “There is no place like Home for the Holidays”. During this time of year, I pray that you take time for your families, friends and loved ones. Unplug and be intentional and enjoy every moment. As I reflect over this year, I am so encouraged by our students and pharmacists.

In the face of unprecedented challenges, I want to take a moment to recognize the unwavering dedication and resilience that you have demonstrated as frontline healthcare professionals. The ongoing global health crisis has placed immense strain on our healthcare system, and pharmacists like you have been at the forefront of the response ensuring that patients receive the medications and support they need.

Your commitment to providing essential healthcare services during these trying times has not gone unnoticed. You have faced numerous obstacles from supply chain disruptions to increased workload and exposure risks, yet you have continued to serve your communities with professionalism and compassion. Your resilience in the face of these challenges is truly remarkable, and it serves as an inspiration to all of us. As we continue to navigate the evolving landscape of healthcare, I want to encourage you to remain steadfast in your dedication to your profession and your patients. Resilience is not simply about enduring hardships, but also about adapting and persevering in the face of adversity. It is about drawing upon your strength and expertise to overcome obstacles and continuing to provide high-quality care.

I urge you to prioritize self-care and well-being as you confront the demands of your profession. Taking care of your physical, mental, and emotional health is essential to sustaining the resilience that you demonstrate every day. Reach out for support when needed and remember that you are valued and appreciated for the critical role you play in healthcare delivery. In addition, I want to emphasize the importance of teamwork and collaboration within the pharmacy community. By coming together, sharing best practices, and supporting each other, we can bolster our collective resilience and better serve our patients and communities.

By fostering a culture of support and camaraderie, we can navigate challenges more effectively and ensure that no pharmacist feels isolated in their efforts. I understand that the demands placed upon you have been extraordinary, and I want to express my deepest gratitude for your unwavering commitment to your patients and profession. Your resilience in the face of adversity is crucial to our healthcare system's ability to weather this storm and to emerge stronger on the other side. In closing, I want to reiterate my support for you and all pharmacists across the state. Your resilience, dedication, and professional expertise are integral to our healthcare system, and I am confident that together we can overcome the challenges that lie ahead. Thank you for your exceptional service and for embodying the true spirit of resilience. MPhA is committed to advocate on your behalf to provide robust continuing education, and to be a resource for our pharmacists. We are working diligently advocating for provider status and PBM reform. Thank you for what you do every single day.

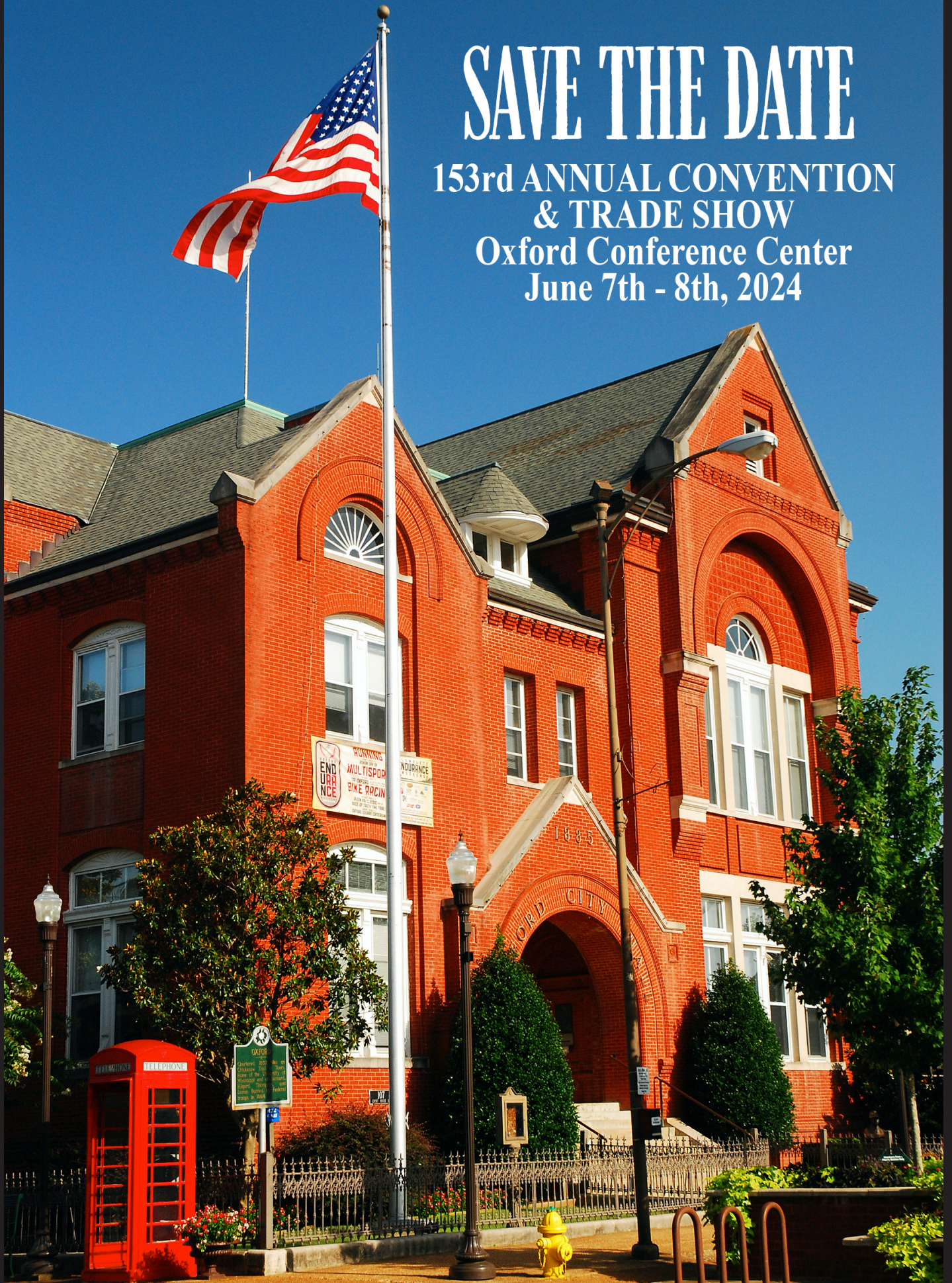
Sincerely,

A handwritten signature in cursive script that reads "Mona Arnold-McBride".

Mona Arnold-McBride, PharmD
Executive Director

SAVE THE DATE

153rd ANNUAL CONVENTION
& TRADE SHOW
Oxford Conference Center
June 7th - 8th, 2024



MISSISSIPPI PHARMACISTS ASSOCIATION



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2023 CONSULTANT SEMINAR



The Mississippi Pharmacists Association held the 2023 Consultant Seminar on Thursday, September 28, 2023, at the Community Bank Building in Flowood, Mississippi. It was a wonderful day of learning for Consultants and Pharmacists.

Our Education Committee pulled together 8 hours of Continuing Education. The topics were very informational, and the speakers kept the crowd involved and engaged, even after a large meal was served for lunch.

We would like to thank everyone that attended and made the event such a huge success. It was a great day of learning. A special thanks to Noble Health Services for sponsoring a great lunch!

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2023 Student Scholar Leaders Program

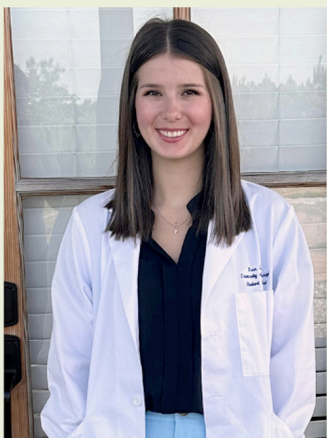
In an effort to foster leadership qualities and networking skills in pharmacy students with an interest in community pharmacy, the American Association of Colleges of Pharmacy and Academia-Pharmacy Transformation (ACT) Pharmacy Collaborative have partnered with various national pharmacy associations to develop the Student Scholar Leaders Program. This program will consist of 50 students from around the nation who will meet virtually and work together throughout this upcoming spring to participate in synchronized learning alongside national community pharmacy professionals and faculty leaders. Of the 50 students that were selected nationwide to complete this program, we are proud to say that 4 of them (pictured below) are students at The University of Mississippi School of Pharmacy. This program is set to kick off in January of 2024.



**DELANCY
ANDERSON**



**ELIZABETH
JENKINS**



**ERIN
PEARSON**



**JOHN
WHITE**

UNIVERSITY OF MISSISSIPPI ADVOCACY COUNCIL

The University of Mississippi Advocacy Council - School of Pharmacy (UMAC-SOP) aims to foster student advocacy within the profession, coordinate policies affecting it, and involve external constituents in supporting pharmacy-related policies and legislative initiatives. In an effort to do so, UMAC will host events, such as Capitol Day, which provides students the opportunity to network with local legislators and discuss pertinent pharmacy related issues. UMAC will also host multiple speaker events throughout the spring semester focused on different areas in pharmacy advocacy. Pictured below is the 2023-2024 UMAC executive team.



Jacob McGregor
Co-Chair



Eliza Cossar
Co-Chair



John White
Director of Legislative Engagement



Tate Pepper
Director of Student Affairs



Kayla White
Director of Policy



Aly Banys
Director of Communications

Please reach out to sopadvocacy@gmail.com with any questions or recommendations regarding speakers or events!

What's Your Favorite Christmas Tradition?

Ann M. Franklin

Over the years, my family collected holiday books. I wrap 24 of them each year and every night beginning December 1, my children take turns picking a book to unwrap and read as a family. Some are older and more traditional, some are new, but we enjoy slowing down and reading as a family during the busy season. We end on Christmas Day reading the Bible and the story of Jesus' birth.

Andy Stepp

Getting together with family and friends and exchange gifts, laughter and love.

Cindy Noble

Waiting up for St. Nick to arrive.

**Ice skating,
listening to festive
music and seeing
all the wonderful
Christmas lights.**

Callie Finch

Cameron Buss

My favorite Christmas tradition is putting our Christmas tree up with my family and decorating it while listening to Christmas music, drinking boiled custard and eggnog, and eating candy canes. We pick out a new ornament at each family vacation we take, so this night always gives us time to reflect on all of our memories together as we put these ornaments on the tree.

**Putting
lights on the
Christmas
tree with my
kids.**

Matthew Strum

My favorite Christmas tradition is Christmas Eve with my family!

We have a big family, so it's tons of food and there's always wrapping paper everywhere when kids are opening their gifts. I also love putting up my decorations every year. I always turn on Christmas movies and take my time putting everything together.

Anna Touchstone





I love going home for Christmas because my sister and I work together to decorate the house and set up the Christmas tree. I also love baking and icing cookies with my mom to give as gifts to neighbors and coworkers. My dad and I enjoy peppermint hot chocolate and Chick-fil-A's peppermint chip milkshakes as we blast Christmas music. Overall, it makes for a wonderful time of the year!

Kathryn Cavitt



My favorite tradition on Christmas has always been having family over on Christmas Eve. I love it when the house is decorated. The smell of our favorite foods and the excitement of the kids at Christmas. As my children get older, they have left my home to make traditions in their own homes with their own children, but the excitement is contagious. It is such a wonderful time of year. And to think, it all started with the very first Christmas baby. Our Savior was born, and he is the real miracle of Christmas.

Lorie Irby

When asked what his favorite thing about going home for the holidays was, Rocky said that it was without a doubt eating all the home cooked meals!

Rocky Foster



Jennifer Duncan

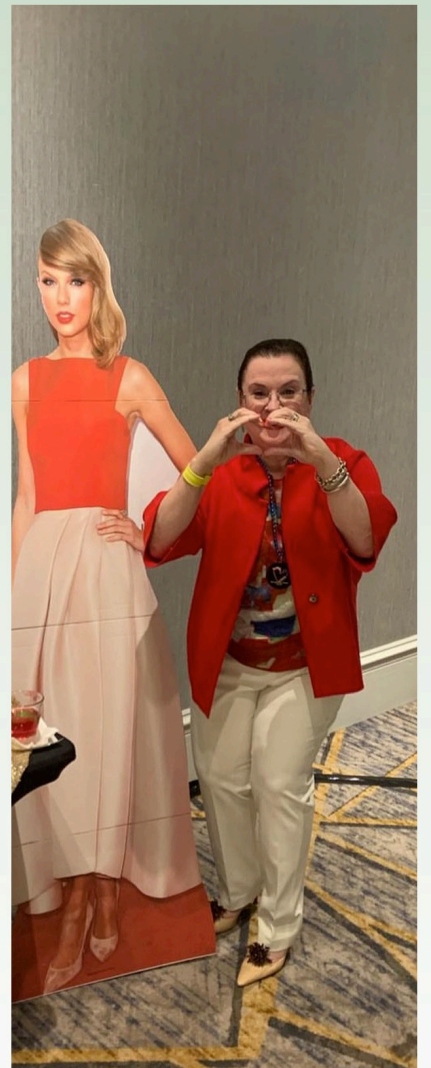
We have two family traditions that are special to me. My mother hands everyone the lyrics to a prayer which we sing as our grace before holiday meals. Hearing twenty to thirty loved ones harmonizing in sung prayer is simply beautiful, from my father's bass to my alto and soprano sisters.

My Aunt Linda made the entire family large, knitted Christmas stockings when we were children. This was in the early 1970s. As the family grew, she knitted more, each one personalized with the name and a unique image. At 85 years, she just sent a package with a stocking for the newest great grandchild.



You've Been Spotted







Mississippi
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Student Spotlight



KATHERINE POLLAN

My name is Katherine Pollan, and I'm currently a fourth-year student at the University of Mississippi School of Pharmacy. I'm originally from Calhoun City, Mississippi, and before starting school at Ole Miss, I attended Northwest Mississippi Community College. I grew up with a lot of influence from different pharmacists in my community and as soon as I got the chance, I began working at our local pharmacy, Chandler's Drug Store in Calhoun City. From there, my love for helping people only grew further. I decided to follow my passion and here we are!

After graduation, I would love to pursue a residency. Since moving to Jackson, I have been able to see how pharmacists are able to build relationships with providers and patients alike, and I am passionate about continuing to do so in order to better serve my community. I have enjoyed getting to see the continued efforts of our pharmacists across the state in advocating for our profession, and I hope to one day have the opportunity to make a difference in some of the laws we pass that ultimately affect our patients' healthcare.

I have truly learned so much about our profession, as well as myself, from being involved in organizations such as Kappa Psi and APhA throughout my time in school. I have also been able to form great relationships with patients while working at both Kroger pharmacy in Madison and in the central pharmacy at UMMC. When I can catch a break from work and school, I enjoy playing golf, reading, and playing with my roommate's dog!

My name is John White, and I am currently a fourth-year pharmacy student at the University of Mississippi School of Pharmacy. I am originally from the small town of Puckett, Mississippi. After attending Copiah-Lincoln Community College for one year, I was able to graduate and begin pursuing my passion for pharmacy at Ole Miss.

My deep-rooted connection with my community is something I take pride in, and I am grateful for the opportunity to serve through aiding my community's medication-related needs. I have seen the impact that a passionate pharmacist can have on his or her community, and I would love to be that pillar in my own small community. My passion for medical studies emerged during high school, fueled by the ambition to provide direct care to my community through the avenue of independent pharmacy. Soon after graduating high school, I began working at an independent drug store, where I worked as a technician all through undergraduate classes as well as the professional program. I already knew much of my community, but this position has given me the ability to grow even closer to members of my community by helping with their medication-related needs. As of now, my plan is to graduate from pharmacy school in May and begin working in the independent setting locally. My ultimate goal is to move into ownership in the independent setting one day if I am blessed enough to do so.

As a student, I strive to stay actively involved in various organizations such as APhA, MPhA, Kappa Psi Pharmaceutical Fraternity, and The University of Mississippi Advocacy Council (UMAC), where I currently serve as the Director of Legislative Engagement. Outside of school, I like to spend my time playing golf, hunting, fishing, and enjoying the outdoors.



JOHN WHITE

OPERATION
IMMUNIZATION
APhA ACADEMY OF STUDENT PHARMACISTS

Special thanks to all the students, faculty, and staff across from both University of Mississippi School of Pharmacy as well as William Carey School of Pharmacy for making Operation Immunization such a success!

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Oxford Campus**



WCUSOP



MPhA would like you to meet our Lobbyist



About Keystone Strategies

Keystone Strategies offers a unique perspective and expertise to help public and private sector clients successfully navigate the complexities of Mississippi state government. Keystone's principal Mark Baker brings experience as a government professional who has been immersed in the public policy and political processes his entire career. As a legislator, Mark secured millions of dollars for authorized, appropriated and grant-funded projects. Coupled with this

are numerous successes on the policy side, many of which broke new ground in the legislative and regulatory processes. Mark's guidance and experience will help you understand and navigate the complex state processes while strategically positioning you to be ready to fight the next battle or capitalize on the next opportunity.



About Mark Baker

Mark graduated from the University of Memphis in 1984 (B.A., Criminal Justice) and Mississippi College School of Law in 1987 (J.D., with distinction). He has been an active member of the Mississippi Bar since 1987 and engages in private practice in Brandon. His main practice areas include government/regulatory law, general litigation, and business and real estate transactions.

Mark served in the Mississippi House of Representatives from 2004 to 2020 and was the House Republican Leader from 2007-2011. As Republican Leader he coordinated the recruitment, fundraising and campaign efforts which led to a Republican majority in the Mississippi House in 2012. Mark served as Chairman of the House Judiciary En Banc and Judiciary A Committees from 2012-2020 and was a member of numerous committees including Appropriations and Ways and Means, Public Utilities, Banking and Finance and Transportation. During

his tenure in the legislature, Mark received various awards and recognitions including the 2012 State Legislative Achievement Award from the U.S. Chamber Institute for Legal Reform, the 2012-2013 Champion for Children Award from Prevent Child Abuse Mississippi, Outstanding Legislator for 2013 by the Mississippi Association of Realtors, 2014 Legislator of the Year by the Mississippi Homebuilders Association, the 2015 Legislative Award from the Mississippi Municipal League, the 2019 MS Top 50 distinction as an elected official, and the 2019 Community Health Center Association of Mississippi's Legacy Award, and received highly favorable ratings from Mississippi Right to Life, the National Rifle Association, Americans for Prosperity, the American Conservative Union, the Mississippi Farm Bureau Federation, Empower Mississippi, the National Federation of Independent Business, and the Business and Industry Political Education Committee.

Mark was born on May 13, 1962, and has been married for 33 years to the former Lady Collins, an English teacher at Brandon High School. They have one son, Chase, who is a recent graduate of Ole Miss School of Law and who is presently serving as a law clerk for Mississippi Supreme Court Chief Justice Mike Randolph. The Bakers are members of Lakeside Presbyterian Church.



Save THE Date



PHARMACY CLASS OF 1974 50-YEAR REUNION

SATURDAY | APRIL 13, 2024 | NOON
OXFORD, MS

The 50 Year Class Reunion will take place during the
2024 Pharmacy Weekend. Schedule of events and
registration to follow.

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Email Judy Polk Clark at judithpclark@gmail.com or Christy Hamachek
Koban at koban8246@bellsouth.net for reunion-related questions.



For Pharmacy Weekend questions, call Mary Kate Skelton
at 662-915-2377 or email marykate@olemissalumni.com



AND THE LAW

By Don. R. McGuire Jr., R.Ph., J.D.

This series, **Pharmacy and the Law**, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

COMPOUNDING DIFFICULTIES

The Food and Drug Administration (FDA) has a number of lists concerning compounding, especially compounding from bulk drug substances. There are lists for both 503A and 503B compounders and there are substantial differences in the lists for these two types of compounders. This article is focused on 503A compounding. The relevant lists are: bulk drug substances that can be used to compound, the withdrawn or removed list, and the Demonstrably Difficult to Compound list. One current issue is the addition of bio-identical hormones being added to the Demonstrably Difficult to Compound list.

Under current law, pharmacies wishing to compound preparations using bulk drug substances under Section 503A of the Food, Drug and Cosmetic Act must use bulk drug substances that meet one of the following criteria: (a) comply with an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph if one exists, and the USP chapter on pharmacy compounding, (b) are components of FDA-approved drug products if an applicable USP or NF monograph does not exist; or (c) appear on FDA's list of bulk drug substances that can be used in compounding if such a monograph does not exist and the substance is not a component of an FDA-

approved drug product. Provision (c) is the list of bulk drug substances that are permitted to be used for compounding for humans.

Pharmacies' compounded preparations that meet these criteria are exempted from some requirements of the Food, Drug and Cosmetic Act, such as the New Drug approval requirements, labeling with adequate directions for use, and current Good Manufacturing Practices requirements. Compounding by pharmacies that is not done within this framework is not exempted from the Food, Drug and Cosmetic Act requirements and those products are considered misbranded and/or adulterated.

The Demonstrably Difficult to Compound list is intended to identify drug products that are, as the name implies, difficult to compound. These difficulties result in an adverse effect on the safety or effectiveness of the preparation. Inclusion of a drug product on the Demonstrably Difficult to Compound list also precludes it being exempted from the Food, Drug and Cosmetic Act requirements as outlined above. The current battle is over the inclusion of bio-identical hormones on the Demonstrably Difficult to Compound list. Pharmacy groups, especially pharmacy

compounding groups, are opposing the addition due to the long safety record of compounded bio-identical hormone use and the potential reduction in therapy choices for patients. The FDA commissioned a report by the National Academies of Sciences, Engineering, and Medicine to investigate compounded bio-identical hormone therapy. Their report was published in July 2020 and recommends the inclusion of hormone compounds on the Demonstrably Difficult to Compound list.

The controversy here is the rationale on which the committee based the recommendation. The stated basis for inclusion on the Demonstrably Difficult to Compound list is complexities involving the formulation, the drug dose delivery mechanism, the dosage form, the ability to control bioavailability, analytical testing, or the compounding process itself. The presence of one or more of these complexities then causes a negative effect on the safety or effectiveness of the compounded preparation. The report cites the lack of data regarding the safety and effectiveness of bio-identical hormone therapy, but does not necessarily cite that this concern stems from the difficulty in compounding these preparations.

The concern is the lack of safety and effectiveness data that meets the standards of FDA approved products. Preparations compounded within the regulatory framework are exempt from meeting the New Drug approval requirements. It seems like a very circular argument that a preparation should not be allowed to be compounded because of the lack of safety and effectiveness data that it is not required to have. This could be said for any compounded preparation, not just bio-identical hormones.

Another concern was the lack of complete labeling for compounded bio-identical hormones. Preparations compounded within the regulatory framework are exempt from the labeling requirements of the Food, Drug and Cosmetic Act. Again, not meeting

a requirement that they are not required to meet.

The report highlights other risks and complexities associated with compounding in general that are not necessarily restricted to only compounded bio-identical hormones, with the exception of pellets.

One of the givens of compounding is that the resulting preparation is not approved by FDA and FDA does not evaluate these medicines for safety, effectiveness, and quality. However, compounded preparations are prescriptions; there is a provider prescribing the compounded drug, it is labeled according to state pharmacy regulations, and pharmacists are performing drug utilization reviews and counseling patients.

Regardless of the basis for inclusion, adding bio-identical hormones to the Demonstrably Difficult to Compound list will remove exemptions from meeting requirements of the Food, Drug and Cosmetic Act and regulatorily prohibit their compounding. Bio-identical hormones have not been added to the list yet, so the battle is not over. The conflict will certainly continue in the courts if they are added.

© Don R. McGuire Jr., R.Ph., J.D., is General Counsel, Senior Vice President, Risk Management & Compliance at Pharmacists Mutual Insurance Company.

This article discusses general principles of law and risk management. It is not intended as legal advice. Pharmacists should consult their own attorneys and insurance companies for specific advice. Pharmacists should be familiar with policies and procedures of their employers and insurance companies, and act accordingly.



Member News

Congratulations!

AND BABY MAKES 3! TYLER AND REGAN MCINTOSH ARE JOINT PHARMACISTS WITH THE MISSISSIPPI PHARMACISTS ASSOCIATION.

THEY ARE WELCOMING A LITTLE OLE MISS REBEL TO THEIR HOME!



Congratulations!

Andy Stepp was elected to the House of Representatives of District 23.

John Read was re-elected to the House of Representatives of District 112.

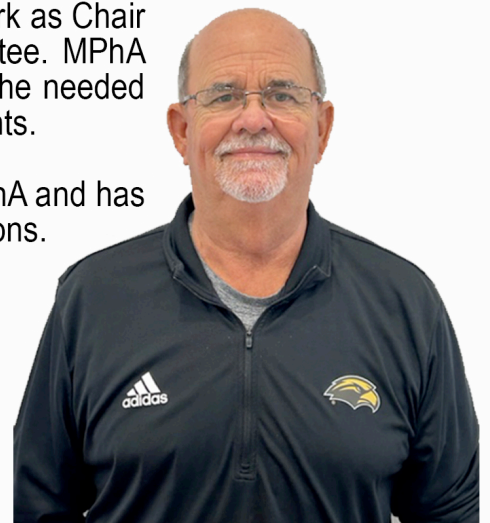
THANK YOU!

Cliff Kelly will be replacing Judith Clark as Chair of the Governmental Affairs Committee. MPhA would like to thank Judith, as well. She needed to step down due to other commitments.

Cliff has been a loyal member of MPhA and has served the Association in other positions.

In addition, Cliff is the Mayor of Mount Olive. He is a devoted fan of the University of Mississippi.

We would like to show our appreciation for his willingness to serve his community and MPhA.



FRANK E. GAMMILL, JR.

Frank E. Gammill, Jr. passed away on November 9th, 2023.

After a 34-year career as an independent pharmacist, Frank began his second career in 1997 as a Senior Compliance Agent with the Mississippi Board of Pharmacy. In 2009, he was promoted to Executive Director until his retirement in 2018.

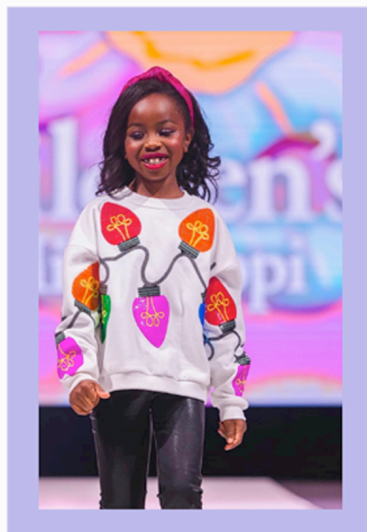
Congratulations



AND BABY MAKES 5!
MEET LENNON KATE FRANKLIN, THE NEWEST
ADDITION TO THE FRANKLIN FAMILY. HER
BROTHERS, DAYSON AND TENNYSON NOW
HAVE A BABY SISTER TO PROTECT.
CONGRATULATIONS WES AND ANN FRANKLIN
SHE IS BEAUTIFUL!

Isn't She Lovely

THE UNIVERSITY OF MISSISSIPPI SPONSORED THE "LAND OF SWEETS" FASHION SHOW AT MISTLETOE MARKETPLACE. RACHEL McBRIDE, DAUGHTER OF RYAN McBRIDE AND DR. MONA ARNOLD-McBRIDE, EXECUTIVE DIRECTOR OF MISSISSIPPI PHARMACISTS ASSOCIATION WAS ASKED TO MODEL. SHOWN HERE WITH ROSEMARY CARGIN, CADENCE BANK, JACKSON, MS. IT WAS A FUN WAY TO KICK OFF THE HOLIDAY SEASON!



BOB LOMENICK

CONGRATULATIONS

Congratulations to Bob Lomenick for winning the 2023 CPESN Luminary of the Year! The University of Mississippi School of Pharmacy is so grateful for his commitment to improving and innovating pharmacy practice.

Bob Lomenick, owner of Tyson Drug Company, is the Lead Luminary for CPESN Mississippi and a Board member of CPESN USA. He is a proud partner with UMSOP. He has been an active member of the Mississippi Pharmacists Association for many years and we appreciate his loyalty to our organization.

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Pharmacists
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As we advocate for our membership, we are always here for you. However, you have things going on in your pharmacy, towns and with your people that we would love to know about! We want to know you and have you know us. We want to share your victories and get to know your people.

We are working on making our Quarterly Journals more about you. We want to have pages that feature pictures that are sent to us from you - students, pharmacists, staff and all our membership and family. If someone gets an award, or someone retires or even just photos of you out and about at parties or weddings, etc. We would love to make our social media and Quarterly Journals as much about you as it is about CE and other issues of importance that are our everyday business.

If you would like to participate, please send your photos with names and what is happening in the photos to Lorie Irby at info@mspharm.org.

We look forward to getting to know each of you and allowing our membership to connect with old friends and make new ones!



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CONTINUING EDUCATION

Update to the 2016 CDC Opioid Guidelines

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OBJECTIVES

By the end of this program, the participant will be able to.

1. Summarize the significant trends and findings related to overdose deaths in Mississippi
 2. Recognize the key updates and differences between the 2016 and 2022 CDC opioid prescribing guidelines, including their development process.
 3. List actionable recommendations from the 2022 CDC opioid prescribing guideline
 4. Characterize the role of a pharmacist in opioid risk mitigation
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The opioid epidemic has rocked the nation, and the state of Mississippi is no exception. The Mississippi 2023 Substance Use Surveillance System report highlights significant trends and findings related to overdose deaths in the state during 2020 and 2021. Their findings suggest there has been an overall increase in overdose deaths in the state which rose by 34% between 2020 and 2021, increasing from 586 to 788 fatalities. Two population groups have been particularly affected by the opioid crisis in recent years. Alarming, one out of every three overdose deaths in 2021 occurred among individuals younger than 35 years of age, indicating a significant impact on younger populations. The majority of overdose fatalities were among Caucasians. ¹

While opioids were the primary substance involved in overdose deaths in 2021, accounting for 70% of fatalities, the number of deaths involving synthetic opioids, particularly fentanyl, increased sharply by 51% during the same period. Synthetic opioids constituted 60% of drug-related overdose deaths, nearly doubling from 35% in 2019. There has been a substantial increase in polysubstance overdose deaths from 2011 to 2020. In 2011, cases of polysubstance use were documented in 17.9% of all overdose fatalities. By 2020, this percentage had risen to over half of all overdose fatalities in our state. The report attributes the steep rise in overdose deaths to two major factors: the ongoing COVID-19 pandemic and increased usage of fentanyl and fentanyl-contaminated drugs. Overdose deaths began to rise before the onset of the COVID-19 pandemic but experienced a significant surge during the pandemic. Fentanyl was identified as a major driver of this increase, with overdose deaths related to fentanyl

escalating during the pandemic's first year, followed by moderate increase in the second year. However, the new Centers for Disease Control and Prevention (CDC) guideline may provide some more insight with regard to the other contributory factors. ¹

The CDC released a new opioid prescribing guideline in 2022, an update from the 2016 offering. While the 2016 guideline was focused on chronic pain, the newer one addresses pain in general. The CDC Clinical Practice Guideline for Prescribing Opioids for Pain is intended to provide clinicians with practical recommendations to reduce risk of developing opioid use disorder secondary to treatment of pain with opioids. The CDC Clinical Practice Guideline for Prescribing Opioids for Pain provides 12 recommendations divided into four key actionable recommendations. The four main areas addressed are: determining appropriateness of initiating opioids, selecting the type and dose of the opioid, determining duration and follow-up time frames, and assessing and addressing risk of opioid use harm. The CDC opioid prescribing guideline updates were developed by conducting five systematic reviews of available evidence on the benefits and risks of prescription opioids. An independent federal advisory committee, peer reviewers, and the public provided reviews for the guideline. The authors of the guideline sought insights from patients, caregivers, and medical providers via a virtual meeting. All this input was reviewed, refined, and incorporated into the final version of the guideline. ² In general, some of the key differences in the updates focused on providing non-opioid treatment for pain, language that promotes slower tapering, prevention of patient abandonment, increased flexibility of opioid use that promotes

clinician professional judgment, plus a greater focus on management of acute pain.^{3,4} Since the release of the 2016 CDC opioid guidelines, there has been a rapid decline in the rate of opioid prescribing by providers.⁴ There has been some increase in the prescribing of non-opioid pain management medication, however, not enough to avert patients turning to illicit use.⁶ According to the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention of the 106,699 drug-involved overdose deaths in 2021, including illicit drugs and prescription opioids, 75% were opioid related.⁵ While the number of prescription opioid overdose deaths have remained relatively the same, there has been a close to doubling in the number of overall opioid related deaths. We have seen a spike in synthetic opioid overdoses, contributing to the increase in fatalities from roughly 47,000 deaths in 2017 to 80,411 in 2021.⁵ These changes were not observed for other drug groups or in other countries.^{5,7}

There are a number of unintended consequences resulting from the 2016 guidelines. States and boards of pharmacy and medicine across the nation developed regulations restricting dose, duration, amount, and when to prescribe opioids to patients.³ These changes may have resulted in consequences that are harmful to patients including rapid tapering of opioids⁸ and patient discharge without recommendation of further care.³ There

are incidences in which the guidelines are being applied to patients excluded from these guidelines, namely cancer and palliative care patients. Other consequences of the misapplication of the guidelines resulted in clinics closing their chronic pain services, certain insurance companies withdrawing coverage for opioid treatment for chronic pain and some prescribers ceasing to prescribe opioids.⁴

CDC Clinical Practice Guideline for Prescribing Opioids for Pain - A Review of Updates^{2,3}

The following is a comparison between four actionable recommendations from the 2016 and 2022 guidelines. A review of the 12 current recommendations which comprise the 2022 guideline are found in Table 1.

1. Determining whether to initiate opioids for acute, subacute, or chronic pain

The 2022 guideline offers additional clarity on the vital role of opioids in managing acute pain, while also highlighting the importance of use in appropriate diagnosis and patient selection. The use of opioids to treat acute pain is recommended in scenarios such as severe traumatic injuries, invasive surgeries with significant postoperative pain, and other cases of intense acute pain where NSAIDs and other treatments are likely to be ineffective or not suitable. The guidance concerning the process of initiating opioid therapy involves considering various factors. These include: the identification of appropriate candidates for opioid treatment, the duration of

Table 1

2022 Recommendation Overview
1. Nonopioid therapies exhibit efficacy for acute pain and should be utilized in conjunction with nonpharmacologic therapies prior to considering the addition of an opioid therapy.
2. Maximize nonpharmacologic and nonopioid treatments. Prior to initiating opioid treatments, engage in conversations about their expected advantages and disadvantages.
3. Initiate opioid treatment with immediate-release preparations as opposed to extended-release preparations.
4. Start with the minimal effective dosage for opioid naïve patients, conducting a comprehensive evaluation of benefits and risks.
5. When dealing with patients already under opioid therapy exercise caution while adjusting doses. Abrupt cessation or rapid reduction of opioids should be avoided.
6. In cases of acute pain, when the severity warrants opioid usage, prescribe the briefest necessary duration.
7. Regularly reassess the balance between benefits and risks, taking into account patient-specific factors in determining visit frequency, not solely dose adjustments.
8. Assess the potential for harm and identify ways to minimize the potential for an overdose including providing information about and access to naloxone.
9. Examine Prescription Drug Monitoring Program (PDMP) data at the beginning of treatment and on a regular basis during chronic opioid treatment.
10. Consider the advantages and disadvantages of utilizing toxicology testing in practice.
11. Exercise prudence when prescribing opioids alongside benzodiazepines due to their additive depressive effects on the Central Nervous System.
12. Extend the offer or arrangement for evidence-based opioid use disorder (OUD) treatment, such as medication-assisted treatment (MAT), involving buprenorphine or methadone. Detoxification alone, without medication, is not recommended for OUD due to the risk of overdose and mortality.

symptoms of the condition, the specific condition under treatment, the presence of alternative treatment options, and consideration of careful analysis in special patient populations.

In response to the constrained prescribing of opioids resulting from the 2016 guidelines, certain providers abstained from opioid prescriptions entirely. The 2022 guideline outlines the scope of application beyond primary care providers to encompass a broader clinical audience. This includes additional clinicians in outpatient settings, such as emergency clinicians who manage pain for patients discharged from emergency departments, as well as dental and oral health clinicians. Clinicians are encouraged to prescribe opioids contingent on the anticipated duration of pain. The specified time frames are as follows: acute pain (enduring less than 1 month), subacute pain (persisting for 1 to 3 months), and chronic pain (extending beyond 3 months). When it comes to addressing subacute and chronic pain, the updated guideline stresses a preference for nonpharmacologic and non-opioid therapies to be maximized prior to initiating opioid options. Opioids are not to be the primary option for routine treatment of subacute or chronic pain, and healthcare providers should consider initiating opioid therapy only if the potential benefits of pain relief and improved function outweigh the associated risks for the patient.

The 2022 update strongly underscores the importance of excluding particular patient populations from this guideline. This effectively rectifies the misconceptions that arose from the 2016 guidelines which caused clinicians to apply the recommendations to all patients despite certain patient populations requiring exceptions for opioid prescribing. These exceptions apply to individuals under palliative care and hospice, undergoing treatment for cancer-related pain, grappling with unmanageable pain conditions, and those facing acute and/or post-operative pain, which includes individuals afflicted with sickle cell disease.

2. Selecting opioids and determining opioid dosages

The CDC guideline no longer imposes specific constraints on the dosage and duration of opioid treatment. The revised guideline adopts a broader and more adaptable approach. Healthcare providers are advised to administer the minimal effective dosage to achieve the intended outcomes, which generally translates to individual doses of around 5 to 10 morphine milligram equivalents (MME), and a daily dosage ranging from 20 to 30 MME for opioid

naïve patients. Current evidence seems to indicate not only does higher daily MME prescription elevate the risk of adverse events, but it is often observed that most individuals do not derive additional pain relief or functional improvement beyond a threshold of 50 MME/day. Both the 2016 and 2022 guidelines remain consistent in recommending that clinicians should initially prescribe immediate-release opioids as opposed to extended-release/long-acting (ER/LA) opioids due to the increased risk for overdose in opioid naïve patients utilizing ER/LA options.

3. Deciding duration of initial opioid prescription and conducting follow-up

During follow-up appointments, the updated 2022 CDC guideline suggests discussing various topics with each patient, including treatment goals, the source of pain, common side effects, and the risk of overdose. When addressing acute pain, clinicians are advised to refrain from prescribing opioids for a period longer than the anticipated duration of pain. The introduction of follow-up appointments enables clinicians to adopt a more personalized and patient-centric approach, liberating them from the previous constraint of prescribing within a 3 to 7-day timeframe. For individuals receiving opioids for acute pain, assessments should occur at least every 2 weeks.

In situations involving subacute and chronic pain, it is plausible to consider an initial follow-up interval of approximately 4 weeks when initiating an immediate-release opioid. However, for individuals commencing treatment with ER/LA opioids, or those undergoing a dosage escalation beyond 50 MME per day, a follow-up interval of 2 weeks is recommended due to the heightened potential for overdose.

It is important to emphasize a notable absence of robust clinical trial evidence regarding the precise timing of follow-up and its correlation with opioid-related adverse events. These adverse events encompass respiratory depression, misuse of opioids, the onset of opioid use disorder, opioid-induced constipation, potentially fatal overdose, and others. Consistent with the 2016 guidelines, the CDC recommends reviewing PDMP data before every opioid prescription, with each visit, and at least every 4 months for individuals on long-term opioid therapy. Additionally, clinicians should regularly assess patient perspectives and goals, inquiring about preferences for continuing opioid treatment based on its effects on pain relief, function, and any encountered adverse effects.

4. Assessing risk and addressing potential harms of opioid use

To mitigate potential risks, the guideline incorporates a patient-centered approach, underscoring the necessity of long-term comparisons between pharmacological and nonpharmacological therapies to ensure the availability of diverse treatment options. The guideline advocates for the inclusion of NSAIDs, exercise, therapy, massage, and other approaches. In accordance with the 2022 guideline, the recommendation is to avoid dosage escalation. Caution is suggested when considering dose increases. Discussion with patients regarding risk, benefits, and treatment goals should play an important part in this decision. Healthcare providers should exercise clinical judgment and be mindful that increases in dosage beyond 50 MME per day tend to yield diminishing returns in benefits relative to risks.

When discontinuing opioids, it is important to acknowledge the considerable adverse effects linked with sudden cessation or rapid tapering of opioid therapy. This process should involve shared decision-making with the patient, allowing them to have a say in the tapering plan, including the pace of reduction and the timing of breaks. It is crucial to emphasize that opioid therapy should never be halted abruptly due to the potential for withdrawal. Therefore, the guideline recommends more frequent scheduled follow-up appointments, ideally on a monthly basis. The 2016 version of the guidelines stated to avoid concurrent use of benzodiazepines and opioids. According to the CDC this resulted in most healthcare providers, governing boards, and agencies making concurrent use of the two an absolute contraindication. The new CDC guideline is more relaxed on this issue, encouraging the use of clinical judgment and prudence when considering prescribing the two medications together.

Guideline recommendations that remained the same

Although there are key changes in the area of risk mitigation, some aspects that remain the same, include offering naloxone and utilization of the state prescription drug monitoring programs. PDMPs are valuable tools for improving patient care, promoting medication safety, and combatting prescription drug abuse. PDMPs help pharmacists identify patients who may be at a higher risk of opioid misuse or addiction, enabling them to intervene with counseling or referrals to addiction treatment programs when necessary. PDMPs allow pharmacists to detect patterns of “doctor shopping” or obtaining multiple

prescriptions from different healthcare providers. This helps deter prescription drug abuse and diversion.⁹ The most immediate and vital advantage of naloxone dispensing is its potential to prevent opioid overdose deaths. Studies and real-world data consistently show that naloxone administration by trained individuals can mean the difference between life and death in overdose situations. Naloxone dispensing programs empower bystanders and communities to take an active role in addressing the opioid crisis. Friends and family members of individuals at risk of overdose are often the first to witness an overdose event. Equipping them with naloxone and training on how to properly administer the medication provides them with the confidence and capability to respond quickly.¹⁰ It is important to remind our patients and their loved ones that anyone can be trained to administer naloxone without any additional specialized training and/or education. Surviving an overdose due to naloxone administration can be a pivotal moment for individuals with opioid use disorder. It can serve as a wake-up call, motivating them to seek treatment and support for their addiction. Naloxone dispensing, therefore, not only prevents immediate harm but also opens doors to long-term recovery and rehabilitation.¹¹

The guideline continues to recommend maximizing non-opioid alternatives prior to initiating chronic opioids. A study comparing the use of opioids versus non-opioid medications for patients with chronic back pain, hip pain, or knee osteoarthritis pain over a 12-month period found that opioids did not significantly improve pain-related function compared to a non-opioid regimen. This study provides evidence that long-term opioid therapy has been associated with poor pain outcomes and functional impairment.¹² Maintaining resources and literature for patients helps them find alternatives to opioids. The CDC guideline also points to various noninvasive, nonpharmacologic strategies of potential benefit in managing subacute or chronic pain. Physical therapy, massage, weight loss and exercise may be beneficial. Other potentially useful strategies include yoga, tai chi, acupuncture and acupressure. Immobilization and the use of ice and heat are inexpensive strategies that can be easily incorporated with other strategies.^{2,3}

Pharmacists can consider offering naloxone, educating patients on risks vs. benefits of opioid use, assessing for signs of opioid use disorder, and providing resources for opioid alternatives. Clinicians should be vigilant for signs of opioid use disorder. These signs may originate from a patient expressing concerns or describing side effects

of the opioid, concerning patterns observed on the PDMP, toxicology screenings, and/or visible alterations in alertness, behavior, or speech. When suspicions arise, clinicians are advised to discuss their concerns with the patient, creating an open dialogue for patients to disclose their related concerns or problems. For patients diagnosed with opioid use disorder (OUD), clinicians are encouraged to offer or arrange evidence-based treatment. This typically involves medication-assisted treatment (MAT) with buprenorphine or methadone, complemented by behavioral therapies.¹³

Role of the pharmacist

Considering the core principles in this updated guideline, pharmacists should be vigilant in reducing the risks associated with opioids by offering naloxone to patients at risk of overdose and using state PDMPs to track opioid prescriptions. Prior to filling an opioid prescription pharmacist should evaluate the patient for any signs of misuse, addiction, or adverse events. Pharmacists should consider the duration of therapy, dose, formulation, and amount of opioids being prescribed. When filling an opioid prescription for a new acute condition for an opioid naïve patient, consider pharmacist intervention when the prescription is not IR formulation, and a single dose is greater than 5 to 10 morphine milligram equivalents (MME). When pharmacists are not able to fill an opioid prescription due to risk mitigation reasons, the pharmacist should provide resources for non-opioid alternatives including physical therapy, non-opioid medications, and non pharmacological interventions.

Engaging in conversations about the advantages and disadvantages of opioid use, risk of overdose, and opioid use disorder treatment discussion is vital to help prevent opioid related complications. Conversations relating to opioids can be sensitive and challenging. Understanding that stigma surrounding opioids requires tact, as patients may be reluctant to discuss opioid use and the risk or presence of substance use disorder. Utilization of motivational interviewing in patients exhibiting signs of abuse could be beneficial to getting the conversation started.¹⁴ The new CDC guideline emphasizes patient-centered care and shared decision-making. Pharmacists should tailor opioid-related conversations to the specific needs and circumstances of each patient by considering the patient's experience with opioids, pain needs, patient goals, culture, etc. Utilization of open-ended questions and active listening will help to ensure understanding between pharmacist and patient. Pharmacists should pay

attention to non-verbal cues and express empathy. Pharmacists should refrain from using stigmatizing language including words like addict, junkie, abuser, dirty vs. clean drug screen or needle, and failed drug screens.¹⁵ The use of stigmatizing language poses significant barriers to individuals with opioid use disorder. It perpetuates social, legal, and health inequities and is deeply ingrained in multiple systems and structures. Such language dehumanizes and isolates patients, leading to feelings of shame and low self-esteem resulting in the loss of rapport between the patient and the pharmacist. The adoption of person-first language, which emphasizes the individual as a whole rather than their affliction, has been shown to reduce stigma and enhance well-being.¹⁶ Some useful tips to consider when initiating the conversations is to outline why you are offering to have the conversation in the first place, explain your goals in talking to the patient. This should include, for example, that there are potential risks associated with your findings on the PDMP or fill history. Outline those risks to include unintentional overdose and opioid use disorder. Express your commitment to the safety of the patient. Pharmacists and patients should engage in shared decision-making, discussing the risks and benefits of opioid therapy, considering alternatives or discontinuation, and discussing treatment for opioid use disorder if deemed appropriate.¹⁷

Strategies that Mississippi has utilized to combat the opioid crisis¹⁸

Mississippi has employed various strategies in response to the opioid epidemic. Firstly, Mississippi has established a comprehensive drug abuse surveillance system. This system collects extensive data on overdose deaths, emergency room visits, hospitalizations, drug-related crimes, medical records, law enforcement agencies, and public health institutions. The surveillance system monitors trends in drug abuse and overdose cases over time. It helps identify which substances are most commonly involved in overdoses, the demographics of affected individuals, and geographical hotspots for drug-related incidents. This information is crucial for tailoring prevention and intervention strategies. The system acts as an early warning system, allowing public health officials to detect spikes or unusual patterns in drug-related incidents. This timely information enables rapid responses and targeted interventions to prevent further harm. Ultimately, the surveillance system allows Mississippi to assess the impact of various interventions and strategies aimed at reducing drug abuse and overdose deaths. By monitoring outcomes, the state can refine

its approaches for greater effectiveness. This is vital in light of the unintentional consequences of implementing the 2016 CDC guidelines. The hope is this system will help to inform the development of evidence-based policies and interventions.

Possibly resulting from the 2016 version of the CDC opioid prescribing guidelines for chronic pain, the state of Mississippi imposed regulation of opioid and benzodiazepine prescriptions. In light of the lessening of these restrictions within the guideline, a review of Mississippi surveillance system data with regard to the relative risk of utilization of the combination of opioids and benzodiazepines compared to single drug use is warranted. Other steps taken by the state include expansion of access to naloxone, and education of medical professionals about the extent of the opioid epidemic.

While these approaches have shown promise, there is a need to adapt new prevention strategies due to changing patterns of overdose fatalities, particularly related to illicit synthetic opioids and polysubstance abuse. The fight against polysubstance abuse should involve collaboration between various state agencies, community stakeholders, and the medical community. Pharmacists play a key role here as we are one of the groups most familiar with utilizing the PDMP in our state and are able to identify patients who are getting multiple prescriptions from different pharmacies and providers.

Conclusion

The updates in the 2022 guideline underscore the importance of fostering patient-centered decision-making and effective communication between clinicians and patients. The strategy involves optimizing nonpharmacological and non-opioid treatments as suitable for various pain scenarios. Opioid therapy for acute pain is now suggested only when potential benefits are projected to surpass potential risks to patients.

The 2022 Clinical Practice Guideline's recommendations are discretionary and designed to be adaptable, enhancing the framework for tailored, patient-focused care rather than displacing it. For the purpose of ensuring access to secure and efficient pain care, individuals responsible for decisions—such as legislators, licensing boards, and regulatory bodies—might consider reevaluating opioid prescribing regulations, policies, and educational initiatives for clinicians. This reevaluation should account for the intricacies of pain management, the

need for subtlety, and the emphasis on patient-centric care, as embodied by the 2022 Clinical Practice Guideline.

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CONTINUING EDUCATION ARTICLE QUESTIONS

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Update to the 2016 CDC Opioid Guidelines

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1. What percentage increase in overdose deaths was observed in Mississippi between 2020 and 2021, as reported in the Mississippi Substance Use Surveillance System?
 - a) 15%
 - b) 25%
 - c) 34%
 - d) 50%
2. According to the Mississippi report, what percentage of drug-related overdose deaths in 2021 were attributed to synthetic opioids like fentanyl, and how does this compare to the percentage in 2019?
 - a) 35% in 2021, no data for 2019
 - b) 60% in 2021, 35% in 2019
 - c) 60% in 2021, no data for 2019
 - d) 40% in 2021, 60% in 2019
3. Of the following, which most accurately represents the 2022 CDC opioid prescribing guideline and how it differs from the 2016 version.
 - a) The 2022 guideline focuses on increasing opioid prescriptions, unlike the 2016 guidelines.
 - b) The 2022 guideline focuses on the same areas and language as the 2016 guidelines.
 - c) The 2022 guideline has more flexible language and focus on opioid treatments, whereas the 2016 guidelines had stricter language.
 - d) The 2022 guideline has no significant differences from the 2016 guidelines.
4. What unintended consequences resulted from the language of the 2016 CDC opioid guidelines, as discussed in the review?
 - a) Increased access to opioid prescriptions.
 - b) Decreased opioid-related overdose deaths.
 - c) Rapid tapering of opioids and patient discharge without adequate care.
 - d) No consequences were observed.
5. What are the suggested future directions for addressing the issue of polysubstance overdoses, as outlined in the review?
 - a) The future directions involve providing more opioids to patients.
 - b) The review does not suggest any future directions.
 - c) Future directions involve collaboration among different state agencies.
 - d) Prevention of substance abuse is considered key because it increases the demand for illicit drugs.
6. According to the 2022 guideline, in which scenario is the use of opioids recommended to treat acute pain?
 - a) Opioids are recommended for all cases of acute pain.
 - b) Opioids are recommended when NSAIDs are effective.
 - c) Opioids are recommended for intense acute pain when other treatments fail.
 - d) Opioids are recommended only for minor injuries.

7. Who is included in the expanded clinical audience mentioned in the 2022 guideline?
- Only primary care providers
 - Emergency clinicians and dental health clinicians
 - Palliative care specialists
 - Patients with chronic pain
8. What is the specified timeframe for subacute pain in the 2022 guideline?
- Less than 1 week
 - 1 to 3 months
 - 3 months to 1 year
 - Over 1 year
9. What is the primary focus of the 2022 guideline regarding therapy for subacute and chronic pain?
- Encouraging long-term opioid use
 - Recommending opioids as the first-line treatment
 - Emphasizing non-opioid therapies
 - Excluding patients with chronic pain from treatment
10. According to the 2022 guidelines, which patients are exceptions and should not be excluded from opioid therapy?
- Patients with acute pain
 - Patients under palliative care and hospice
 - Patients with mild pain conditions
 - Patients with opioid use disorder
11. What is the recommended initial single dosage range of morphine milligram equivalents (MME) according to the 2022 guideline?
- 50-75 MME
 - 100-150 MME
 - 5-10 MME
 - 200-250 MME
12. In the 2022 guideline, what is the threshold dosage beyond which the risk of adverse events tends to increase significantly?
- 5 MME/day
 - 20 MME/day
 - 50 MME/day
 - 100 MME/day
13. What communication approach is emphasized when discussing opioid-related topics with patients, according to the text?
- Using stigmatizing language to create awareness.
 - Employing open-ended questions and active listening.
 - Avoiding any discussions about opioid risks.
 - Focusing solely on patient goals.
14. What is a notable change in the 2022 CDC guideline regarding concurrent use of benzodiazepines and opioids?
- The guideline prohibits concurrent use entirely.
 - The guideline recommends concurrent use without restrictions.
 - The guideline allows for clinical judgment in concurrent use.
 - The guideline recommends higher doses of both medications together.
15. What is one of the primary roles of pharmacists concerning opioids?
- Pharmacists should fill opioid prescriptions without evaluating patients.
 - Pharmacists should offer naloxone to patients only when absolutely necessary..
 - Pharmacists should evaluate patients for signs of misuse, addiction, or adverse events.
 - Pharmacists should always fill opioid prescriptions without any intervention.



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Use As Directed – What is Your Attack Plan?

The top audit discrepancy year after year is invalid days' supply or refill too soon – which are essentially the same issue. Submitting prescription claims with an accurate days' supply is often the responsibility of a pharmacy technician doing data entry, while pharmacists are focused on clinical accuracy and may not be paying attention to this “clerical” issue. It is important that all pharmacy staff members (technicians and pharmacists) understand the audit implications of submitting an incorrect days' supply and how each staff member can contribute to success. With that in mind, the pharmacy team can develop an attack plan to be both accurate and consistent.

First, understand that the submission of an accurate days' supply is important for appropriate claims adjudication and impacts patient copay, pharmacy reimbursement, and PBM refill edits. While PBMs require pharmacies to submit an accurate days' supply, it may be helpful to think of these implications – knowing why helps pharmacy staff understand the importance and may help justify spending the extra time (where appropriate).

Second, staff must be trained how to perform the mathematical calculations. How would your staff estimate the days' supply for an insulin or topical cream prescription with a sig of “use as directed”? If each staff member gives you a different answer, then you have an audit problem waiting to happen. In general, days' supply is simply the total quantity dispensed divided by the daily (or weekly, monthly) dose. Data entry staff should perform the calculations and document, while dispensing technicians and/or verifying pharmacists can double check those calculations for accuracy.

Third, you must have a plan for how to address certain dosage forms where the basic calculation does not come so easily. Common examples include topical creams, vaginal creams, insulin, diabetic test strips, bowel prep kits, migraine meds, starter kits and pancreatic enzymes.

- If a prescription sig reads “use as directed”, then you don't have enough information and must contact the prescriber's office for more information and make a clinical note
- If a days' supply is not calculable, consider a maximum daily dose for insulin, test strips and pancreatic enzymes
- Migraine meds may require an estimated number of headaches per month
- Starter kits should be confirmed “as directed on package”
- Confirm dosing for bowel prep kits – remember products generally have a beyond use date of 48 hours upon reconstitution
- Use the manufacturer dosing calculator for Santyl (santyl.com/hcp/dosingv)

PBM auditors will expect that any clarifications regarding instructions for use end up on the dispensing label to communicate instructions to patients.

PAAS Tips:

- Do not rely on the days' supply field on e-prescriptions alone as it is often incorrect and would not satisfy an auditor (you might even consider the pros versus cons of having e-prescription days' supply field auto-populate)
- Make sure that dispensing technicians and verifying pharmacists can “see” the days' supply during verification, whether performing on screen or reviewing printed “back tags”
- Consider performing small “self-audits” to spot check your team for accuracy and consistency
- If you cannot mathematically estimate the days' supply (with an equation), then an auditor will consider the prescription to be essentially “use as directed” and require more information\

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

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

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

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