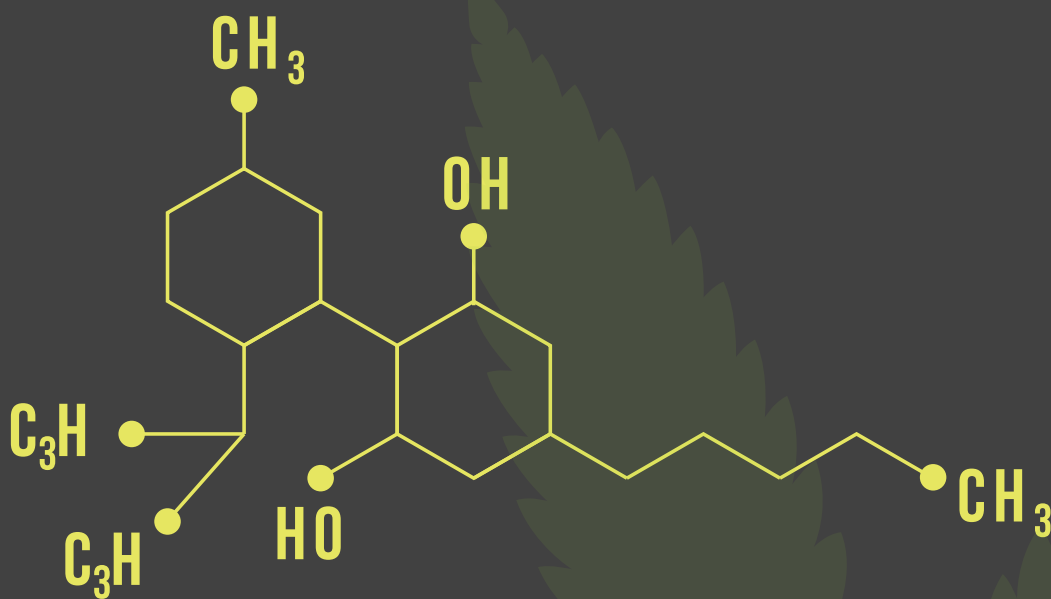


INNOVATIONS®



Growing Market of **CBD** Products Presents Member Boards With **Regulatory Uncertainty, Questions**





INNOVATIONS®

table of contents

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NABP Mission Statement

NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

4 Policy Perspectives

Access to Health Care in Rural America: Are Pharmacists Key to the Solution?

8 Interactive Forum

Compliance Officers, Legal Counsel Address Pertinent Issues at NABP Interactive Forum

14 Association News

NABPLAW Online Transitions to New, Enhanced Platform

16 Interview With a Board Member

Leah Giambarresi, PharmD, RPh

18 State Board News

Ohio Pharmacists Now Required to Report Conduct to the Board

19 Professional Affairs Update

FDA Releases Draft Best Practices Document for Postmarket Drug Surveillance



Feature News

Growing Market of CBD Products Presents Member Boards With Regulatory Uncertainty, Questions



Association News

Illegal Online Opioid Sales Continue to Threaten Public Health

Interview With a Board Executive Director



**Donna C. Yeatman, RPh,
Executive Secretary,
Alabama State Board
of Pharmacy**

Donna C. Yeatman, RPh, Executive Secretary, Alabama State Board of Pharmacy

**How long have you served as director of the Alabama State Board of Pharmacy?
What was your role prior to working with the Board?**

I have been executive secretary of the Alabama State Board of Pharmacy since September 3, 2018. Prior to joining the Board as executive secretary, I was a district manager for CVS Pharmacy in Birmingham, AL, and served as the chain representative on the Board.

What is one of the most significant challenges or issues your Board addressed in the past year or so?

Our Board has been working diligently to address unlawful conduct by compounders in and outside of Alabama. We have worked conscientiously to address entities that compound and/or sell products that are noncompliant with

Food and Drug Administration guidelines and entities that have been identified with insurance fraud.

What actions were taken by the Board to address the issue?

The Board has been active in investigating entities that have a proclivity for abusing their status and potentially injuring patients in Alabama. The Board continues to perform in-depth reviews of new permit applications to ensure any new entity is operating in a manner compliant with Alabama statutes and rules and serves public protection.

What other key issues has the Board been focusing on?

The Board continues to focus on protecting the public health through its investigations and inspections. In addition, the Board had a very active legislative session last year. While not final, we hope to have collaborative practice agreements available to practitioners in Alabama in order to improve patient care.

What insights do you have for other states that may be facing similar challenges?

I encourage all boards, staff, and members to always be vigilant to ensure actions by the boards are always in the best interests of the patients they are charged to protect. Pharmacy has become a much more complicated business model in recent years. It is incumbent upon boards of pharmacy to stay in front of the trends and regulate in a manner that improves health care for patients, while maintaining a strong resolve to uphold the statutes and rules in each state. ■

Alabama State Board of Pharmacy

Number of Board Members: 5 pharmacists

Number of Compliance Officers/Inspectors: 7

Rules and Regulations Established by: State board of pharmacy

Number of Pharmacist Licensees: 9,581

Number of Pharmacies: 2,039

Number of Wholesale Distributors: 598

Access to Health Care in Rural America: Are Pharmacists Key to the Solution?



Sarah-Lloyd Stevenson
Faegre Drinker Biddle & Reath LLP

“... in recent years, hospital closures, physician shortages, and health disparities have made it clear that new, innovative solutions must be brought forward to address continuing health challenges in rural America.”

For decades, members of Congress and health policy thought leaders have prioritized policies to improve rural health through increased federal appropriations, special reimbursement structures, and distinct models of care delivery for rural health providers. For the nearly 60 million (one in five) Americans who live in census-designated “rural” areas outside of cities and suburban communities,¹ this federal support has been a lifeline. However, in recent years, hospital closures, physician shortages, and health disparities have made it clear that new, innovative solutions must be brought forward to address continuing health challenges in rural America. Washington has taken notice, and, in 2020, rural health debates are likely to continue as Congress and the Trump Administration identify and implement policies to improve the health of rural Americans.

One of the most popular issues with voters heading into the 2020 election is access to quality health care. Given the ongoing challenges particular to rural areas, it is not surprising that the vast majority of voters recently identified access to health care in rural communities as a top priority. This widespread interest in rural health is putting rural policy near the top of the list for many candidates. The Trump Administration has prioritized rural health policies, and each of the leading Democratic candidates for

president has proposed some form of rural health policy.²

This article describes the rural health landscape, reflects on ways that pharmacists could be at the center of health reform in these underserved communities, and outlines some of the policies being considered in Washington, DC, to achieve this.

Rural America Is Facing a Health Crisis

The Centers for Disease Control and Prevention’s (CDC’s) data demonstrates the need for improved care in rural America. Rural populations are at greater risk than their urban counterparts of dying from heart disease, cancer, chronic respiratory disease, stroke, and unintentional injuries.³ Meanwhile, rates of death by drug overdose have continued to rise in rural America, surpassing rates in urban communities.⁴ All of these issues are underscored by a growing rural hospital crisis: Half of all hospitals are rural, and nearly a quarter of them are at risk of closing their doors due to financial problems.⁵ Mortality rates rise in patient populations that do not have access to a local hospital.⁶

These statistics may sound dire, but they represent an opportunity for real reform of how health care is delivered in rural communities. The Centers for Medicare and Medicaid Services (CMS) and the Rural Health Task Force at the Health Resources and Services

¹ United States Census Bureau. www.census.gov/library/stories/2017/08/rural-america.html. Accessed November 18, 2019.

² Rural Health Care Polling Presentation. Bipartisan Policy Center. <https://bipartisanpolicy.org/wp-content/uploads/2019/06/BPC-AHA-Rural-Healthcare-Powerpoint-FINAL-6-11-19.pdf>. November 18, 2019.

³ CDC. www.cdc.gov/ruralhealth/cause-of-death.html. Accessed November 18, 2019.

⁴ CDC. www.cdc.gov/ruralhealth/drug-overdose/index.html. Accessed November 18, 2019.

⁵ National Bureau of Economic Research. www.nber.org/papers/w26182?utm_campaign=ntwh&utm_medium=email&utm_source=ntwg12. Accessed November 18, 2019.

⁶ National Bureau of Economic Research. www.nber.org/papers/w26182?utm_campaign=ntwh&utm_medium=email&utm_source=ntwg12. Accessed November 18, 2019.

Administration (HRSA) have prioritized finding solutions to the growing health care challenges in rural America. Because of the complexity of the issue, HRSA issued a request for information to engage stakeholders on the biggest challenges and most promising solutions that are needed at the federal level.⁷ CMS initiated a rural health strategy⁸ to apply a rural lens to federal programs and has advanced policies around rural hospital payments and maternal health in recent months.⁹

While there will not be a simple solution to fixing access to quality health care in rural areas, ensuring access to health care providers is arguably the first step. Because hospitals are often the main employer in a rural town, serving as a health and economic center for most of the population, there is a lot of focus on maintaining the viability of rural hospitals. Many policy proposals, therefore, aim to shore up funding for rural hospitals, but funding extensions that fuel an out-of-date care delivery model are not a long-term solution.

Other proposals consider addressing the well established physician shortage in rural communities. However, enticing providers to move to rural – and often impoverished – areas is easier said than done. Proposals must be multifaceted, and an essential part should be to consider the providers who are already living and working in these communities – enter pharmacists.

Pharmacists Could Be Part of the Solution for Rural Communities

Deservedly so, hospitals and physician shortages receive a lot of attention in the rural health policy debate that is raging across the country. There are also shortages of rural pharmacies and pharmacists due to reimbursement challenges in

recent years, forcing many to close their doors.

However, in most rural communities, pharmacists are still practicing and seeing patients day in and day out. Rural pharmacists play an essential role in care delivery and disease management. In fact, for many rural areas, the pharmacist may be the only or one of only a few health care providers for miles,¹⁰ meaning that they are the first line of defense and the provider with whom patients routinely have direct access. This presents an excellent opportunity for rural pharmacists to serve as a key solution, as policymakers and candidates consider the future of health care delivery and improved health outcomes in these underserved communities. To do this, policies must acknowledge that pharmacists can do more than “just count pills.”

Too often, policymakers forget that pharmacists – providers who are already invested and located in the communities – have advanced doctorate training and a license that allows them to do much more than hand out prescriptions. Allowing pharmacists – and reimbursing them – to practice to the full scope of their license, in accordance with state laws and regulations, could be a big piece of the solution to provider shortages in rural areas.

Congress Is Looking for Solutions

The health care delivery challenges of rural America have captured the attention of the powerful US House Committee on Ways and Means in Washington. Near the end of 2019, the newly formed Rural and Underserved Communities Health Task Force, chaired by Representatives Jodey Arrington (R-TX), Danny Davis (D-

IL), Terri Sewell (D-AL), and Brad Wenstrup (R-OH), issued a request for information soliciting new policy ideas to address these challenges. The task force collected information from stakeholders and communities on, among other topics, health care and community factors that impact health, successful models currently improving outcomes in rural America, provider access, and use of data and technology. The ultimate goal of the task force is to identify sensible, bipartisan policy options that can improve health outcomes in rural and underserved communities. In 2020, we should expect to see continued stakeholder engagement led by the task force and potentially new legislation introduced. Through this process, pharmacists and boards of pharmacy can engage and provide ideas for reform in their communities.

One idea members of Congress have considered in recent years is reimbursing pharmacists in rural or underserved areas through the Medicare program for cognitive, patient care services, rather than tying reimbursement to the dispensing of a product. The idea is simple: If state law authorizes and the respective board of pharmacy issues a license allowing a pharmacist to provide a patient care service, Medicare should reimburse for that service. This is a policy goal for which pharmacists have advocated for years. Achieving Medicare “provider status” for all pharmacists may be a heavy – and costly – policy lift at the federal level. However, recent proposals that provide for a limited expansion of reimbursed services in rural or underserved communities could be a popular and simple fix to some of the health care problems plaguing America’s rural communities.

continued on page 12

⁷ HRSA. www.hrsa.gov/rural-health/rfi-rural-health-care-access. Accessed November 18, 2019.

⁸ CMS. www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf. Accessed November 18, 2019.

⁹ CMS. www.cms.gov/newsroom/press-releases/cms-advances-agenda-re-think-rural-health-and-unleash-medical-innovation. Accessed November 18, 2019.

¹⁰ U.S. News & World Report. <https://health.usnews.com/health-care/patient-advice/articles/2018-10-17/rural-pharmacies-are-closing-where-does-that-leave-patients>. Accessed November 18, 2019.

Growing Market of CBD Products Presents Member Boards With Regulatory Uncertainty, Questions



“The new legal status has helped to contribute to a booming market of cannabis-derived products, creating new challenges for regulators ...”

Although the national landscape concerning cannabis has changed dramatically over the last decade, Drug Enforcement Administration continues to classify marijuana as a Schedule I controlled substance (CS) under the federal Controlled Substances Act (CSA). In 2018, an exception was made when the Agriculture Improvement Act of 2018 (more commonly known as the 2018 Farm Bill) became law. Among other provisions in the expansive law, the bill removed “hemp” from the CSA’s definition of marijuana. Under the bill, “hemp” is now defined as any part of the cannabis plant, including its derivatives, extracts, and cannabinoids, with a delta-

9-tetrahydrocannabinol (THC) concentration of not more than 0.3% on a dry weight basis. In short, this means that hemp-derived cannabidiol (CBD) – a non-psychoactive cannabinoid – is no longer considered a CS under the CSA. This new legal status has helped to contribute to a booming market of hemp-derived CBD products, creating new challenges for regulators, especially concerning the legality of food, beverages, and dietary supplements that contain CBD.

Federal Regulatory Status of CBD Products

Although hemp-derived CBD is no longer federally controlled, CBD products must comply with all federal and state regulations and must be derived from hemp plants produced by licensed growers. Hemp-derived products that do not meet all state and federal requirements are still considered illegal, according to the bill.

The day the 2018 Farm Bill was passed, Food and Drug Administration (FDA) released a statement asserting that the law “explicitly preserved the agency’s current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act.” On that same day, FDA announced that it had: (1) completed its evaluation of three generally recognized as safe (GRAS) notices related to hulled hemp seeds, hemp seed protein, and hemp seed oil; and (2) accepted the conclusion that these three ingredients are safe for use in human food. It is important to note that hemp seeds contain only trace amounts of CBD and THC that may be picked up during harvesting and processing. More recently, the agency announced that it cannot conclude that CBD is GRAS for use in human or animal food.

As of early 2020, FDA has given formal approval to only one CBD-based product, a prescription drug called Epidiolex®, which is indicated for the treatment of two rare and severe forms of epilepsy primarily found in children. Because FDA has classified

CBD as a drug ingredient, the agency does not consider its use in dietary supplements legal. FDA also asserts that food, beverages, and ingestible animal products may not contain CBD.

It is important to note that, to date, hemp-derived CBD is not federally prohibited in cosmetics, which is why topical CBD is sold by many national retailers. According to FDA, “[c]ertain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients.” Of course, if a CBD cosmetic is marketed with claims to prevent, diagnose, treat, or cure diseases or claims to affect the structure or function of the body, then that product would also be viewed as a drug by FDA, and would be considered violative.

FDA recognizes the significant public interest in CBD and has announced that it is exploring potential pathways for various types of CBD products to be lawfully marketed. As an initial step, FDA held a public hearing on May 31, 2019. During the hearing, then-Acting Director Ned Sharpless, MD, issued a prepared statement that reviewed most of the information above. “. . . CBD and THC cannot lawfully be added to a food or marketed as a dietary supplement. Although the law says that FDA can issue regulations to create new exceptions to these statutory provisions, FDA has never issued a regulation like that for any substance. So, if we were thinking about doing that for a substance like CBD, it would be new terrain for the FDA.”

Since May 31, 2019, FDA has issued warning letters to 19 companies for illegally selling CBD products, including food, dietary supplements, beverages, topical products, and animal treats. In a statement, FDA explained that the companies were marketing these products with impermissible claims about treating or preventing serious medical conditions. In 15 of the 19 warning letters, FDA noted that the recipient marketed CBD with claims to treat cancer.

“In line with our mission to protect the public, foster innovation, and promote consumer confidence, this overarching approach regarding CBD is the same as the FDA would take for any other substance that we regulate,” said FDA Principal Deputy Commissioner Amy Abernethy, MD, PhD, in the statement. “We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD ‘can’t hurt.’”

In November 2019, FDA published a revised *Consumer Update* article on CBD products, where it outlined known risks of CBD. “CBD has the potential to harm you, and harm can happen even before you become aware of it,” the update warns. Three major concerns include the risk of liver injury, risks of drug interactions, and male reproductive toxicity (only observed in animals). Other issues FDA is investigating include the effects of cumulative exposure, the effects of CBD on special populations (eg, pregnant women and children), and the use of CBD in pets and other animals.

In that same *Consumer Update*, FDA expressed concern about CBD product quality, as a “lack of appropriate processing controls and practices can put consumers at additional risks.” For example, the agency confirmed, via testing, that many CBD products do not contain claimed levels of CBD. FDA is also investigating reports of CBD potentially containing unsafe levels of contaminants (eg, pesticides, heavy metals, THC).

Although FDA has not yet clarified its regulatory approach toward CBD, many in the industry believe that it is exercising “enforcement discretion” by targeting only those products that are marketed with claims to treat serious diseases. Perhaps for this reason, CBD products in a diverse range of forms – including oil drops, capsules, syrups, food products, and topical lotions and creams – remain available in many states.

State-Level CBD Regulatory Trends

Although hemp-derived CBD is no longer federally controlled, some states prohibit or tightly restrict its sale. For example, in Idaho, “CBD must both contain zero THC and be derived from one of the five identified parts of the cannabis plant, otherwise it is illegal in Idaho under current law.” Likewise, “[c]urrent South Dakota law makes industrial hemp illegal and all forms of CBD oil illegal.” The Hawaiian Department of Health (DOH) has asserted that – in addition to being illegal in food, dietary supplements, and beverages – CBD is also prohibited in cosmetics in the state.

Other states require CBD retailers to register with state authorities in order to engage in legal sales within the state. For example, in Louisiana, retailers (including online retailers) must hold a Louisiana CBD dealer permit. In addition, all hemp-derived CBD products sold into Louisiana must be registered with the Louisiana DOH. According to the Louisiana DOH, “[i]f you are a manufacturer or authorized distributor of industrial-hemp-derived cannabidiol products, you will need to register those items with this office in order to legally distribute them in or into the state of Louisiana, irrespective of whether you are located in- or out-of-state.” Likewise, Alaska and New York are in the process of drafting rules that will require CBD retailers to register with state authorities.

Because CBD is fraught with regulatory peril, most experts advise caution to pharmacists who may be selling or thinking about selling CBD products. In a meeting of the National Community Pharmacists Association, attendees were advised to “[b]e careful what you say about CBD. Be careful what you communicate about CBD. Pay attention to your state and the federal regulations of CBD as well. Pay attention to the FDA’s website for warning letters . . . Pharmacists need to be careful.”

continued on page 12

Compliance Officers, Legal Counsel Address Pertinent Issues at NABP Interactive Forum

Continuing the 2019 forum theme “Turning Data Into Information, and Information Into Insight,” compliance officers and legal counsel gathered in Rosemont, IL, on December 4-5, 2019, for two days of discussion on topics related to their roles at the boards of pharmacy. The NABP Interactive Compliance Officer and Legal Counsel Forum included breakout sessions tailored to each group and joint sessions for open discussion on topics related to both groups. The event drew 37 compliance officers and 24 legal counsel from 39 member boards of pharmacy. ■



(Above) The first joint compliance officer/legal counsel session on December 4 featured discussions on exam breaches, information breaches, and cybersecurity. Pictured are (left to right) session moderator Bradley S. Hamilton, RPh, member, NABP Executive Committee; Steve Pyun, JD, deputy attorney general, California State Board of Pharmacy; Maureen Garrity, PharmD, RPh, NABP competency assessment director; Justin Ortique, PharmD, RPh, supervisory pharmacist, District of Columbia Board of Pharmacy; Cristal Anderson, PharmD, RPh, director of compliance, Alabama State Board of Pharmacy; Nicole M. Schuster, JD, deputy attorney general, Indiana Board of Pharmacy; and Philip P. Burgess, MBA, DPh, RPh, member, NABP Executive Committee, who moderated the joint compliance officer/legal counsel shared discussion topics session that followed.



(Above) Standards of care for prescribing pharmacists and the new **NABPLAW®** Online were addressed during the second joint session on December 4. Pictured are (left to right) session moderator Caroline D. Juran, RPh, DPh, NABP treasurer; Maureen Schanck, PharmD, RPh, NABP professional affairs manager; Brianne Efremoff, PharmD, RPh, compliance director, Oregon State Board of Pharmacy; Jaime Thompson, compliance officer, Idaho State Board of Pharmacy; Eileen Lewalski, PharmD, JD, NABP professional affairs senior manager; and Eric Irwin, JD, staff attorney, Hawaii State Board of Pharmacy.



(Above) During the final joint session on December 4, panelists provided litigation, state, and provincial updates as well as discussed using facts to protect the integrity of the drug supply. Pictured are (left to right) Kevin McGlynn, NABP accreditation and inspection programs director; Valerie Tsui, RPh, senior investigator, College of Pharmacists of British Columbia; Munaza Aman, JD, associate general counsel, Illinois Department of Financial and Professional Regulation – Illinois State Board of Pharmacy; Melissa A. Madigan, PharmD, JD, NABP policy and communications director; and session moderator Lenora S. Newsome, PD, member, NABP Executive Committee.



(Above) During the first compliance officer session on December 5, session panelists shared tales from the field. Pictured are (left to right) session moderator Shane R. Wendel, PharmD, RPh, member, NABP Executive Committee; Andrew Hudson, JD, manager, Drug Monitoring Section, Michigan Board of Pharmacy; Philip P. Burgess, MBA, DPh, RPh, member, NABP Executive Committee, who moderated the compliance officer shared discussion topics session that followed; and Mark Klawitter, RPh, board inspector, Montana Board of Pharmacy.

continued on page 10

Presenters

continued from page 9



(Above) During the first legal counsel session on December 5, panelists provided case analysis insights and examined what constitutes discipline. Pictured are (left to right) session moderator Richard B. Mazzoni, RPh, member, NABP Executive Committee; Luke Daniel, JD, general counsel, Arkansas State Board of Pharmacy; Kerstin Arnold, JD, general counsel, Texas State Board of Pharmacy; David Scott, JD, legal counsel, Mississippi Board of Pharmacy; Carlos Finalet III, JD, general counsel, Louisiana Board of Pharmacy; Jodi Krugman, JD, deputy attorney general, New Jersey State Board of Pharmacy; Nicole M. Schuster, JD, deputy attorney general, Indiana Board of Pharmacy; Kathleen Jensen, JD, NABP staff attorney; and Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee, who moderated the legal counsel shared discussion topics session that followed.



(Above) During the second compliance officer session on December 5, panelists focused on ARCOS data and how it can help discover diversion, and on updates to United States Pharmacopeia Chapters <795>, <797>, and <800>. Pictured are (left to right) Eric A. Griffin, director of compliance and enforcement, State of Ohio Board of Pharmacy; Michelle McCreary, RPh, pharmacist compliance officer, Delaware State Board of Pharmacy; session moderator Tejal J. Patel, MBA, PharmD, RPh, member, NABP Executive Committee; Brenda McCrady, PD, assistant director, Arkansas State Board of Pharmacy; and Zaneta Nunnally, PhT, compliance director, Indiana Board of Pharmacy.



(Above) During the second legal counsel session on December 5, panelists focused on conflict of interest, recusal, and board members' electronic communications; board member involvement in the legislative process; and licensee and witness information security. Pictured are (left to right) session moderator Susan Ksiazek, RPh, DPh, NABP chairperson; Kerstin Arnold, JD, general counsel, Texas State Board of Pharmacy; Anthony Gray, JD, general counsel, Kentucky Board of Pharmacy; Michele Wagner-Gutkowski, JD, assistant attorney general, Michigan Board of Pharmacy; Hans Anderson, JD, assistant attorney general, Minnesota Board of Pharmacy; Daryl Hylton, JD, legal counsel, Missouri Board of Pharmacy; and Carlos Finalet III, JD, general counsel, Louisiana Board of Pharmacy. Nicole Dehner, JD, chief legal counsel, State of Ohio Board of Pharmacy (not pictured) was also a session panelist.



(Above) The joint session on December 5 provided information about a Food and Drug Administration grant to develop a data sharing system for improved oversight of compounding pharmacies and other compounding updates from the boards. Pictured are (left to right) Timothy D. Fensky, RPh, DPh, FACA, NABP president-elect, who moderated the joint shared discussion topics session that followed; Melissa Martin, compliance inspector, Kansas State Board of Pharmacy; Joanne M. Trifone, RPh, director of pharmacy investigations, Massachusetts Board of Registration in Pharmacy; Melissa A. Madigan, PharmD, JD, NABP policy and communications director; and session moderator Jack W. "Jay" Campbell IV, JD, RPh, NABP president. Tony Qi, PharmD, RPh, specialized credential investigator III, New Jersey State Board of Pharmacy (not pictured) was also a session panelist.

Growth of CBD Products

continued from page 7

Regardless of the legal status of CBD and other cannabis-related products in each state, however, experts advise pharmacists to be prepared to address the products and their potential impact on medication therapy. For example, in vitro studies have illustrated multiple potential drug interactions for CBD – interactions that may be complicated by a lack of standardized products and mislabeled CBD and THC strengths. For example, CBD has been found to be an inhibitor of several enzymes of drug metabolism, specifically CYP3A4 and CYP2D4. Moreover, CBD is often used by chronic pain patients, increasing the potential for drug-drug interactions with dramatic safety concerns. Research suggests CBD use enhances the effects of opiates and exhibits other interactions with barbiturates, fluoxetine, sedatives, and antihistamines, as well as having synergistic effects with alcohol.

NABP Continues to Monitor and Educate

NABP continues to keep its members apprised of the changing regulatory landscape concerning cannabis and does so by offering educational opportunities and publishing updates. For example, NABP held an invitation-only interactive webinar in October 2018. The webinar, titled “Disciplinary Cases and Marijuana: Regulatory and Clinical Overview,” featured multiple speakers and a live question and answer session. Similarly, NABP hosted a continuing pharmacy education (CPE) session on the regulation of medical cannabis at its 114th Annual Meeting in Denver,

CO, in May 2018. A detailed summary of the CPE session is available in the 2018 Special Issue of *Innovations* (pages 12-13; 18). Most recently, in the November/December 2019 issue of *Innovations*, NABP published an article titled “Impact of CBD-Derived Products on State Boards of Pharmacy.”

NABP continues to monitor developments involving cannabis that are relevant to its member boards of pharmacy and the shared mission of protecting the public health and will continue to provide opportunities to discuss ongoing developments. ■

“Regardless of the legal status of CBD and other cannabis-related products in each state, however, experts advise pharmacists to be prepared to address the products and their potential impact on medication therapy.”

Policy Perspectives

continued from page 5

There may also be an opportunity for the Trump Administration to move on this topic without congressional action. In October 2019, President Donald J. Trump signed an executive order on Protecting and Improving Medicare for Our Nation’s Seniors. The executive order directs CMS to eliminate Medicare requirements that “limit professionals from practicing at the top of their profession.” Within weeks of the executive order, CMS Administrator Seema Verma confirmed that granting pharmacists provider status could be something considered in the rulemaking required within one year of the signing of the order.

Improved Medicare reimbursement for pharmacists could be one part of the solution to the ongoing rural health crisis across the country, but even without change at the federal level, pharmacists should be at the center of any reforms in rural communities. Pharmacists know their communities and see their patients regularly. They are the providers who detect and avoid negative drug interactions, provide preventive services like vaccines, and help patients manage chronic diseases.

In rural America, where disease rates and comorbidities remain high and provider access continues to decline, pharmacists should be an accessible and appropriate health care option. These providers should be considered

as the rural health debate continues, and boards of pharmacy should keep an eye on the 2020 election and the growing conversation around rural health care to see how the rural population could help determine the type of solutions considered in Washington for rural Americans and their pharmacists.

This article was written by Sarah-Lloyd Stevenson, with Faegre Drinker Biddle & Reath LLP. Please note, the opinions and views expressed by Faegre Drinker Biddle & Reath do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated. ■

Illegal Online Opioid Sales Continue to Threaten Public Health

Ninety-nine percent of the 1,543 new pharmacy websites added to NABP's Not Recommended List in the first half of 2019 that sell controlled substances (CS) did not require a prescription, according to the *Rogue Rx: Activity Report*. Released by NABP in November 2019, the report highlights the continued pervasiveness of illegal online opioid sales and provides important statistics from the Association's continuous review of the online pharmacy landscape.

In addition, of the new pharmacy websites added to NABP's Not Recommended List in the first half of 2019:

- nearly one-third sold CS, including Adderall®, Valium®, Xanax®, and opioids, such as codeine, oxycodone, and fentanyl, a drug that is up to 100 times stronger than morphine; and
- 94% of Not Recommended sites sold drug compounds not approved by Food and Drug Administration (FDA).

Despite pockets of improvements, the opioid epidemic in the United States continues to be a major problem, with opioid-related overdose deaths increasing 90% from 2013 to 2017, according to Centers for Disease Control and Prevention (CDC). CDC data also shows that opioid-related overdose deaths increased in 18 states in 2018.

Fentanyl, the center of the “third wave” of the nation's opioid epidemic, can be ordered from illegal online drug sellers and has been found in counterfeit drugs of all kinds sold both online and on the streets. Solutions to this problem require collaboration between multiple entities, including the government, advocates, and internet stakeholders. FDA and patient advocates have called on internet stakeholders to restrict access to illegal online drug sellers. Some, including Google and Bing, are acting by deindexing illegally operating websites. Facebook and Instagram have begun



redirecting users looking for opioids to a government helpline. NABP urges internet stakeholders, such as search engine companies and social networks, to take additional proactive steps to help stem the opioid crisis.

The full report, *NABP 2019 Rogue Rx: Activity Report*, is available in the Program and Committee Reports section on the Publications and Reports page of www.nabp.pharmacy. ■

Work Group Addresses Interstate Endorsement Credential



The Work Group on the Development of an Interstate Endorsement Credential convened on September 5, 2019, in Rosemont, IL, to discuss the development of an interstate endorsement credential for non-dispensing or cognitive pharmacy practices and expand on NABP's current Electronic Licensure Transfer Program®. Pictured are (front, left to right) Cathy Winters, RPh, Wisconsin Pharmacy Examining Board; Barbara Ellen Vick, PharmD, JD, RPh, North Carolina Board of Pharmacy; Traci Collier, PharmD, RPh, South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy; Virginia “Giny” Herold, MS, California; Laura Rang, RPh, Colorado State Board of Pharmacy; (back, left to right) Malcolm J. Broussard, RPh, Louisiana Board of Pharmacy (chairperson); Sam Lanctin, BScPharm, MBA, New Brunswick College of Pharmacists; Dennis Wiesner, RPh, Texas State Board of Pharmacy; Steven W. Schierholt, Esq, State of Ohio Board of Pharmacy; Mark J. Hardy, PharmD, RPh, North Dakota State Board of Pharmacy; and Jeffrey J. Mesaros, PharmD, JD, RPh, NABP Executive Committee liaison. Richard A. Palombo, RPh, New Jersey, participated in the meeting via telephone. ■

NABPLAW Online Transitions to New, Enhanced Platform

With improved functionality and display, the enhanced **NABPLAW®** Online launched in December 2019. This comprehensive database of state pharmacy laws and regulations now offers subscribers numerous improvements, including:

- a modern and visually appealing interface;
- improved search functionality for a more intuitive experience;
- prominent display of recently updated content on the home page; and

- ability for users to export search results in a Word or pdf format.

NABPLAW Online continues to offer high-quality content and access to state pharmacy laws and regulations from all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Bahamas, and Canadian provinces.

Current subscribers were automatically transitioned to the new platform when it launched on December 2 and may log in to **NABPLAW** Online at www.nabplaw.pharmacy. Customers who wish to subscribe or renew may do so via the NABP e-Profile site.

NABP member boards receive a special discounted rate of \$295 with unlimited users. To receive the member rate, contact nabplaw@nabp.pharmacy.

More information, including subscription rates, is available in the Publications and Reports section of www.nabp.pharmacy.

Information about additional enhancements to **NABPLAW** Online will appear in future issues of *Innovations*. ■

New NABP Accreditations and Verifications

The following entities were recently granted NABP accreditation or verification through the select programs noted below. Full listings of .Pharmacy Verified Websites and Verified Internet Pharmacy Practice Sites® (VIPPS®)-accredited facilities can be found in the Programs section at www.nabp.pharmacy. ■

Accredited VIPPS Facility

CareFirst Specialty Pharmacy LLC, dba CareFirst Specialty Pharmacy Corporation

www.cfspharmacy.pharmacy
www.amberpharmacy.com

.Pharmacy Verified Websites

All-Care Pharmacy LLC

www.avriorx.pharmacy
www.avriorx.com

Alphascript, Inc

www.alphascriptrx.pharmacy
www.alphascriptrx.com

American Advantage Association

<http://truscript.pharmacy>
www.truscript.com

Avita Drugs, LLC

<http://avita.pharmacy>
www.avitapharmacy.com

Bux Healthcare

www.familypharmacy.pharmacy
www.familypharmacy.org

FirstLight Health System

<http://firstlightpharmacy.pharmacy>
www.firstlighthealthsystem.org

Franklin Square Pharmacy Inc

www.square.pharmacy
www.franklinsquarepharmacy.com

HEBCO GP, LLP

www.heb.pharmacy
www.h-e-b.pharmacy
www.hebrx.pharmacy
www.heb.com

IHC Health Services Inc

www.intermountainhealthcare.pharmacy
www.intermountain.pharmacy
www.intermountainhealthcare.org/services/pharmacy

MedImpact Healthcare Systems, Inc (americaspharmacy.com)

www.americaspharmacy.pharmacy
www.americaspharmacy.com

Midwest Compounding, Inc

www.mwcpharmacy.pharmacy
www.mwcpharmacy.com

Northern VA Compounding

www.akina.pharmacy
www.akinapharmacy.com

NowRx

<http://nowrx.pharmacy>
www.nowrx.com

OnePoint Patient Care

www.palliativecare.pharmacy
www.hospice.pharmacy
www.onepoint.pharmacy
www.oppc.com

PANTHERx Specialty LLC (pantherxrare.com)

www.pantherxrare.pharmacy
www.pantherxrare.com

Pet Care Rx Inc

www.petcare.pharmacy
www.petcarerx.pharmacy
www.petcarerx.com
www.petplus.com

Pharmaprix

www.pharmaprix.pharmacy
www.pharmaprix.ca

Rx South

www.rx3.pharmacy
www.rx3pharmacy.com

SortPak Rx, Inc

www.sortpak.pharmacy
www.sortpak.com

The North West Company

www.ntc.pharmacy
www.nwc.pharmacy
www.northwest.ca
www.northwesttelepharmacy.ca

Reminder: Annual Meeting Travel Grant Available

Travel grant opportunities are still available for the 116th NABP Annual Meeting. Eligible individuals may receive up to \$1,500 to cover the costs of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

- One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer.
- Active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

To obtain a grant application, board administrative officers may contact the NABP Executive Office at ExecOffice@nabp.pharmacy. ■



Important Deadlines

- **Proposed CBL Amendments – Due March 30, 2020**
- **Early Registration Rate – Ends April 10, 2020**
- **Voting Delegate Submissions – Due April 14, 2020**

Proposals Requested for Educational Poster Session

NABP is seeking proposals for the annual Educational Poster Session held during the Annual Meeting.

Proposals must be submitted via email by Wednesday, February 26, 2020. Proposed posters should reflect the theme of “Uniting to Protect the Public Health.” Those selected to display posters have the opportunity to share information about policy development, public health initiatives, legislative issues, or other topics as they relate to this year’s theme. Proposed posters may be descriptive, scientific, or informational.

For instructions on submitting a poster concept for consideration, please contact NABP Professional Affairs staff via email at Prof-Affairs@nabp.pharmacy.

Board of pharmacy members and staff as well as schools and colleges

of pharmacy are invited to submit poster proposals. Students are welcome to submit proposals and, if selected, must be accompanied by a credentialed adviser or licensed pharmacist. Selected poster presenters must be available in March and April for correspondence with NABP staff and to submit required materials and should be able to personally attend the poster session on Friday, May 15, 2020.

Poster Session participants may be eligible to earn Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) credit, as long as they interact with the other presenters for a total of one hour during the one-hour-and-45-minute offering and pass the post-session test. Additional details will be provided to individuals selected to present. Those selected to present

Educational Poster Session: Uniting to Protect the Public Health

- Proposals must be submitted via email by Wednesday, February 26, 2020
- Friday, May 15, 2020, 10:30 AM - 12:15 PM
- Eligible for one contact hour (0.1 CEU) of ACPE-accredited CPE credit

will receive a complimentary meeting registration. Pharmacy student presenters will receive a voucher for a free Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination®. The voucher is valued at \$65. ■

Interview With a Board Member



**Leah Giambarresi, PharmD,
RPh, Member, Massachusetts
Board of Registration
in Pharmacy**

Leah Giambarresi, PharmD, RPh, Member, Massachusetts Board of Registration in Pharmacy

When were you appointed to the Board of Pharmacy? Are you a pharmacist, technician, public member, or other type of member?

I was appointed to the Board in November 2017 as a pharmacist member.

In your opinion, what steps should a board member take to be successful in his or her role?

I think it is important to try to understand the practice of pharmacy outside of the role that you practice. In addition to my role as director of operations for Genoa Healthcare in New England, I try to stay active in various pharmacy organizations. For example, I stay active with the Massachusetts College of Pharmacy and Health Sciences pharmacy students. I think it is important to keep up with what is going on in the

pharmacy profession, so you know where the profession is going.

What are some recent policies, legislation, or regulations your Board has implemented or is currently working on?

We recently updated our pharmacy technician guidelines. In addition, Massachusetts enacted a policy that allows pharmacists and pharmacy interns to administer certain long-acting medications for mental illness and substance use disorder. It is not something they were able to do before. Pharmacists and pharmacy interns have been able to administer immunizations for some time, but this policy now increases patient access to psychiatric medications.

Has the Board encountered any challenges to developing and/or implementing these new policies, legislation, or regulations? If so, explain.

We have Board members from various practice settings. Everyone works well together to overcome whatever roadblocks the Board faces and to identify any challenges that there may be. We have been doing a lot of rule rewrites lately, and we like to get everyone's input.

What advice would you give a new board member?

It is important to see the big picture. A lot of people who join the Board only have experience in one practice setting. It is important to know that the pharmacy profession now encompasses many areas of practice, specialties, and expanded scope. Also, do not hesitate to ask people who have been on the board longer for advice. And if you are unsure about something, speak up and ask for clarification. It is always good to find out everything that is going on.

continued on page 17

Massachusetts Board of Registration in Pharmacy

Number of Board Members: 8 pharmacist members, 2 public members, plus 1 physician, 1 nurse, 1 pharmacy technician, 1 representative of the public with experience in health care service delivery administration or consumer advocacy, and 1 expert in patient safety and quality improvement

Number of Compliance Officers/Inspectors: 1 compliance officer, 12 inspectors

Rules and Regulations Established by: Board of Registration in Pharmacy

Number of Pharmacist Licensees: 13,259

Number of Pharmacies: 1,159 (includes home infusion, mail-order pharmacies, and nuclear pharmacies)

Number of Wholesale Distributors: 42

Around the Association

Board Member Appointments

- **Sajal Kumar Roy, PharmD, CGP, CPSO, CSP, CACP, RPh**, has been appointed a member of the Louisiana Board of Pharmacy. Roy's appointment will expire June 30, 2025.
- **Thomas Carey, EdD**, has been appointed a public member of the Pennsylvania State Board of Pharmacy. Carey's appointment will expire September 24, 2025.
- **Cheri Ann Kraemer, RPh**, has been appointed a member of the South Dakota State Board of Pharmacy. Kraemer's appointment will expire October 1, 2022.
- **Richard Breeden, PharmD**, has been appointed a member of the Tennessee Board of Pharmacy. Breeden's appointment will expire July 15, 2025.
- **Donna Montemayor, RPh**, has been appointed a member of the Texas State Board of Pharmacy. Montemayor's appointment will expire August 31, 2025.
- **Richard "Rick" Tisch** has been appointed a public member of the Texas State Board of Pharmacy. Tisch's appointment will expire August 31, 2025.
- **Karen M. Gunning, PharmD, BCACP, BCPS, RPh**, has been appointed a member of the Utah Board of Pharmacy. Gunning's appointment will expire June 30, 2023.

Board Member Reappointments

- **Donald "Donnie" Lewis, RPh**, has been reappointed a member of the Texas State Board of Pharmacy. Lewis' appointment will expire August 31, 2025.
- **Bradley A. Miller, PhTR**, has been reappointed a member of the Texas State Board of Pharmacy. Miller's appointment will expire August 31, 2025. ■

Interview With a Board Member

continued from page 16

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings? If so, in your experience, what are the benefits of participating in these NABP activities?

I have attended district meetings and the NABP Annual Meeting, which I found very beneficial. It was very helpful to meet and get to know members from other states and hear what is happening throughout the country, since it varies so much. It is nice to meet people who you are able to reach out to for best practices or resources. ■

NABP Mourns Passing of Former President Bryan H. Potter

NABP is saddened to report that Bryan H. Potter, DPh, an active contributor to NABP and the pharmacy community, passed away on November 22, 2019.

Potter provided dedicated service as an executive director of the Oklahoma State Board of Pharmacy, where he acted to promote, preserve, and protect the public health for more than 30 years. As a part of this commitment, Potter served on the NABP Executive Committee as a member, president-elect, president, and chairperson. Prior to and during his position with the Board, Potter owned and operated a pharmacy in Elk City, OK.



In 2008, NABP presented Potter with the Lester E. Hosto Distinguished Service Award for his years of service. His accomplishments included successfully changing the Board's designation of pharmacists from "registered pharmacist" to "doctor of pharmacy" and establishing an electronic tracking program for Schedule II prescription drugs.

Among his other accolades, Potter received the Knoll Pharmaceutical Company Dedication to Pharmacy Award in 1999 and the Bowl of Hygieia Award in 2005. He was inducted into the Oklahoma Pharmacy Hall of Fame in 1996. In 2013, the Bryan H. Potter Oklahoma State Board of Pharmacy Building was named in his honor. ■

Ohio Pharmacists Now Required to Report Conduct to the Board

Effective December 1, 2019, Ohio-licensed pharmacists are required to report to the State of Ohio Board of Pharmacy certain types of conduct of which the licensed pharmacist has knowledge. Pharmacists must report:

- Conduct indicating that an individual licensed or registered by the Board is addicted to or is suspected to be abusing alcohol, drugs, or other chemical substances, or is impaired physically or mentally to render the individual unfit to carry out his or her professional duties
- Violations, attempts to violate, or aiding and abetting in the violation of any of the provisions of Ohio Revised Code (ORC) Chapters or any rule adopted by the Board under those provisions by an individual or entity licensed or registered by the Board
- Conduct by a pharmacy technician trainee, registered pharmacy technician, certified pharmacy technician, pharmacy intern, or pharmacist that constitutes unprofessional conduct or dishonesty

A pharmacist is not required to report an error in dispensing or a prescription error except when the error is the result of reckless behavior or unprofessional conduct per the National Coordinating Council for Medication Error Reporting and Prevention's Index for Categorizing Medication Errors. Per Section 4729.23 of the ORC, the identity of the pharmacist making a report in accordance with this rule will remain confidential.

The rule also requires a pharmacist to self-report to the Board any of the following:

- Any criminal conviction within 10 days after the date of conviction, except for minor traffic violations, or if the pharmacist is convicted of, pleaded guilty to, or is subject to a judicial finding of eligibility for intervention in lieu of conviction. The conviction must be reported regardless of whether the case has been expunged or sealed or the equivalent thereof.
- Entry into a diversion program, deferred prosecution program, or equivalent within 10 days after the individual is granted entry into a program.
- Any arrest for a felony within 10 days after the arrest.
- Any disciplinary licensing or registration action taken by another state against the licensee within 10 days of the notice action.

More information is available in the Board's November 2019 *Newsletter*.

Virginia Transitions to Paperless Process for Licenses, Registrations, and Permits

The Virginia Board of Pharmacy is implementing a process to cease mailing on an annual basis the hard copy licenses, registrations, and permits that bear an expiration date. A final hard copy will be issued that contains no expiration date. As of July 1, 2019, all newly issued, reinstated, or duplicate copies of pharmacy technician registrations began following this new process and thus, do not bear an expiration date. Additional licensure categories will continue to be phased in during the calendar year and during the upcoming renewal cycle. State health regulatory boards, employers, insurance providers, and citizens seeking verification of current licensure status of any license, registration, or permit in the Commonwealth of Virginia may obtain this information via the License Lookup feature at <https://dhp.virginiainteractive.org/Lookup/Index>.

Washington Passes House Bill 1412

During Washington's 2019 Legislative Session, House Bill 1412 was passed, which requires a nonresident pharmacy to submit a copy of an inspection report that has substantially equivalent standards to those of the Washington State Pharmacy Quality Assurance Commission and was issued within the last two years of application for initial licensure or renewal of a license. This change in law aligns the Commission's standards for nonresident pharmacies with those of resident pharmacies, continuing its efforts to ensure patient safety.

The Commission established a list of states with inspection standards that are substantially equivalent to those in Washington state. That list has been posted on the Commission's web page at www.doh.wa.gov/Portals/1/Documents/2300/2019/690330.pdf. If a pharmacy is in a state that is not on the approved list but has a nonresident inspection report done by a state that is on the approved list, the Commission will accept that.

The Verified Pharmacy Program® has also been identified as an approved third-party inspection.

The standards used to determine equivalency were based on the state requirement of meeting the minimum standards of United States Pharmacopeia. For those pharmacies that do not compound, the Commission has created a chart identifying from which additional states the Commission will accept inspection reports. In order for those additional inspection reports to be accepted, the pharmacy will have to attest on its application that it does not compound. If a pharmacy begins compounding, it will need to submit an approved inspection report. This law became effective on July 28, 2019. ■

Newsletters of state boards that participate in the NABP State Newsletter Program are available on the NABP website. Five years' worth of issues are posted on each participating state's page.

FDA Releases Draft Best Practices Document for Postmarket Drug Surveillance

As part of Food and Drug Administration's (FDA's) efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The document can be accessed from the FDA website at www.fda.gov/media/130216/download.

FDA Releases New Draft Guidance on Bulk Compounding for Animals

FDA has released new draft guidance that, if finalized, would advise veterinarians on circumstances under which FDA does not intend to take action for certain violations of the Federal Food, Drug, and Cosmetic Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk drug substances.

Compounding Animal Drugs from Bulk Drug Substances specifically addresses:

- compounding patient-specific prescriptions for nonfood-producing animals;
- compounding office stock for nonfood-producing animals; and
- compounding antidotes for food-producing animals.

The full text of the draft guidance can be accessed on the FDA website at www.fda.gov/regulatory-information/search-fda-guidance-documents.

Ohio Pharmacists Association Launches New Initiative to Expand Pharmacist Services

The Ohio Pharmacists Association (OPA) has launched a new initiative aimed at expanding patient access to pharmacist services across the state. The effort seeks to utilize a new state law signed by former Governor John Kasich in April 2019, which grants provider status

to pharmacists. The initiative seeks to better integrate pharmacists into health care teams to improve patient outcomes. Additionally, OPA has developed a task force made up of pharmacy leaders representing the geographic regions and the variety of practice expertise across the state. The group will lend its expertise to assist OPA staff in its push to advance pharmacist-provided services in Ohio communities.

"Provider status is the next step for pharmacists to grow in an evolving healthcare system," said OPA President Brigid Groves, PharmD, MS, in a statement. "We are excited about the pharmacist-provided patient care services that will be leveraged for patients across the state through this initiative. Working together with the Ohio colleges of pharmacy and other pharmacist leaders in the state will allow Ohio pharmacists to move quality care forward."

DEA Reports Strong Participation During Latest Prescription Drug Take-Back Day

Nearly 883,000 pounds of unused and unwanted prescription medications were properly disposed of during Drug Enforcement Administration's (DEA's) 18th National Prescription Drug Take-Back Day. On October 26, 2019, DEA and its law enforcement partners set up nearly 6,200 collection sites nationwide, according to a news release posted on the DEA website. The next DEA Take-Back Day will take place on April 25, 2020.

In addition to opportunities provided by DEA Take-Back Days, many locations offer medication disposal kiosks year-round. More than 8,000 locations can be found by using NABP's Prescription Drug Disposal Locator Tool, available on NABP's consumer website, www.safe.pharmacy, which is continually updated with new locations. By entering a zip code or city and state, consumers can find the nearest drug disposal sites on a map.

SAMHSA Launches New Substance Abuse Treatment Locator Website

The Substance Abuse and Mental Health Services Administration (SAMHSA) has launched *FindTreatment.gov*, a new website that helps people find and learn about treating substance abuse disorders. The website is an update to SAMHSA's previous treatment directory and is intended to make finding treatment more user-friendly. Compiled data from 13,000 treatment facilities across the United States is available on the new website. ■



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UPCOMING EVENTS

FPGEE Administration
April 2, 2020

**Committee on Constitution
and Bylaws**
April 6, 2020
Teleconference

116th NABP Annual Meeting
May 14-16, 2020
Baltimore, MD

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