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INNOVATIONS

New Business Models, Revised Regulations

Improving Pharmacy Access in Rural Communities

NABP
National Association of Boards of Pharmacy

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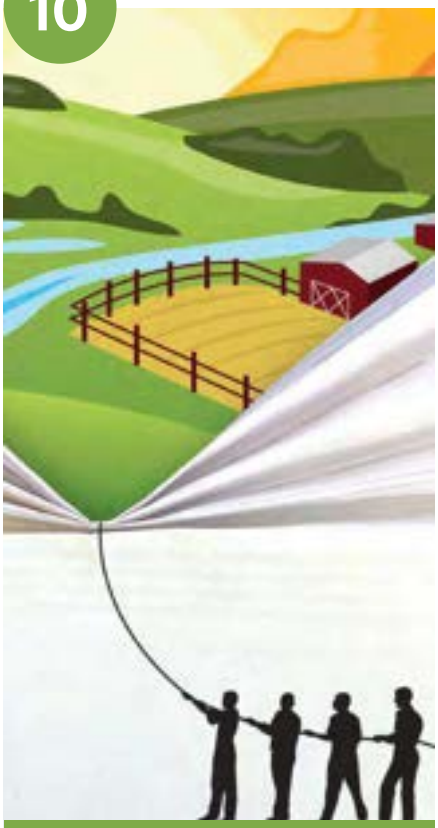

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National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056
847/391-4406 | *www.nabp.pharmacy*
help@nabp.pharmacy

Lemrey "Al" Carter
Executive Director/Secretary

Amy Sanchez
Publications and Editorial Manager

NABP Mission Statement
NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health.

NABP
National Association of Boards of Pharmacy

Timothy D. Fensky,
RPh, DPh, FACA
NABP Chairperson

Fellow Members,

February is here and most of us are still experiencing short days, long nights, and cold weather. I try to keep in mind that spring is just around the corner, even as I throw on my winter coat or shovel snow off the sidewalk. That type of anticipatory thinking reminds me of the proverbial "glass half full or half empty" discussion. As the common version goes, those who see a glass of water as "half full" are optimists, and those who see it as "half empty" are pessimists. As regulatory professionals, I think many of us understand the need to see the glass as both half full and half empty. If we look at issues with this dual mindset, we find that being presented with regulatory challenges often brings about positive outcomes for patient safety.

Many people speak of the COVID-19 pandemic in this light. That is, while we must acknowledge the serious impact of the virus and the loss of life it has caused, we can also appreciate the lessons learned during the pandemic. And in health care, we hope such lessons ultimately help us improve patient outcomes in a variety of ways.

For example, there have been many advances to telehealth systems and related regulations over the last two years. At the height of the pandemic, telehealth visits accelerated at an unprecedented rate. And even though the rate has declined from this peak, telehealth usage remains much higher than it was before COVID-19. For pharmacy patients, particularly those in rural areas that are traditionally underserved, telehealth services, including telepharmacy, can be a big benefit. Increased access to pharmacy services means more advising on the safe use of medicines, medicine reviews, management of long-term conditions, and public health and screening services. However, these changes may also raise regulatory challenges that fall on the boards of pharmacy. These challenges and opportunities are the focus of this month's cover story on telepharmacy and improved access to pharmacy services in rural communities.

Another important topic covered in this issue is the review process for the Multistate Pharmacy Jurisprudence Examination® competency statements. Each of NABP's examinations undergoes a thorough and regular review process to ensure that the standards set are in line with the minimum expected competency of pharmacists. The process is exhaustive and time-consuming, but NABP continues to make it a priority due to the important role these exams play in helping the boards make licensure decisions.

This issue also recaps the recent Interactive Compliance Officer and Legal Counsel Forum, and I want to thank all those who attended. The forum included a wide range of topics for discussion, and I was pleased that so many states were able to take advantage of the opportunity to engage in this meeting. More information about the forum is available on page 5.

Even though a dual mindset is an asset, I do wholeheartedly look forward to spring, not only because of the warmer weather, but also because it will be the first opportunity in some time to see many of you in person at the Annual Meeting in Phoenix, AZ. Please save the date for the 118th Annual Meeting, which will take place May 19-21, 2022, with a pre-meeting continuing pharmacy education session the afternoon of May 18. Online registration will soon be available. Whether this will be your first year attending, or your 50th, I encourage you to participate if you can.

Sincerely,

Timothy D. Fensky, RPh, DPh, FACA
NABP Chairperson

Compounding Update: Status of FDA's Compounding MOU

Jonathan A. Keller, PharmD, JD, RPh
Faegre Drinker Biddle & Reath LLP

Genevieve M. Razick, JD
Faegre Drinker Biddle & Reath LLP

This article is part one of a two-part series. The second article will be published in the March 2022 issue of Innovations *and will provide information about Food and Drug Administration's (FDA's) revised draft guidance for hospitals related to compounding.*

FDA's Compounding MOU

On September 21, 2021, the DC District Court ruled in favor of seven compounding pharmacies that challenged FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (the "final MOU"). The case, *Wellness Pharmacy, Inc, et al v Becerra et al*, represents the latest of the long-standing battle between FDA and compounding pharmacies regarding the issue of distinguishing between legitimate compounding versus new drug distribution. Even though the compounding pharmacies have won the latest battle, the court declined to rule on the plaintiffs' two other arguments, and this case is far from over.

FDA's Authority

FDA has historically left the regulation of compounded drugs to the states, rather than regulating such drugs under the framework governing new drugs set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In 1992, FDA's growing concerns regarding the level of compounding at pharmacies led the agency to issue a compliance policy guide to clarify that the agency may initiate enforcement action(s) against a pharmacy whose activities raise concerns typically associated with the manufacturing of drugs and "results in significant violations of the new drug, adulteration, or misbranding provisions of the [FD&C] Act."

Five years later, the Food and Drug Administration Modernization Act added Section 503A (21 USC §353a) to the FD&C Act, setting forth certain conditions that would allow compounded drugs to be exempt from the regulatory framework that governs new drug products. Pursuant to Section 503A's general exemption, a drug may be compounded if the drug is compounded in a state that has "entered into a [MOU] with the Secretary," addressing the distribution of "inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State." Pharmacies in states that do not sign the MOU are exempt from the agency's regulatory framework only if the pharmacy's distribution of drug products out of state does not exceed 5% of the total prescription orders dispensed or distributed by the pharmacy. This is commonly known as the 5% rule.

The statute also directs FDA to develop an MOU for use by the states in complying with these requirements, and in October 2020, FDA issued the long-awaited final MOU.

The Final MOU

In accordance with the FD&C Act, the final MOU provides that the compounding of drugs by pharmacies located within signatory states will be exempt from the FD&C Act new drug requirements. Pharmacies in states that do not sign the MOU will be required to comply with the 5% rule on the interstate distribution of compounded drug products.

The final MOU also addressed when a pharmacy has distributed an inordinate amount of compounded drug products interstate. It states that a pharmacy has distributed an inordinate amount of compounded drugs interstate when prescription orders for compounded drugs distributed interstate during a given calendar year are greater than 50% of the sum of:

- the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

- the number of prescription orders for compounded human drug products that were dispensed (eg, picked up by a patient) at the facility in which they were compounded during that same calendar year.

States that sign the MOU are required to identify pharmacies that meet this threshold through "surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency]." For each pharmacy that exceeds the 50% threshold, states are required to gather and report certain information (eg, the total number of prescription orders for sterile compounded human drugs distributed interstate) using the data submitted to an information sharing network or obtained by other available mechanisms.

Notably, the final MOU does not prohibit pharmacies from engaging in the interstate distribution or dispensing of compounded drug products should its resident state sign the final MOU; it only requires the applicable state board of pharmacy (or such other regulatory agency) to gather and report certain data regarding those pharmacies once the interstate distribution of compounded drug products by those pharmacies meet the 50% threshold. It is only in those states that do not sign the final MOU that pharmacies will be prohibited from distributing or dispensing greater than 5% of its compounded drug products interstate.

The Plaintiffs' Challenge

On October 27, 2020, the day that FDA issued the final MOU, plaintiff pharmacies initiated a lawsuit and moved for partial summary judgment. The pharmacies argued that FDA: (1) violated Section 503A by not developing the MOU through regulations; (2) violated the Regulatory Flexibility Act by failing to conduct an analysis of the MOU's impact on small pharmacies; and (3) exceeded its statutory authority by defining "distribution" in the MOU to include instances of dispensing compounded drugs pursuant to a prescription.

The Court's Decision

After going through a lengthy standing analysis and finding that plaintiffs had standing to bring the suit, the court concluded that the final MOU is subject to the Regulatory Flexibility Act because it is a legislative rule. The court found the final MOU to fall "on the legislative side of the line" because it included "key statutory terms in Section 503A that have binding legal consequences," evincing FDA's "intent to speak with the force of law in the MOU." Furthermore, the court found that the agency's decision to set a 50% threshold to be "arbitrary," noting that "when agencies base rules on arbitrary choices they are legislating."

The court described the Regulatory Flexibility Act's requirement that an agency issuing a final rule is required to either conduct "an analysis of the rule's impact on small businesses," or "certify" that there will be no impact if a small business is subject to the regulations. Having found that the MOU is subject to the Regulatory Flexibility Act, and because the defendants did not dispute that plaintiffs qualify as small businesses, the court determined that FDA was required to comply with the provisions of the Regulatory Flexibility Act. Accordingly, the court remanded the final MOU to FDA to either prepare the necessary regulatory flexibility analysis, or to certify that the MOU "will not . . . have a significant economic impact on a substantial number of small entities."

Interestingly, the court focused its ruling solely on whether FDA violated the Regulatory Flexibility Act. The court did not rule on the plaintiff pharmacies' other two arguments – that FDA violated Section 503A by not developing the MOU through regulations and that FDA exceeded its statutory authority by defining "distribution."

In the ruling, the court required FDA to submit a progress report within 60 days. On November 22, 2021, FDA submitted the required progress report, confirming that the agency has begun the process of determining whether to prepare a regulatory flexibility analysis or certify that the MOU will not result in a "significant economic impact" on a substantial number of small entities. FDA requested the opportunity to submit a second progress report on February 22, 2022, if, by that date, it has not informed the court of its determination regarding the preparation of its regulatory flexibility analysis or significant economic impact MOU certification.

FDA had previously announced that it would begin to enforce the statutory 5% limit on out-of-state distribution of compounded human drug products for pharmacies in states that were not signatories to the MOU on October 27, 2022. The rationale by FDA was to provide state governments and boards of pharmacy additional time to evaluate the final MOU and modify laws and regulations as necessary. Given that the court declined to address the two other issues brought by the plaintiff pharmacies in the case, it appears unlikely that this case will have any final resolution by that time.

This article was written by Jonathan A. Keller, PharmD, JD, RPh, and Genevieve M. Razick, JD, 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 noted. ●

Oklahoma State Board of Pharmacy

Number of Board Members
5 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors
6

Rules & Regulations Established by
State Board of Pharmacy

Number of Pharmacist Licensees
8,150

Number of Pharmacies
1,920

Number of Wholesale Distributors
805

Marty Lee Hendrick, PharmD, DPh

Executive Director, Oklahoma State Board of Pharmacy

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

I have been the executive director of the Oklahoma State Board of Pharmacy for about two and a half years. I have had a career in retail pharmacy and was also a compliance officer for the Board for two years.

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

The coronavirus disease 2019 (COVID-19) has definitely been a challenge for all boards of pharmacy across this country. For us here in Oklahoma, it has been a chance to put together a playbook, as I call it, of things in our rule book that need to be adjusted or changed in the near future to address other possible pandemics or situations.

In addition, we have been dealing with inadequate staffing and pharmacy issues. Obviously, pharmacists are under a lot of stress right now. Many pharmacies are frantic with phone calls and with people going through the drive-through, dropping prescriptions off at the counter, and requesting immunizations and COVID-19 testing. That is an awful lot for one person to manage. But it is not just an Oklahoma issue, it is an issue all over the United States that has been brought on even more by COVID-19.

What actions were taken by the Board to address these issues?

All of our compliance officers are pharmacists. Most of them have worked in retail pharmacy, so they have a lot of experience when they go into pharmacies and are able to notice signs of stress or other problems that may be happening there. We do a deeper dive into those pharmacies to see if there are any internal problems that are possibly linked to inadequate staffing.

We also created a COVID-19 waiver because, when COVID-19 first started, we had no idea what we were going to see. We had no idea what our registrants and licensees would need going forward, so we kept the COVID-19 waiver as broad as possible. The waiver provided our staff with the ability to waive rules in the best interest of public safety during this challenging and unprecedented time. One small example was the allowance to waive the notary requirement on licensing applications. It allowed a lot of freedom for people to continue to operate during the pandemic and still provide things like safe service, safe transport of medication into Oklahoma, and licensing.

What other key issues has the Board been focusing on?

We are in the process of rulemaking right now. We are looking at several of our rules and deciding whether to revamp them or take them out altogether. We have talked about a strong push for provider status for pharmacists and the expansion of the pharmacist's role as it is seen in the pharmacy. The pandemic has been a real eye-opener for many, providing the opportunity to demonstrate how much that pharmacists are valuable assets and, in my mind, frontline providers. Our pharmacies stayed open during the pandemic and served patients. I do not know how much more "front line" you can get than that.

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

Do not be afraid to call other state boards to ask them what they are doing to address a problem and if they have any possible solutions. I think it is easier if we all reach out to one another because there is no need to reinvent the wheel. If you can solve a problem by doing what someone else is doing, go ahead and do that because it is going to make everyone's life easier and increase patient safety and the happiness of your public. ●

Compliance Officers, Legal Counsel Discuss Timely Issues at NABP Interactive Forum

Continuing the 2021 forum theme of "Sharing Solutions, Advancing Regulation," compliance officers and legal counsel gathered on November 30-December 1, 2021, 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 43 compliance officers and 42 legal counsel from 46 member boards of pharmacy. NABP held this meeting as a hybrid event, providing a virtual option for those participants who could not attend in person in Northbrook, IL.

The first joint compliance officer/legal counsel session on November 30, "What's Going on in Digital Health Care?" featured discussions on digital health care, including the regulation of telepharmacy, online pharmacy trends, and remote clinical services. Pictured are (left to right) Niamh Lewis, JD, digital health regulatory expert, NABP; Justin Macy, PharmD, JD, digital health senior manager, NABP; Sue Mears, RPh, compliance officer, Iowa Board of Pharmacy; Tyler Laetsch, PharmD, RPh, pharmacy inspector, South Dakota State Board of Pharmacy; and session moderator Fred M. Weaver, RPh, member, NABP Executive Committee.

An update on the NABP information sharing network and the Food and Drug Administration (FDA) memorandum of understanding, as well as physician and veterinary compounding, were addressed during the joint session on November 30, titled "Mixing It Up – Let's Talk About Compounding." Pictured are (left to right) Jenni Wai, MBA, RPh, chief pharmacist, State of Ohio Board of Pharmacy; session moderator Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee; Melissa Madigan, PharmD, JD, associate executive director, professional affairs, NABP; Jason Smith, senior investigator/inspector, North Carolina Board of Pharmacy; Linda Bethman, JD, assistant attorney general, Maryland Department of Health; and Peg Panella-Spangler, MS, RPh, RD, FASHP, supervising inspector, California State Board of Pharmacy. Not pictured is Tony Qi, PharmD, RPh, section supervisor, supervising investigator, New Jersey Attorney General's Office, who presented virtually.

During the final joint session on November 30, "What's the Buzz in Medical Marijuana Cases? – From Investigation to Hearing," panelists offered attendees their insights on medical marijuana. Pictured are (left to right) Amy Branson, PharmD, RPh, pharmacy inspector, Virginia Board of Pharmacy; session moderator Tejal J. Patel, MBA, PharmD, RPh, member, NABP Executive Committee; and Eric A. Griffin, director of compliance and enforcement, State of Ohio Board of Pharmacy. Not pictured is Becky Parker, RPh, pharmacist compliance officer, Louisiana Board of Pharmacy, who presented virtually.

The first compliance officer session on December 1, "Advancing Workplace Safety and Well-Being," included discussions on patient safety and pharmacy working conditions. Pictured are (left to right) session moderator Shane R. Wendel, PharmD, RPh, member, NABP Executive Committee, and Marjan Fardadfard, PharmD, DPh, BCGP, compliance officer, Oklahoma State Board of Pharmacy. Not pictured are Joanne M. Trifone, RPh, director of pharmacy investigations, Massachusetts Board of Registration in Pharmacy, and Cheryl Fox, RPh, compliance officer, Oregon State Board of Pharmacy, who presented virtually.

The first legal counsel session on December 1, "Case Law Review," provided information about some recent legal cases involving various boards around the country. Pictured are (left to right) Christopher Dierlam, MBA, JD, assistant attorney general, Florida Office of Attorney General; Kristina Jarvis, JD, deputy attorney general, California Attorney General; Daryl Hylton, JD, legal counsel, Missouri Board of Pharmacy; session moderator Deborah C. Mack, RPh, CHC, CCEP, member, NABP Executive Committee; and Gretchen Mrozinski, JD, lead attorney, Wisconsin Department of Safety and Professional Services. Not pictured is Hans Anderson, JD, assistant attorney general, Minnesota State Attorney General, who presented virtually.

The second legal counsel session on December 1 focused on "Vaccinators, Emergency Rules, and Federal PREP Act," and included additional discussion of the topics that were submitted by the attendees. Pictured are (left to right) Luke Daniel, JD, general counsel, Arkansas State Board of Pharmacy, and session moderator Fred M. Weaver, RPh, member, NABP Executive Committee. Not pictured is Laura Steffensmeier, JD, assistant attorney general, Office of Attorney General of Iowa, who presented virtually.

The second compliance officer session on December 1 also focused on "Vaccinators, Emergency Rules, and Federal PREP Act." Pictured are (left to right) session moderator Lenora S. Newsome, PD, member, NABP treasurer; Terri Burrows, PharmD, RPh, compliance officer, Texas State Board of Pharmacy; Shannon Ridge, compliance officer, Wyoming State Board of Pharmacy; and Zaneta Nunnally, PhT, compliance director, Indiana Board of Pharmacy.

During the second legal counsel session on December 1, panelists provided their insights on "Attorney View – Bringing a Case Before the Board of Pharmacy: Complaint Screening, Probable Cause, Hearing." Pictured are (left to right) session moderator Bradley S. Hamilton, BSPharm, RPh, member, NABP Executive Committee; Nicole Schuster, JD, staff attorney, NABP; Amanda Cassidy, JD, assistant section chief, licensing enforcement, Office of the Indiana Attorney General; and Jessica Krug, JD, deputy attorney general, Office of the Indiana Attorney General.

The final joint session on December 1 titled "Advancing the Implementation of the DSCSA" included discussions on an update provided by FDA and what boards need to be aware of regarding the implementation of the Drug Supply Chain Security Act (DSCSA). Pictured are (left to right) session moderator Caroline D. Juran, BSPharm, DPh (Hon), NABP president and executive director, Virginia Board of Pharmacy, and Gregg Jones, RPh, compliance senior manager, NABP. Not pictured is Connie Jung, PhD, RPh, senior advisor for policy, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, FDA, who presented virtually.

Two joint Shared Discussion Topics sessions and one Shared Discussion Topics session specific to each group of attendees were held during the forum. The sessions enabled attendees to discuss issues of special interest provided by invitees. Pictured are (left to right) session moderators Jeffrey J. Mesaros, PharmD, JD, RPh, member, NABP Executive Committee; Reginald B. "Reggie" Dilliard, DPh, NABP president-elect; Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee; and Fred M. Weaver, RPh, member, NABP Executive Committee.

New Business Models, Revised Regulations

Improving Pharmacy Access in Rural Communities

For people living in the most isolated parts of the country, access to pharmacy services may be difficult. These individuals may need to travel long distances to traditional brick-and-mortar services or may rely on telepharmacy and mail-order pharmacy practices for most of their needs. However, physical, economic, and regulatory barriers continue to have an impact on these patients.

The United States Census Bureau identifies any territory that is not urban, or part of an urban cluster, as "rural." In other words, any area with a population of less than 2,500 people is considered rural. As of the 2010 census, 19.3% of the US population (roughly 60 million people) live in rural areas, which comprise about 97% of the country's total land area. Given the vast area of sparsely populated land, it may not be surprising that several states have an average population density of less than 12 people per square mile.

For the people living in these areas, access to many services, including pharmacies and other health care resources, requires travel to a more urban area. When distance is complicated by other barriers, such as lack of transportation, inclement weather conditions, or illnesses that limit mobility, a trip to the pharmacy or hospital is even more challenging. Further, populations in rural communities are skewing older, and therefore, patients in rural settings have more chronic health conditions, on average, than those in more urban areas, increasing the importance of reducing barriers and expanding access to care in rural communities.

Rural Pharmacies Have Been Closing at Alarming Rates

One of the biggest issues facing pharmacy patients in rural communities is the collapse of independently owned rural pharmacies. According to a report from the Rural Policy Research Institute Center for Rural Health Policy Analysis, more than 16% of the independently owned rural pharmacies in the US closed between March 2003 and March 2018, lowering the number to just 6,393. The report indicates that some communities have seen a disappearance of retail pharmacies altogether, with the

data showing that 630 rural communities that had at least one retail pharmacy in March 2003 no longer had one in March 2018.

Further, research conducted by the National Council for Prescription Drug Programs has revealed that independent pharmacies, which represent 52% of all rural pharmacies, are often the only operating pharmacy in a community. As of 2018, just over 1,800 of the independent community pharmacies in operation across the US are the lone source for many miles.

Many of the ongoing business concerns affecting pharmacies throughout the US have had a disproportionate impact on rural pharmacies. For example, independent pharmacies may not have as much leverage when negotiating reimbursement rates with insurers and may also face challenges maintaining stock of certain medications due to cost.

Even before the coronavirus disease 2019 (COVID-19) pandemic, telehealth and telepharmacy services were growing more popular in rural areas.

Another frequent challenge is recruiting pharmacists who are willing to live in rural areas. Because metropolitan areas typically provide more career opportunities and more lucrative wages, most pharmacists choose to live outside of rural communities.

Such issues may place financial pressures on rural pharmacies that can lead to closure, further limiting access to pharmacies and pharmacy services for patients. However, recent data suggest the pace of pharmacy closures in rural communities has slowed. This may be, in part, because rural pharmacies are finding new business models as rural pharmacists embrace new technologies.

Telepharmacy May Open Path to New Business Models for Rural Pharmacies

Even before the coronavirus disease 2019 (COVID-19) pandemic, telehealth and telepharmacy services were growing more popular in rural areas. However, the pandemic caused an unprecedented surge in the utilization of telehealth services, as detailed in the September 2020 issue of *Innovations*. According to research from one health care system consulting firm, telehealth utilization for office visits and outpatient care was 78 times higher in April 2020 than in February 2020. By summer 2021, utilization had declined significantly, but remained about 38 times higher than it was before the pandemic.

Although research is still limited in the effectiveness of telepharmacy compared to traditional programs, the data seem to suggest that telepharmacy can be just as effective. A study published in *Preventing Chronic Disease* in September 2020, for example, found that there was no significant difference between telepharmacies and traditional pharmacies for noninsulin diabetes medications, renin-angiotensin system antagonists, statins, and high-risk medications. The researchers concluded that telepharmacies provide a suitable solution for expanding medication access and that using telepharmacy would not negatively affect the quality of medication use.

Some rural providers have also been experimenting with less traditional telehealth business models. One example is the Rural Virtual Infusion Program, which serves cancer patients in 26 rural counties in Iowa, Minnesota, and South Dakota. The program provides telehealth-based oversight from a tertiary care oncology team, including oncology-certified nurses and pharmacists, for the administration of chemotherapy. Through this model, dozens of patients have been transitioned to receive chemotherapy at rural infusion centers, saving almost 130 patients an estimated $71,000 in travel costs and more than 1,800 hours of travel time.

A similar project, the North Dakota Telepharmacy Project, allows pharmacists to provide services to rural residents at long distances. This project, which has been active since the early 2000s, currently includes 94 pharmacies (32 central pharmacies and 62 remote telepharmacy sites). Approximately 80,000 rural citizens have had their pharmacy services restored, retained, or established through the project, which has also added approximately $26.5 million in economic development to local rural economies, according to North Dakota State University.

According to the NABP 2022 *Survey of Pharmacy Law*, about half of US states currently authorize the use of retail (outpatient) telepharmacy services. In other states, telepharmacy authorization is currently under review.

Lawmakers, Boards of Pharmacy Exploring Ways to Improve Rural Health Care

In July 2019, the House Committee on Ways and Means formed a Rural and Underserved Communities Health Task Force to collect information from stakeholders and communities. The task force continues to review the factors that impact health care access as well as successful models and policies for improving health outcomes in rural communities.

In November 2021, the Biden Administration announced $1.5 billion in funding secured by the American Rescue Plan that will help to support nearly 23,000 rural health care providers through the National Health Service Corps and Nurse Corps.

Although not exclusively focused on rural pharmacies, NABP and the boards of pharmacy have been taking action to help states keep telepharmacy regulation up to date. In October 2016, the Association hosted the Task Force on Telepharmacy Practice in Rosemont, IL, in accordance with a resolution passed at the 112th Annual Meeting. The task force members recommended that NABP collaborate with the boards of pharmacy to discuss the regulation of telepharmacy practices that are occurring between pharmacies and

medical clinics or other facilities that are not regulated by the board. The task force also recommended changes to NABP's *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to include definitions of telepharmacy practice and technologies. This language was further amended by the Committee on Law Enforcement/Legislation in 2017. Detailed reports on both the task force and committee are available in the Reports section of the NABP website. The most recent version of the *Model Act* is available for download from the Board Resources section of the website.

NABP will continue to monitor developments impacting rural access to pharmacy services, as well as other relevant pharmacy regulatory concerns related to this issue.

NABP, Examination Committees Review MPJE Competency Statements and Passing Standard

Process Ensures That Exams Serve Board Needs

NABP is currently in the process of reviewing the Multistate Pharmacy Jurisprudence Examination® (MPJE®) competency statements and passing standard to ensure that the exam continues to be a valuable tool for participating boards of pharmacy to evaluate candidates for licensure. Changes to the competency statements and blueprint, as well as a possible change to the passing standard resulting from this regularly occurring process, would be implemented in January 2023.

The MPJE is designed to assess a candidate's application of laws and regulations for the specific state or jurisdiction in which they are seeking licensure. Examination candidates include new pharmacy graduates seeking initial licensure and practicing pharmacists seeking licensure in a new jurisdiction, as well as Foreign Pharmacy Graduate Examination Committee™ Certification recipients who are seeking initial licensure in a United States jurisdiction.

To ensure that the exam blueprint continues to mirror the current state of pharmacy practice, a job or practice analysis is periodically conducted to review the competency statements and test blueprint weighting that support the interpretation and use claims of the exam. The competency statements describe the specific knowledge, skills, and abilities being measured, and the blueprint weights describe the proportion of the test devoted to each knowledge, skill, and ability. There are numerous methods for conducting a practice analysis, but the most common involves asking subject matter experts to determine a list of competency statements and then conducting a survey to determine how important, frequent, and critical each task is to safe and effective practice. Additional details about the overall test development process area available in an article published to the NABP blog, "Pharmacists, Here's How We Develop the Exams You Take." The current MPJE competency statements and associated blueprint weights can be found in the Examinations section of the NABP website.

Review of MPJE Competency Statements

The review of the MPJE competency statements began in late 2020 by the MPJE Review Committee, which is composed of experts in pharmacy law and regulation who are representative of the diversity of pharmacy practice. The committee conducted an environmental scan of the practice of pharmacy law, which included a literature review of peer-reviewed journals, a review of job descriptions, and other data reviews. The data gathered from these activities informed NABP's recommendations for changes to the current competency statements. These recommendations were then reviewed by NABP's MPJE Review Committee and the Advisory Committee on Examinations prior to approval by the NABP Executive Committee. Once the new competency statements were granted approval through the multistep process, NABP surveyed state boards of pharmacy to determine the appropriate blueprint weights for each content domain. The resulting blueprint weights followed the same review and approval process as the competency statements.

Review of the MPJE Passing Standard

Best practice for high-stakes examinations include a periodic review of an exam's passing standard, as well as a review of the passing standard whenever changes are made to the blueprint. In the summer of 2022, NABP plans to host a standard setting panel charged with reviewing the current passing standard and considering whether a change is necessary. More information is available in the NABP blog article, "Rigorous Process to Set Exam Passing Standard Shows It's More Than Just a Number."

The recommendation from this panel will be reviewed by the MPJE Review Committee and the Advisory Committee on Examinations before being sent to the NABP Executive Committee for approval. The new MPJE competency statements and blueprint, as well as a possible change to the passing standard, are scheduled to be implemented in January 2023. More information about the final changes will be provided in future NABP communications. ●

Coming Soon! Digital Issue of *Innovations*

Beginning with its April 2022 issue of *Innovations,* NABP will be launching a digital version of the newsletter that will be accessible via the NABP website. *Innovations* will continue to be printed as a monthly newsletter and mailed to subscribers and the NABP membership. However, as an additional benefit, an interactive digital version of the newsletter will also be available. Compared with the current pdfs, all dynamic digital *Innovations* issues will include new navigation options and be mobile-friendly. In addition, future digital issues will include access to some of the following "digital-only" content:

- audio and video of interviews, meetings, and public service announcements,
- extended article content and resources,
- shareable infographics,
- interactive visuals, and more.

Keep a lookout in your email inbox for the upcoming digital issue this spring!

Reminder: Annual Meeting Travel Grant Available

Travel grant opportunities are still available for the 118th NABP Annual Meeting in Phoenix, AZ. Eligible individuals may receive up to $1,500 to cover the cost of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include 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 ExecOffice@nabp.pharmacy.

Important Deadlines

- **Poster Proposals** – Due February 23, 2022
- **Proposed CBL Amendments** – Due April 4, 2022
- **Voting Delegate Submissions** – Due April 19, 2022
- **Cut-off Date to Secure Hotel Room** – Ends April 28, 2022

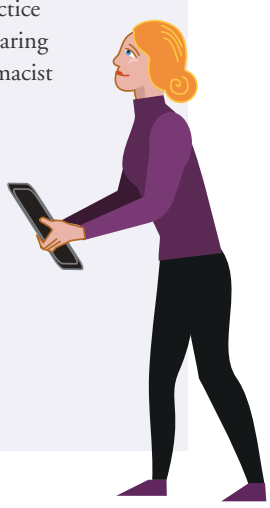
Time Is Running Out to Submit Your Poster Proposal

NABP is seeking proposals for the annual Educational Poster Session to be held the morning of Saturday, May 21, 2022, at the 118th NABP Annual Meeting in Phoenix, AZ. **Proposals must be submitted by Wednesday, February 23, 2022.** Posters should reflect this year's Poster Session theme of "Sharing Our Vision to Advance Public Health Protection," and may be descriptive, scientific, or informational in nature. Possible topics include policy development, public health initiatives, and legislative issues, among others.

Interested in submitting a proposal? Contact NABP Professional Affairs staff via email at Prof-Affairs@nabp.pharmacy for detailed instructions.

Board of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to submit their proposals. Students are welcome to submit poster proposals, and, if selected, they must be accompanied by a credentialed advisor or licensed pharmacist. To be considered for the Poster Session, individuals must be able to attend the in-person meeting on May 21. Selected poster presenters must also be available in March and April for correspondence with NABP staff and to submit required materials.

Poster Session presenters may be eligible to earn Accreditation Council for Pharmacy Education-accredited continuing pharmacy education credit. Details will be provided to individuals who are selected to present posters. Those selected to present a poster will receive a complimentary meeting registration. All participating pharmacy school students will receive a complimentary voucher in their NABP e-Profile valued at $75 to take the Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination®.

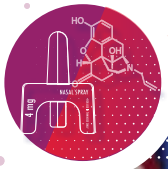


20th US Surgeon General Dr Jerome Adams to Present Keynote Address

Merging his expertise at the forefront of national and global health policy with his own personal experiences, former United States Surgeon General Dr Jerome Adams will present to Annual Meeting attendees on an array of health topics. Never backing down from tough questions, Adams will bring a passion for engagement that pulls him from behind the podium to genuinely interact with attendees.

After growing up poor and Black in a Southern rural community, Adams went on to lead the 6,000-person US Public Health Service as "America's doctor" during a worldwide pandemic. As the 20th US surgeon general, Adams brought a passionate commitment to fighting issues that his family and community experienced, including limited health care access, chronic disease, substance use disorder (SUD) and ensuing stigma, tobacco addiction, maternal health, mental illness, and the opioid epidemic. Growing up with life-threatening asthma, and as a brother to someone with an SUD, Adams navigates politics to tirelessly champion the health of the vulnerable and voiceless during times of crisis.

As a student, Adams excelled in science, math, and technology, and was awarded a scholarship to study biochemistry at the University of Maryland, Baltimore County. It was there that he first met a Black physician ("You have to see it to be it!") and was inspired to pursue a career in medicine. And throughout his career, Adams has continued a hands-on approach to medicine, maintaining hospital privileges and becoming the only surgeon general in recent history to actively practice while in office.



The Keynote Luncheon will take place after the First Business Session on Thursday, May 19. More information, including a full schedule of events, will be available soon at *www.NABPAnnualMeeting.pharmacy.*

Online registration will be available soon at *www.NABPAnnualMeeting.pharmacy.*

Virgin Islands Board of Pharmacy

Number of Board Members
4 pharmacist members and 1 vacancy

Number of Compliance Officers/Inspectors
4 (board members conduct pharmacy inspections)

Rules & Regulations Established by
Board of Pharmacy

Number of Pharmacist Licensees
125

Number of Pharmacies
22

Laura Forbes, RPh, BCSCP, CPPS, CPM, PRS

Virgin Islands Board of Pharmacy

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

I was initially appointed to the Virgin Islands Board of Pharmacy as a pharmacist member in December 2013. I was reappointed for my second term in December 2019.

What steps should a board member take to be successful in their role?

Listen and learn! Being a member of the board is not a passive activity. There is definitely a lot of work to do. You may want to hit the ground running to make changes or improvements as soon as you begin your tenure on the board, but my suggestion is to temper that urge just a little bit. Remember that the actions and decisions you make will affect many. Talk to veteran members on your board as well as members from various areas of the pharmacy community and other stakeholders. It is important to understand "how we got to this point" or "why we do it like this." Take some time to get the background on whatever you are working on. It is possible that your "perfect solution" was tried before and failed. Maybe it could have a negative impact that you did not consider. If it is something new, determine who it is going to affect and get their opinions and buy-in. I have found that this analysis helps me take a fair and balanced approach. As a result, sometimes my final actions/decisions were not what I had initially thought of, or even wanted. Remember: It is not about you; it is about protecting public health.

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

The Board has a lot going on right now. We are near completion of updating our practice act and rules and regulations. We are also developing a registry for our pharmacy technicians and updating our Non-Resident Pharmacy Registration Program. Additionally, in collaboration with the Legislature of the Virgin Islands and the commissioner of health, we are also working on implementing our prescription drug monitoring program.

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

Our biggest challenge is funding for the programs as well as for the necessary staffing to oversee and monitor our many initiatives.

What advice would you give to a new Board member?

Get involved! Remember that you are not alone; partnerships are very important. Reach out to the awesome staff at NABP, other NABP member boards, and boards of other professions in your state.

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 served on several task forces and committees, most recently in August 2021 on the Work Group to Consider Permanently Extending Certain Waivered Provisions. Since my first appointment to the Board in 2013, I have only missed one NABP Annual Meeting. The experience of attending, the information that is shared, the knowledge that is gained, the friendships that are formed, and the connections that are made are *priceless*. ●

Executive Officer Change

- **Angel E. Sostre Cintron** has been named executive director of the Puerto Rico Office of Regulation and Certification of Health Professionals, succeeding Norma Torres-Delgado.

Board Member Appointments

- **Ashley Schaber, MBA, PharmD, BCPS,** has been appointed a member of the Alaska Board of Pharmacy. Schaber's appointment will expire March 1, 2024.
- **Ivan Figueroa-Agrinsoni, MBA, PharmD,** has been appointed a member of the Puerto Rico Board of Pharmacy. Figueroa-Agrinsoni serves at the discretion of the appointing body.
- **Sara Vega** has been appointed a member of the Puerto Rico Board of Pharmacy. Vega serves at the discretion of the appointing body.
- **Vernique Caswell, PharmD, RPh,** has been appointed a member of the Virgin Islands Board of Pharmacy. Caswell's appointment will expire December 20, 2024.
- **Amy Durand, PharmD, RPh,** has been appointed a member of the Virgin Islands Board of Pharmacy. Durand's appointment will expire May 4, 2026.
- **Danson Nganga, PharmD, RPh,** has been appointed a member of the Virgin Islands Board of Pharmacy. Nganga's appointment will expire December 20, 2024.
- **Ann Wolken, PharmD, RPh,** has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Wolken's appointment will expire January 19, 2025.

Board Member Reappointments

- **James Henderson, RPh,** has been reappointed a member of the Alaska Board of Pharmacy. Henderson's appointment will expire March 1, 2025.
- **Tammy Lindemuth** has been reappointed a public member of the Alaska Board of Pharmacy. Lindemuth's appointment will expire March 1, 2025.
- **Laura Forbes, RPh, BCSCP, CPPS, CPM, PRS,** has been reappointed a member of the Virgin Islands Board of Pharmacy. Forbes' appointment will expire December 20, 2024.

NABP Accreditations and Verifications

NABP awarded a total of 107 accreditations and verifications from September 1 to October 31, 2021. The breakdown by program is as follows:

Drug Distributor Accreditation: 42

DMEPOS Pharmacy Accreditation: 26

Digital Pharmacy Accreditation: 5

Compounding Pharmacy Accreditation: 8

Home Infusion Therapy Pharmacy Accreditation: 2

Specialty Pharmacy Accreditation: 2

.Pharmacy Verified Websites: 21

Community Pharmacy Accreditation: 1

To see the names of businesses accredited and verified by NABP, visit the Programs section of the Association's website at *www.nabp.pharmacy*.

Missouri Amends Rules Related to Prescription Transfer Orders

The Missouri Board of Pharmacy has amended its rules to modify time frames for medication and prescription orders. Requests that are from patients or caregivers must be transferred within one business day of the request. Licensees are to use their professional judgment when additional time may be needed during a transfer. More information about the amended rules can be found in the Board's *Newsletter* at *https://pr.mo.gov/boards/pharmacy/newsletter/2021-06-10.pdf.*

South Dakota PDMP Automates Verification Processes to Positively Impact Patient Care

The South Dakota Prescription Drug Monitoring Program (SD PDMP) has partnered with South Dakota professional licensing boards in a license integration project to enable auto-approval of new PDMP accounts, if required criteria are met, and daily reverification of all current users. Upon submission of the online account application and successful automated verification with professional licensing board data, accounts are auto-approved and ready for immediate access, positively impacting patient care. SD PDMP staff is now able to shift the significant amount of time previously spent in the manual account approval and reverification processes to other program priorities. South Dakota patients also benefit from the elevated program user integrity that this project provides to assist in ensuring appropriate patient access.

Virginia Explores the Definition of 'New Prescription'

Virginia Attorney General Mark Herring recently opined that a subsequent prescription "for the same medication without a change in dose, directions, or drug formulation is considered a 'new prescription' under §54.1-3319 of the Code of Virginia for which a pharmacist must offer counseling." Since the term "new prescription" is not defined in the Code of Virginia or in Virginia Board of Pharmacy Regulations, the attorney general's opinion relies upon the "plain and ordinary meaning" of the word "new."

Washington Now Requires Telehealth Training

Washington State health care professionals who offer telemedicine services to patients must now complete telemedicine training before offering those services. This is a mandate of Revised Code of Washington (RCW) 43.70.495.

The RCW defines telemedicine as "the delivery of health care services through the use of interactive audio and video technology, permitting real-time communication between the patient at the originating site and the provider, for the purpose of diagnosis, consultation, or treatment."

Additionally, Engrossed Substitute House Bill 1196, passed during the 2021 legislative session, requires that audio-only telemedicine is reimbursed at the same rate as if the services were performed in person. Certain services such as those that are customarily performed over audio-only technology (eg, facsimile and email) are not considered audio-only telemedicine. ●

Most articles published in State Board News are selected from the newsletters of state boards that participate in the NABP State Newsletter Program. Issues are posted on the NABP website on each participating state's page.

Study Shows More Americans Turn to Social Media for Their Health Information

Where are Americans going for trusted health care sources? New data from a PatientsLikeMe survey showed that 11% of Americans admit to looking to social media for reliable health information. Data from the survey also showed that about 9% of Americans use social media to evaluate treatment information, and 7% of Americans use social media to search side effects of medications.

In May 2021, NABP launched its 2021 consumer awareness campaign to inform consumers about the dangers of buying medicine from unlicensed pharmacies online and through social media accounts. Boards of pharmacy and other health care organizations and providers are encouraged to use NABP's patient education kit to share important online medication safety information with patients in their state. The education kit includes social media posts and images, a public service announcement video, a newsletter article, and a PowerPoint presentation that can be shared through various social channels to support NABP's #BuySafely initiative. The education toolkit can be found on NABP's consumer website by visiting *safe.pharmacy/resources.*

FDA Revises Hospital and Health System Compounding Guidance

Food and Drug Administration (FDA) has revised its hospital and health system compounding guidance to continue its efforts of preserving patient access to compounded drugs for patients who have a medical need for them. FDA recognizes that compounded drugs can serve an important role for patients in hospitals and other health care settings whose medical needs might not be met by an FDA-approved drug. The revisions to the draft guidance include removing the one-mile radius provision based on comments FDA received after the 2016 published guidance.

Revisions to the draft guidance can be found on FDA's website by visiting *www.fda.gov/media/97353/download.*

NIH Study Suggests Individuals With SUDs May Be at Higher Risk of Breakthrough SARS-CoV-2 Infections

The risk of SARS-CoV-2 breakthrough infections among vaccinated patients with substance use disorders (SUDs) is higher than the risk for vaccinated patients without SUDs, according to a study analysis of nearly 580,000 fully vaccinated people in the United States. The study, led by researchers at the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), and Case Western Reserve University in Cleveland, OH, found that 7% of vaccinated individuals with a SUD had a breakthrough infection during the study compared to 3.6% of vaccinated individuals without a SUD. Researchers noted that co-occurring health conditions and adverse socioeconomic determinants of health, which are more common in people with SUDs, appear to be largely responsible for the increased risk of SARS-CoV-2 breakthrough infections.

Information on the study can be found on the NIH website at *www.nih.gov/news-events/news-releases/people-substance-use-disorders-may-be-higher-risk-sars-cov-2-breakthrough-infections.*

Data Show Buprenorphine Misuse Decreased in Individuals With OUD

A study conducted by NIDA showed that from 2015 to 2019 the misuse of buprenorphine among people with opioid use disorder (OUD) has continued to decrease. Nearly three-fourths of adults reporting buprenorphine use did not misuse the medication in the past 12 months, according to NIDA. The study, published in *JAMA NetworkOpen* in October 2021, underscores the need to expand access to buprenorphine for OUD treatment.

With pharmacists on the front lines of the opioid epidemic, NABP continues to raise awareness and take steps to reduce OUD. Promoting pharmacist-provided medication-assisted treatment for patients diagnosed with OUD was the focus of 2020-2021 NABP President Timothy D. Fensky, RPh, DPh, FACA.

New In-App Tool to Educate on the Dangers of Drugs

Snap Incorporated, a camera company with its flagship product, Snapchat, announced it is launching an in-app tool that will educate Snapchat users searching for drug-related keywords on the platform. Specifically, a new Snapchat filter and video were created to raise awareness of the dangers of fentanyl and counterfeit pills.

More information about the new tool can be found by visiting *www.reuters.com/technology/snap-launches-in-app-tool-drug-dangers-following-fentanyl-deaths-2021-10-07.*

NABP
National Association of Boards of Pharmacy

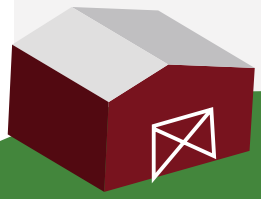
1600 Feehanville Dr
Mount Prospect, IL 60056

UPCOMING EVENTS

Advisory Committee on Examinations
April 7, 2022 | NABP Headquarters

Committee on Constitution and Bylaws
April 11, 2022 | Virtual Meeting

118th NABP Annual Meeting
May 19-21, 2022 | Phoenix, AZ



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