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# iNNOVATIONS

## INSPECT TO PROTECT

NABP Services Help Member Boards  
Secure Pharmacy Supply Chain,  
Advance Patient Safety



**NABP**  
National Association of  
Boards of Pharmacy

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## INNOVATIONS

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**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

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*NABP Executive Committee elections are held each year at the Association's Annual Meeting.*





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

## Fellow Members,

The year has been a mix of continued challenges and renewed hope. The COVID-19 vaccine became widely available throughout the country, while at the same time, the Delta variant and other challenges have made the disease relentless. And though the opioid overdose epidemic threat continues because of illegal fentanyl, many efforts have been renewed by federal, state, and local agencies and organizations to help people suffering from opioid use disorder. These public health crises have been further complicated by the natural disasters causing devastation in various regions of the country. During such challenges, the boards of pharmacy are not always noticed by the general public, but the work we do to protect public health is of vital importance.

Pharmacy inspections have long been an essential part of how the boards pursue that goal. They provide opportunities for the boards to see what is really going on inside a business, a chance to help educate practitioners, and a means to help ensure that businesses have a certain level of accountability when it comes to following appropriate state and federal regulations and guidelines. Personally, the work of skilled inspectors and surveyors brings me much peace of mind when it comes to pharmacy and supply chain safety. This issue's cover story touches on this role, including how NABP inspectors and surveyors supplement Food and Drug Administration's and the boards' inspection resources and also adapted to the ever-changing pharmacy landscape throughout 2021.

With the challenges of 2021 likely continuing into 2022 and beyond, it is important to ensure that the boards of pharmacy have access to as many resources as possible. This includes the NABP Interactive Forums, where members from all over come together to collaborate and develop solutions to shared challenges.

Most recently, Interactive Executive Officer Forum attendees (see page 5) convened to discuss topics ranging from telehealth regulation to continuing pharmacy education to supply chain security. And soon, the Interactive Compliance Officer and Legal Counsel Forum will offer a unique opportunity for these board staff to exchange insights and information.

Appreciation also goes out to staff at each member board who provided updates for the 2022 *Survey of Pharmacy Law*. Published each December, the value of the *Survey* is greatly enhanced by these efforts, and the *Survey* remains an important resource for all member boards and staff, as well as other regulators and stakeholders. That's one of the reasons that NABP will soon be providing the executive officers of each member board of pharmacy with a complimentary copy of the *Survey* that can be utilized by officers and staff.

I would also like to thank the board members who have served or who have been appointed to serve as members of NABP task forces and committees (page 11). The Association's task forces are an important part of how NABP helps its member boards of pharmacy stay informed about timely topics and important trends in pharmacy regulation. They are also helpful for providing guidance to NABP and its member boards through their recommendations. If you are a current or past board of pharmacy representative interested in participating in future task force meetings, please submit a volunteer application form online by spring 2022. NABP President-elect Reginald B. "Reggie" Dilliard, DPh, will be making appointments for 2022-2023 at that time. A link to the form can be found on the Board Resources page in the Members section of the NABP website.

On behalf of the NABP Executive Committee, we wish all members a happy fall and holiday season, and I look forward to addressing you again through *Innovations* in the new year. ●

Sincerely,

A stylized, handwritten signature in dark ink, appearing to read 'Timothy D. Fensky'.

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

## Prescription Drug Importation Policies – Politically Popular, But Problematic for Public Health

High prescription drug prices continue to be a political lightning rod in Washington, DC, as state capitals across the country and policymakers on both ends of the political spectrum consider solutions to this issue impacting American patients and our larger health care system. One idea that continues to emerge during these debates is that importing prescription drugs from Canada could save Americans money. However, independent studies have found that importing drugs from foreign countries would not provide cost savings, and further that the practice could compromise the highly regulated and secure United States drug supply chain. Despite these realities, policymakers continue to promote the false promises of drug importation.

Last year, on November 30, 2020, a Trump Administration final rule went into effect to pave the way for states to apply to the US Department of Health and Human Services (HHS) to be permitted to import drugs into the country from Canada. In rapid succession, a handful of states – starting with Florida – began drafting and submitting proposals to HHS, and nearly 20 states have taken the preliminary steps of introducing legislation to establish a wholesale prescription drug importation program. States have been given flexibility regarding how they can design their importation programs, making no two state plans the same.

Prescription drug importation as a proposed solution to drug pricing is nothing new. The plan, however, is peppered with public health safety risks that NABP has raised for nearly two decades.

NABP understands the efforts to increase patient access to affordable medications, but has argued that such efforts must ensure the safety and security of products.

### Drug Importation Can Compromise the Drug Supply Chain

NABP assists member boards of pharmacy in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. Since the 1980s, NABP

has sought to address the ongoing threat of counterfeit medications entering the nation's drug supply chain. As such, NABP has expressed concerns with any plan to bring drugs into the US that bypasses America's highly regulated drug supply chain. NABP is not alone in this concern. Food and Drug Administration (FDA) has technically had the legal authority to allow for the wholesale importation of prescription drugs since 2003, when Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act. However, time and time again, the agency and public health leaders from both political parties have attested to drug importation's true cost to public health. While drug importation proponents may argue that much has changed since Congress originally granted FDA this authority, the fact remains that the policy still carries with it the risk of allowing counterfeit products to enter our supply chain. For example, the Drug Supply Chain Security Act, enacted in 2013, took major steps toward helping further protect the American drug supply chain. However, that law has yet to be fully implemented and does little to address the type of importation program entertained by recent policy.

Further, drug importation – even if intended to be for wholesale and not personal use – can directly or indirectly drive unknowing consumers to the internet where NABP has found that 96% of online “pharmacies” are operating illegally, with many falsely claiming to be based in Canada. Even worse, these policies are being advertised and advanced during a time when criminals are increasingly seeking opportunities to take advantage of consumers' fears related to the coronavirus disease 2019 (COVID-19) pandemic. As early as March 2020, criminals began creating websites offering cheap COVID-19 cures and treatments online to defraud American consumers as they began to turn to the internet seeking information and legitimate health care. NABP continues to

work with public health stakeholders to monitor and report bad actors peddling illicit and fake drugs on the internet.

Unfortunately, the recent political messaging around “safe and cheap” drugs from Canada, coupled with the ongoing COVID-19 public health emergency, has created a perfect and dangerous storm on the internet. Boards of pharmacy and providers should remember and share with their patients that NABP's .Pharmacy Verified Websites Program can help consumers distinguish rogue websites from verified, safe ones.

### Drug Importation Offers False Promise of Cost Savings

Like many political promises, the supposed cost savings associated with drug importation would likely come up short. In fact, the 2020 Importation of Prescription Drugs final rule, which went into effect in November 2020, explicitly states that HHS could not even estimate the potential cost savings the rule would enable. This inability to prove cost savings is not surprising as it is not the first time the agency has previously indicated that drug importation would have a negligible impact on drug spending in the US. The promise of accessing cheaper drugs from our Canadian neighbors seems simple, but the reality remains that the actual cost of the importation process just adds to the price through packaging, testing, shipping, and compensating middlemen along the way.

### Canada Is Not Eager to Supply the Drugs

Importantly, the process proposed in the Trump Administration's final rule requires the cooperation of at least one Canadian supplier to work with the state seeking approval to import drugs from Canada. However, states may come up short when they look for suppliers in Canada as the National Association of Pharmacy Regulatory Authorities, NABP's counterpart in Canada, has weighed in, stating they do not have enough supply for their own population,



Sarah-Lloyd Stevenson, MPH  
Faegre Drinker Biddle & Reath LLP

let alone for Americans. The Canadian government has even echoed this sentiment, commenting on the Trump Administration's drug importation rule when it was first proposed, stating that the rule "would not provide an effective solution to the problem of high drug prices in the U.S." and that "Canada's drug market is too small to meet American consumer demand . . . or have an impact on high drug prices." The Canadian government further argued that this policy could exacerbate drug shortages in its own country and put the health of Canadians at risk. Canada also has concerns about the safety of American consumers and the integrity of the American supply chain. Leaders in Canada have said their nation does not have the resources to monitor the safety of medicines destined for the US and that American authorities would be responsible for trying to confirm the safety of these imported drugs.

### Drug Importation in the Biden Administration and 117<sup>th</sup> Congress

With any administration change, especially one with a shift in party power, there is always an appetite to overhaul and create a perception, whether real or not, of a new beginning. As drug importation was a promise of the previous administration, it was possible that the Biden Administration could reconsider the future of the 2020 drug importation final rule. However, HHS Secretary Xavier Becerra did vote in favor of drug importation during his time in Congress,



Nisha K. Quasba, MPH  
Faegre Drinker Biddle & Reath LLP

and the policy idea generally remains politically popular on both sides of the political spectrum. While President Joseph R. Biden's HHS will likely try to advance its own ideas for how to curtail the price of drugs in the US, the administration may not prioritize taking drug importation back to the drawing board. On July 8, citing a lack of responses, HHS revoked the previous administration's request for additional proposals related to new pathways for drugs to be imported from other countries, including for personal importation. However, the following day, President Biden signed an executive order aimed at boosting competition in the American economy, including a directive to FDA to engage with states and tribes interested in importing prescription drugs from Canada, cementing the Biden Administration's support of the policy. However, the new administration and new secretary have the authority to apply additional scrutiny to drug importation plans submitted by states.

Meanwhile, importation still piques the interest of many policymakers in Capitol Hill, especially as drug pricing continues to rise to the top of the congressional agenda. Early in the 117<sup>th</sup> Congress, Senators Amy Klobuchar (D-MN) and Chuck Grassley (R-IA) reintroduced the Safe and Affordable Drugs from Canada Act (S 259), which would permit the importation of drugs from approved pharmacies in Canada for personal use. Despite the bipartisan leadership of this legislation, it is unlikely to advance in the 117<sup>th</sup> Congress given the sizable stakeholder opposition.

### NABP's Focus Remains Public Health

States will face challenges securing the drug supply chain under the new drug importation rule. Staying true to its mission, NABP remains committed to protecting and promoting public health before all else. NABP President Caroline D. Juran, BSPHarm, DPh (Hon), has made it her 2021-2022 presidential initiative to leverage NABP's expertise as an accreditation organization to help mitigate the risks in the global supply chain by educating and providing guidance to states, the federal government, and the boards of pharmacy. As a majority of state boards of pharmacy are responsible for regulating the distribution of prescription drugs, the Association stands ready to assist in standardizing processes to ensure that patients continue to receive safe, legitimate, and unaltered medications. ●

*This article was written by Sarah-Lloyd Stevenson, MPH, and Nisha K. Quasba, MPH, 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.*

**Hyperlinks to the following references are available in the November/December 2021 *Innovations* pdf on [www.nabp.pharmacy](http://www.nabp.pharmacy).**

- "Former FDA Commissioners Warn About Drug Importation." The Partnership for Safe Medicines.
- "Government of Canada Comments on the Proposed Rule 'Importation of Prescription Drugs.'" Government of Canada.
- *HHS Task Force on Drug Importation Report on Prescription Drug Importation*. US Department of Health and Human Services.
- *Internet Drug Outlet Identification Program*. NABP.
- "Medication Importation Requires More Study to Ensure Patient Safety, Cautions NABP." NABP.
- *Rogue Rx Activity Report*. NABP.
- *The Washington Post*. Opinion: "Dear Bernie Sanders: Canada is not the United States' drugstore" [editorial].



## Steven W. Schierholt, Esq

Executive Director, State of Ohio Board of Pharmacy

### How long have you served as executive director of the State of Ohio Board of Pharmacy? What was your prior role?

I have been executive director for almost seven years. Previously, I was assistant superintendent of the Ohio Bureau of Criminal Investigation, an agency under the Ohio attorney general that manages the state's criminal database and criminal records repository, operates crime labs throughout the state, and has a large investigation staff. I was in charge of each of those operational divisions.

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

Ohio and other states across the country are still in the middle of an opioid epidemic. Prior to the coronavirus disease 2019 pandemic, that was front and center for us. We believe the Board plays a role in and contributes to the state's efforts to combat that epidemic.

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

One of the first things I think of are prescriber limits and how, despite climbing overdose death rates, the number of deaths attributable to prescription controlled substances has gone down in Ohio year after year. We are not declaring victory, but the Board is proud of the contribution it has made in policing pill mills, educating the pharmacist community, and encouraging pharmacists to be a part of the solution. For example, the Board created a pocket card for pharmacists who might not be comfortable having difficult conversations with a patient exhibiting drug-seeking behavior. One side of the card articulates the Ohio law that deals with corresponding responsibility; the other side provides substance abuse treatment options. A pharmacist can hand the pocket card to that patient and say, "Look, I can't fill this. Here are the rules; here are the laws. And, by the way, on the back are some treatment options if you believe you may benefit from treatment."

While there initially was some pushback on prescribing limits, we received no complaints from pharmacists about the Board's requirements to check Ohio's prescription monitoring program (PMP) and be part of the solution. We are very proud of Ohio's PMP – the Ohio Automated Rx Reporting System (OARRS) – and are working tirelessly to make it an indispensable health care tool. Ohio was the first state in the country to integrate a PMP into the clinical workflow and to fund it. The number of doctor shoppers in Ohio has dropped precipitously, in part due to working OARRS into the clinical workflow.

### What other key issues has the Board been focusing on?

The Board has spent a lot of time making sure that its administrative rules reflect the changes that are occurring in the practice and regulation of pharmacy. We are doing everything we can to make sure that our rules reflect reality and are easy to follow. Trying to harmonize federal and state regulations can be difficult in practice, so we are upping our communication to our licensees and other health care professionals who are impacted by the Board's rules.

In addition, in the last six and a half years, we have rebranded and redesigned our websites. We want them to be one-stop sources of information for the pharmacy community as well as for the prescribing and medical communities.

### What insights do you have for other states?

I think it is incumbent upon the boards of pharmacy to work with other entities, to the extent that their laws allow or require, to fight diversion and overprescribing. The data that we obtain from our PMP are astounding. Our OARRS staff can look at the data and identify prescribers who are operating outside the rules or law. It might be easier to throw up your hands and say, "Well, here is my piece of the puzzle," and that is it. But if you work with other agencies in your state and put all the pieces together, I think you can make a greater difference. ●

#### State of Ohio Board of Pharmacy



##### Number of Board Members

8 pharmacist members and 1 public member (public member must be at least 60 years of age)



##### Number of Compliance Officers/Inspectors

10 clinical and 38 non-clinical site inspectors



##### Rules & Regulations Established by State Board of Pharmacy



##### Number of Pharmacist Licensees

20,979



##### Number of Pharmacies

2,780 (in-state)



##### Number of Wholesale Distributors

1,456



## Executive Officers Collaborate at NABP Interactive Forum

Thirty-eight board of pharmacy executive officers gathered, both virtually and in person, for the annual NABP Interactive Executive Officer Forum, held September 28-29, 2021, in Northbrook, IL. Themed “Sharing Solutions, Advancing Regulation,” the event offered attendees an opportunity to discover solutions to challenges faced

by the state boards, and reinforced the partnership between the boards of pharmacy and NABP in their shared mission to protect the public health. The meeting featured two days of sessions to provide executive officers with an opportunity to discuss specific topics and issues of special interest provided by invitees.

Prior to the Interactive Executive Officer Forum, the New Executive Officer Orientation Program was held the afternoon of Monday, September 27, 2021. The orientation enabled newly appointed executive officers to become acquainted with NABP membership and governance. ●



The session “What’s the Buzz in Digital Health Care?” included discussions about the regulation of telepharmacy, online pharmacy trends, and remote clinical services. Pictured are (left to right) Mark J. Hardy, PharmD, RPh, executive director, North Dakota State Board of Pharmacy; Niamh Lewis, JD, digital health regulatory expert, NABP; Justin Macy, PharmD, JD, digital health senior manager, NABP; and session moderator Kamlesh “Kam” Gandhi, PharmD, RPh, member, NABP Executive Committee, and executive director, Arizona State Board of Pharmacy.



The session “Standards of Care – To Be or Not To Be Regulated?” featured a discussion about the implementation of standards of care models. Pictured are (left to right) Joseph Schnabel, PharmD, RPh, BCPS, executive director, Oregon State Board of Pharmacy; session moderator Fred M. Weaver, RPh, member, NABP Executive Committee; and Steven W. Schierholt, Esq., executive director, State of Ohio Board of Pharmacy. Not pictured is Kimberly Grinston, JD, executive director, Missouri Board of Pharmacy, who presented virtually.



The session "Nonresident Licensure – How Can We Ensure Public Protection?" offered attendees insight into sharing information with NABP e-Profile, data integration and exchange, and the NABP Emergency Passport. Pictured are (left to right) Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy; Bill Cover, RPh, associate executive director, state pharmacy affairs, NABP; Josh Bolin, associate executive director, federal affairs and strategy, NABP; and session moderator Deborah C. Mack, RPh, CHC, CCEP, member, NABP Executive Committee. Not pictured is Jack W. "Jay" Campbell IV, JD, RPh, executive director, North Carolina Board of Pharmacy, who presented virtually.



The session "The Future of Pharmacy Education" provided information about pharmacy school graduates, competency assessment and verification, and continuing pharmacy education. Pictured are (left to right) Maureen Garrity, PharmD, competency assessment director, NABP; Susan B. McCoy, RPh, executive director, Mississippi Board of Pharmacy; John Clay Kirtley, PharmD, RPh, executive director, Arkansas State Board of Pharmacy; session moderator Lenora S. Newsome, PD, NABP treasurer; and Danna Droz, JD, RPh, PMP senior manager, NABP.





The session "Advancing the Implementation of the DSCSA" included a regulatory update as well as discussion on educating stakeholders about importation issues. Pictured are (left to right) Andrew Funk, PharmD, RPh, executive director, Iowa Board of Pharmacy; 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 Leigh Verbois, PhD, director, Office of Drug Security, Integrity, and Response, Office of Compliance, Center for Drug Evaluation and Research, United States Food and Drug Administration (FDA), who presented virtually.



The session "MOU/ISN Update and Issues/Solutions" provided updates about the FDA memorandum of understanding and the NABP information sharing network. Pictured are (left to right) session moderator Shane R. Wendel, PharmD, RPh, member, NABP Executive Committee; Melissa Madigan, PharmD, JD, associate executive director, professional affairs, NABP; Tim Tucker, PharmD, RPh, executive director/secretary, Texas State Board of Pharmacy; and Neal Watson, member relations/government affairs senior manager, NABP.



Three Shared Discussion Topics sessions were held during the forum. The sessions enabled attendees to discuss issues of special interest that they provided via a survey prior to the meeting. Pictured are (left to right) session moderators Reginald B. "Reggie" Dilliard, DPh, NABP president-elect; Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee, and executive director, Idaho State Board of Pharmacy; and Jeffrey J. Mesaros, PharmD, JD, RPh, member, NABP Executive Committee.



The New Executive Officer Orientation Program was held the afternoon of September 27, 2021, prior to the Interactive Executive Officer Forum. The orientation enabled newly appointed executive officers to get acquainted with NABP membership and governance. Pictured are Jessica Sapp, executive director, Florida Board of Pharmacy, and Tim Tucker, PharmD, RPh, executive director/secretary, Texas State Board of Pharmacy. Not pictured is Anne Sodergren, executive officer, California State Board of Pharmacy, who participated virtually.

# INSPECT TO PROTECT

NABP Services Help Member  
Boards Secure Pharmacy  
Supply Chain, Advance  
Patient Safety





## Nearly 10 years ago, contaminated products compounded at a single facility in Massachusetts, the New England Compounding Center (NECC), led to 753 cases of fungal meningitis in 20 states.

At least 64 people died, according to the Centers for Disease Control and Prevention. In the years that followed the initial outbreak, the state boards of pharmacy, federal regulators, and NABP have all taken steps to ensure that pharmacies that engage in sterile compounding are held to minimum standards established in Chapter <797> of the United States Pharmacopeia (USP). When operating as an outsourcing facility, shipping products to health care facilities in multiple states, these facilities must also comply with current Good Manufacturing Practices (cGMPs), as defined in Food and Drug Administration (FDA) rules.

For NABP, one of the most significant steps taken in the wake of the outbreak was the development of the Multistate Pharmacy Inspection Blueprint Program, which was developed in close collaboration with member boards of pharmacy. Since 2015, the Inspection Blueprint has served as a living document that provides a minimum set of criteria for pharmacy inspections based on current USP standards, along with field operations' best practices. This year marks the fifth anniversary since NABP began accepting program participation forms, and the blueprint remains a valuable tool for helping states set minimum safety standards for compounding facilities and other pharmacies.

The blueprint also helps to highlight the connections within the drug supply chain and how those connections result in additional interactions between inspection programs. For example, compounding pharmacies that are subject to sterile or nonsterile compounding regulation are typically sourcing ingredients from entities that sell bulk drugs or active pharmaceutical ingredients, and those companies must get them from licensed drug wholesale distributors, manufacturers, or repackagers. Many of these entities are accredited with NABP as distributors, and many repackage their own ingredients, and so are also registered with FDA under federal regulations.

The NECC case emphasizes the degree to which inspections and the interconnection with the supply chain can intersect with important patient health issues.

## NABP Inspections Complement FDA Regulation

One major change that occurred in the aftermath of the NECC tragedy was the passage of the Drug Quality and Security Act (DQSA), enacted by Congress on November 27, 2013. Title I of the law, the Compounding Quality Act, creates a new category of regulated entity – human drug compounding outsourcing facilities. These facilities are subject to cGMP requirements; however, drug products compounded by or under direct supervision of a licensed pharmacist at an outsourcing facility may qualify for exemptions from certain parts of the Federal Food, Drug, and Cosmetic Act when certain conditions are met. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines the steps needed to build an electronic, interoperable system to identify, track, and trace certain prescription drugs as they are distributed within the US.

Given the important safety measures taken to improve compounding safety since the NECC outbreak, NABP is keeping a close eye on this behavior and reporting to FDA and state regulatory bodies when appropriate.

In June 2021, FDA released four related guidances that set the agency's expectations for how manufacturers should comply with new product tracing requirements. These include guidances on enhancing drug distribution safety, identifying suspicious products, product identifiers, and defining suspect and illegitimate products. The DSCSA requires that trading partners adopt and implement such interoperable and enhanced systems by November 27, 2023.

The requirements highlight an important role that NABP inspections and accreditations have in complementing FDA regulation. For example, a recent area of focus for some inspectors and surveyors has been biologics. From a distribution perspective, biologics are considered prescription drugs. However, FDA regulates biologics as a different type of product. This is particularly evident in how those medications are evaluated and approved. This regulatory dissonance has caused some confusion regarding compounded products that have active biologic ingredients. Until recently, these products were regulated as drugs and could be compounded by qualified facilities. However, as FDA has recently transitioned to regulating these products as biologics, pharmacies that wish to continue compounding them must be registered as a biologic manufacturer with FDA. NABP has recognized these changes in law and regulation and has been helping to identify companies that are compounding biologics as a compounding pharmacy.

Another area of focus has been supply chain inspections in certain states. The NABP Supply Chain Inspection program was created

to provide a regulatory type of inspection for drug supply entities that can be readily shared with the member boards of pharmacy via the information sharing network. For example, starting in 2019, NABP provided supply chain inspections to supplement a state inspection program under contract. During summer 2019, this program helped to identify several unusual behaviors that potentially placed the supply chain at risk of contamination. These included wholesalers that kept certain doors open because they did not have air conditioning, facilities that had not been inspected for several years, and facilities that had been in business for decades without any licensure in the states where they were selling products.

NABP is also in a unique position to see what drugs physicians' offices are purchasing. In recent years, more of these offices have started engaging in compounding. Because these offices are not regulated as compounders, it may represent a loophole in compounding oversight regulations, NABP's insights can help identify unusual and potentially unsafe activity. Given the important safety measures taken to improve compounding safety since the NECC outbreak, NABP is keeping a close eye on this behavior and reporting to FDA and state regulatory bodies when appropriate.

These are just a few examples of issues that NABP inspections and accreditation staff have found while performing inspections. With changes in federal regulations and laws, and particularly as DSCSA requirements continue to go into effect, NABP will monitor these issues and will update programs and guidelines to align with DSCSA requirements and FDA guidance. NABP is also working on additional tools and training to assist member boards with the electronic, interoperable system that is coming in 2023.

NABP currently offers accreditation and inspections services for a wide variety of facilities, including sterile and nonsterile compounding pharmacies, as well as wholesale drug distributors and supply chain inspections. ●

## NABP Accreditations and Verifications

NABP awarded a total of 128 accreditations and verifications from June 1 to August 31, 2021. The breakdown by program is as follows:



**Drug  
Distributor  
Accreditation:**  
61



**DMEPOS  
Pharmacy  
Accreditation:**  
20



**Digital  
Pharmacy  
Accreditation:**  
8



**Compounding  
Pharmacy  
Accreditation:**  
9



**Home Infusion  
Therapy Pharmacy  
Accreditation:**  
1



**.Pharmacy  
Verified  
Websites:**  
29

To see the names of businesses accredited and verified by NABP, visit the Programs section of the Association's website at [www.nabp.pharmacy](http://www.nabp.pharmacy). ●



## 2021-2022 Committee and Task Force Members Appointed by President Juran

NABP provides guidance on current topics of interest to the state boards of pharmacy through the recommendations of commissioned, single-issue task forces. When an issue arises that requires special expertise or a commitment of time and funds, a task force is appointed to address a specific charge and to report its findings to the NABP Executive Committee. Task force and committee reports are published on the NABP website once approved.

NABP President Caroline D. Juran, BSP Pharm, DPh (Hon), made the following appointments for task forces, standing committees, and a work group for 2021-2022.

### Task Forces

The **Task Force on State Oversight of Drug Importation** met at NABP Headquarters on September 20-21, 2021. The task force was established pursuant to Caroline D. Juran's 2021-2022 presidential initiative, which is to increase efforts to support the boards of pharmacy and to educate and protect the public about state drug importation plans.

The task force was charged with the following objectives:

1. Evaluate the current regulatory environment related to prescription drug importation and the challenges that states will face with regulating importation.
2. Review NABP programs to determine how they may support states that implement drug importation programs.
3. Develop educational tools to assist states in the oversight of drug importation.

Chairperson of this task force was Andrew Funk, PharmD, RPh, Iowa Board of Pharmacy.

Individuals appointed to serve as members included:

- Paul Brand, PharmD, AE-C, Montana Board of Pharmacy
- Robert Carpenter, RPh, Vermont Board of Pharmacy
- John Colaizzi, Jr, PharmD, RPh, CCP, New Jersey State Board of Pharmacy



- Brenda McCrady, PD, RPh, Arkansas State Board of Pharmacy
- Shanea D. McKinney, PharmD, RPh, Tennessee Board of Pharmacy
- Rich Palombo, RPh, DPh, New Jersey
- Jeanne D. Waggener, RPh, DPh, Texas
- Stuart T. Williams, JD, Minnesota Board of Pharmacy
- Linda Witzal, RPh, New Jersey State Board of Pharmacy

The Executive Committee liaison was Jeffrey J. Mesaros, PharmD, JD, RPh.

### The Task Force on Safety-Sensitive Measures to Review Medication Errors

met at NABP Headquarters on October 11-12, 2021. The task force was established in response to Resolution No. 117-5-21, passed at the 117<sup>th</sup> NABP Annual Meeting.

The task force was charged with the following objectives:

1. Determine ways to assist state boards of pharmacy in developing alternative regulatory approaches to review medication errors that can result in preventing future errors from occurring.
2. Review systems that implement best practices to reduce medication errors and increase patient safety and develop recommendations regarding their use as an element of implementing a just culture regulatory approach.
3. Amend, if necessary, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to reflect the work of this task force.

Chairperson of this task force was Jack W. "Jay" Campbell IV, JD, RPh, North Carolina Board of Pharmacy.

Individuals appointed to serve as members included:

- Richard de Blaquiére, PharmD, RPh, Idaho State Board of Pharmacy
- Ricardo "Rick" Fernandez, MBA, RPh, Texas State Board of Pharmacy
- Ronald F. Guse, Manitoba, Canada
- Sebastian Hamilton, MBA, PharmD, RPh, Massachusetts Board of Registration in Pharmacy
- Donna M. Horn, MS, RPh, DPh (Hon), CHC, Massachusetts
- John M. Marraffa, Jr, RPh, New York State Board of Pharmacy
- Edward G. McGinley, MBA, RPh, DPh, New Jersey
- Karen Ryle, MS, RPh, Massachusetts
- Kristen Snair, CPhT, Arizona State Board of Pharmacy
- Julie Spier, RPh, Texas State Board of Pharmacy

The Executive Committee liaison was Nicole L. Chopski, PharmD, BCGP, ANP.

### The Task Force on Workplace Safety and Well-Being

met at NABP Headquarters on November 18-19, 2021. The task force was established in response to Resolution No. 117-4-21, passed at the 117<sup>th</sup> NABP Annual Meeting.

The task force was charged with the following objectives:

1. Examine the topics of pharmacy workplace safety and pharmacist well-being and their effects on patient safety.
2. Review existing guidelines and objective tools that address these issues and make recommendations regarding their use.
3. Amend, if necessary, the *Model Act* to reflect the work of this task force.

Chairperson of this task force was John Clay Kirtley, PharmD, RPh, Arkansas State Board of Pharmacy.

Individuals appointed to serve as members included:

- Ashley Duggins, PharmD, RPh, North Carolina Board of Pharmacy
- Diane Halvorson, CPhT, North Dakota State Board of Pharmacy
- Marty Lee Hendrick, PharmD, DPh, Oklahoma State Board of Pharmacy
- Kevin Morgan, PharmD, RPh, Maryland Board of Pharmacy
- Carrie Phillips, MS, PharmD, RPh, Vermont Board of Pharmacy
- Kristopher S. "Kris" Ratliff, RPh, DPh, Virginia Board of Pharmacy
- Ellen B. Shinaberry, PharmD, RPh, Virginia Board of Pharmacy
- Kari Shanard-Koenders, RPh, South Dakota State Board of Pharmacy
- Jeffrey Sinko, RPh, New Jersey State Board of Pharmacy
- Joanne M. Trifone, RPh, Massachusetts Board of Registration in Pharmacy
- Tim Tucker, PharmD, RPh, Texas State Board of Pharmacy
- Keith A. Vance, RPh, North Carolina Board of Pharmacy
- Barbara Ellen Vick, PharmD, JD, RPh, North Carolina Board of Pharmacy

Mark D. Johnston, RPh, DPh, of Idaho, and Joshua Kohler of the North Carolina Board of Pharmacy, served as alternates. The Executive Committee liaison was Shane R. Wendel, PharmD, RPh.

### Standing Committees

As authorized by the NABP Constitution and Bylaws (CBL), the Association's standing committees annually perform specific responsibilities that are essential to the success of NABP's programs. Once a committee has explored its assigned issues, the members submit their recommendations or resolutions to the NABP Executive Committee for consideration.

The **Committee on Law Enforcement/Legislation** will meet at NABP Headquarters on January 19-20, 2022. The committee is charged with the following tasks:

1. Develop model laws and regulations based on resolutions adopted by the members of the Association or reports of task forces or other committees of the Association, or as assigned by the Executive Committee.
2. Review and comment on existing legislation and rules governing the practice of pharmacy and the distribution of prescription medications.
3. Recommend to the Executive Committee areas where model pharmacy practice or prescription drug distribution regulations are needed to improve the protection of the public health.

Malcolm J. Broussard, RPh, Louisiana Board of Pharmacy, will serve as committee chairperson. Committee members include:

- Alexandra Blasi, MBA, JD, Kansas State Board of Pharmacy
- Janet Hart, RPh, Pennsylvania State Board of Pharmacy
- Allison Hill, PharmD, RPh, District of Columbia Board of Pharmacy
- Tony King, PharmD, RPh, Montana Board of Pharmacy
- Jeenu Philip, RPh, Florida Board of Pharmacy
- Deena Speights-Napata, MA, Maryland Board of Pharmacy
- Kim Tanzer, PharmD, Texas
- Jenny Downing Yoakum, RPh, Texas State Board of Pharmacy

Sabrina Beck, PharmD, RPh, of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit, and Andrew "Andy" Truong, PharmD, RPh, of the Kansas State

Board of Pharmacy, will serve as alternates. The Executive Committee liaison is Bradley S. Hamilton, BSPHarm, RPh.

The **Committee on Constitution and Bylaws** will convene virtually on **April 11, 2022**. The charge of this committee, as defined by the CBL, is to review proposed amendments to the CBL, suggest changes where appropriate, and issue a recommendation for each proposed amendment.

David G. Bowyer, RPh, FASHP, West Virginia Board of Pharmacy, will serve as the committee chairperson.

Committee members include:

- Caryn Belisle, MBA, RPh, Massachusetts Board of Registration in Pharmacy
- William A. "Bill" Mixon, MS, RPh, North Carolina Board of Pharmacy
- Donna Montemayor, RPh, Texas State Board of Pharmacy
- Tanya L. Schmidt, PharmD, RPh, North Dakota State Board of Pharmacy

Lisa Flaherty, PharmD, RPh, of the Delaware State Board of Pharmacy, and Jacqueline L. "Jackie" Hall, MBA, RPh, of the Louisiana Board of Pharmacy, will serve as alternates. The Executive Committee liaison is Deborah C. Mack, RPh, CHC, CCEP.

### Work Groups and Other Committees

The **Model Act Review Committee** met virtually on July 12, September 22, October 15, and October 29, 2021. The committee was created in 2021 to help ensure that the *Model Act* reflects the most current regulatory environment. The committee was charged with the following tasks:

- Conduct a thorough review of the *Model Act* to ensure that the following are updated for relevance and accuracy:
  - dates;
  - footnotes;
  - references to federal law and regulations and standard setting organizations, such as the United States Pharmacopeial Convention and the Accreditation Council for Pharmacy Education; and
  - overall language to remove outdated provisions.



## Submit Proposed CBL Amendments by April 4

To be considered during the 118<sup>th</sup> Annual Meeting, proposed amendments to the NABP Constitution and Bylaws (CBL):

- **must be submitted between Friday, February 18, 2022, and Monday, April 4, 2022.** Per the current CBL, proposed amendments will be accepted no earlier than 90 days and no later than 45 days before the First Business Session of the Annual Meeting.
- may be proposed by any active member board of pharmacy, the NABP Executive Committee, or the Committee on Constitution and Bylaws.
- must be submitted in writing to NABP Executive Director/Secretary Lemrey “Al” Carter.
  - by email: ExecOffice@nabp.pharmacy
  - by mail:

NABP Headquarters  
1600 Feehanville Dr  
Mount Prospect, IL 60056

- If necessary, make recommendations to the NABP Executive Committee regarding any section of the *Model Act* that should be considered for revision so that current pharmacy practice is accurately reflected.

Steven W. Schierholt, Esq, State of Ohio Board of Pharmacy, served as the committee chairperson. Committee members included:

- Jeremy “Todd” Dear, PharmD, BCPS, Mississippi Board of Pharmacy
- Susan DelMonico, JD, RPh, Rhode Island
- Kristina Jonas, PharmD, RPh, Idaho State Board of Pharmacy
- Susan “Sue” Mears, RPh, Iowa Board of Pharmacy
- Michael A. Moné, JD, RPh, FAPhA, Ohio
- Denise L. Scarpelli, PharmD, RPh, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy
- Theresa M. “Terry” Talbott, RPh, Pennsylvania State Board of Pharmacy

Michael “Mike” Carroll, RPh, of the Vermont Board of Pharmacy, served as an alternate.

The Executive Committee liaison was Kamlesh “Kam” Gandhi, PharmD, RPh.

On August 25, 2021, NABP convened the virtual meeting of the **Work Group to Consider Permanently Extending Certain Waivered Provisions**. The work group was established in response to Resolution No. 117-2-21, passed at the 117<sup>th</sup> NABP Annual Meeting.

The work group was charged with the following objectives:

1. Review all provisions waived by the state boards of pharmacy during the coronavirus disease 2019 (COVID-19) pandemic.
2. Advise which waivers, if any, could safely remain in effect beyond the COVID-19 public health emergency.
3. Amend, if necessary, the *Model Act* to reflect the efforts of this work group.

Traci Collier, PharmD, RPh, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy, served as the work group chairperson. Work group members included:

- Erick Axcell, PharmD, RPh, Kansas State Board of Pharmacy
- Michael Blaire, RPh, Arizona
- Jennifer Chin, RPh, BCGP, Massachusetts Board of Registration in Pharmacy
- Cindy Fain, PD, Arkansas State Board of Pharmacy
- Laura Forbes, RPh, Virgin Islands Board of Pharmacy
- Mark Klang, MS, PhD, RPh, BCNSP, New York State Board of Pharmacy
- Tamara McCants, PharmD, RPh, District of Columbia Board of Pharmacy
- Eileen Ortega, RPh, Puerto Rico Board of Pharmacy
- David Rochefort, RPh, New Hampshire Board of Pharmacy
- Lorri Walmsley, RPh, FAzPA, Arizona State Board of Pharmacy
- Cathy Winters, RPh, Wisconsin Pharmacy Examining Board

The Executive Committee liaison was Fred M. Weaver, RPh. ●



## Tim Lynch, MS, PharmD, FABC, FASHP

Member, Washington State Pharmacy  
Quality Assurance Commission

### Washington State Pharmacy Quality Assurance Commission



#### Number of Board Members

10 pharmacist members, 4 public members, and 1 pharmacy technician member



#### Number of Compliance Officers/Inspectors

8 field pharmacist inspectors and 1 pharmacist supervisor. The Commission also has 4 pharmacist investigators who operate under the direction of the Commission but report directly to the Office of Legal and Investigative Services.



#### Rules & Regulations Established by

Pharmacy Quality Assurance Commission



#### Number of Pharmacist Licensees

10,969



#### Number of Pharmacies

2,395



#### Number of Wholesale Distributors

1,385 (in-state and out-of-state)

### When were you appointed to the Commission, and what type of member are you?

I was appointed to the Commission in 2013. I am a pharmacist member and have been chair for the last four years. I recently turned over the reins to the vice chair.

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

First, you have to reconcile that when you are sitting in board meetings, you are focusing on what is right for the patient and for public health, and not necessarily on what is right for you as a health care professional. Also, understanding the legislative process can be a challenge for a lot of people because it is not part of their experience. You may not understand the difference between a statute and a rule, who develops them, and why it takes time to formulate them. Understanding the due diligence that is involved in creating a rule is critical.

### What are some recent policies, legislation, or regulations that your Commission has implemented?

In July 2021, the Commission concluded a rewrite of the entire Washington State rule book for pharmacy. It took about two and a half years to go through every single rule. We had quite a number of chapters that had not been updated – in some cases for 30-40 years. Part of the rule rewrite focused on pharmacist responsibility, professional responsibility, and professional judgment. We shifted away from prescriptive, directive-specific rules to a standard-of-care model. We also instituted a number of rules in response to the coronavirus disease 2019 (COVID-19) pandemic, including allowing retired active pharmacists to practice during emergency situations, allowing nurses and other health care professionals to administer COVID-19 vaccines pursuant to a pharmacist's prescription, and enabling pharmacists to receive telehealth training.

### Has the Commission encountered any challenges to developing and/or implementing these new regulations?

Some challenges emerged as a result of the rule rewrite because we did not anticipate the impact of some changes. One of those pertains to controlled substances. We instituted a wholesaler requirement to have zero order reporting, which created an administrative burden and challenge for our wholesalers. Another rule deals with suspicious orders. We are looking at how we can streamline that process to get the information we need without creating an insurmountable burden for wholesalers as well as for the Commission, which manages all the incoming data.

Also, under the new rules, hospitals cannot store medications outside of the pharmacy or a pharmacy-controlled space.

### What advice would you give to a new board member?

Walk into the role with a listening mindset and spend time absorbing how the board functions. We have learned, as a Commission, that we need to be collaborative with our stakeholders. This means working with them, listening to what their challenges are, and making sure that whatever we do we align that with public health and safety. We do not want to create artificial barriers to health care because of a rigid rule.

### Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings?

I have attended district meetings and really enjoy those. One of the benefits is learning from fellow state boards that are experiencing the same things, which is also reassuring. The Annual Meetings are also very valuable. They let you create a network beyond your world that you can tap into. You can phone a colleague, get feedback, and understand how different states are handling similar issues. ●

### Executive Officer Changes

- **Anastasia Shiamptanis, MHSc, PharmD**, has been named registrar of the New Brunswick College of Pharmacists. Previously, she was strategic policy lead at the Ontario College of Pharmacists. Shiamptanis holds a master of health science degree in health administration from the University of Toronto and a doctor of pharmacy degree from Albany College of Pharmacy of Union University.
- **Tim Tucker, PharmD, RPh**, has been named executive director/secretary of the Texas State Board of Pharmacy, replacing Allison Vordenbaumen Benz, MS, RPh. He comes to the Board with decades of experience as a pharmacist in multiple pharmacy settings and with a long history of service to the practice of pharmacy. In addition, Tucker served a six-year term on the Tennessee Board of Pharmacy and has held membership and leadership positions across multiple pharmacy-related organizations, including the American Pharmacists Association, the Tennessee Pharmacists Association, NABP, and the Society of Independent

Pharmacists. He also served on the Accreditation Council for Pharmacy Education for over seven years. Tucker received a doctor of pharmacy degree from the University of Tennessee and a bachelor of science degree in chemistry from Union University.

### Board Member Appointments

- **Rodney Richmond, PharmD, RPh**, has been appointed a member of the Arkansas State Board of Pharmacy. Richmond's appointment will expire June 30, 2026.
- **Cecil H. Cordle, PharmD, RPh**, has been appointed a member of the Georgia State Board of Pharmacy. Cordle's appointment will expire December 31, 2021.
- **Ben Maisenbach, PharmD, RPh**, has been appointed a member of the Minnesota Board of Pharmacy. Maisenbach's appointment will expire January 6, 2025.
- **Mary Douglass Smith, PharmD, RPh**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Smith's appointment will expire June 30, 2027.

- **Christa M. Wilson, PharmD, RPh**, has been appointed a member of the Wisconsin Pharmacy Examining Board. Wilson's appointment will expire July 1, 2025.

### Board Member Reappointments

- **Brian C. Gonzales, MSW, LCSW, LAC**, has been reappointed a member of the Colorado State Board of Pharmacy. Gonzales' appointment will expire July 1, 2023.
- **Rabih Nahas, RPh**, has been reappointed a member of the Minnesota Board of Pharmacy. Nahas' appointment will expire January 6, 2025.
- **Tony King, PharmD, RPh**, has been reappointed a member of the Montana Board of Pharmacy. King's appointment will expire July 1, 2026. ●



## Coming Soon! 2022 Survey of Pharmacy Law

The 2022 edition of the *Survey of Pharmacy Law* will be available in late December 2021. Published in a downloadable pdf format, the *Survey* continues to be a valuable resource for anyone looking for an overview of the laws and regulations that govern pharmacy practice in all 50 states and three jurisdictions: District of Columbia, Guam, and Puerto Rico.

The *Survey* consists of four chapters: a state-by-state overview of organizational law, licensing law, drug law, and census data. The 2022 *Survey* includes two new questions addressing pharmacy technician scope for administering vaccines (beyond what is allowed under

the Public Readiness and Emergency Preparedness Act), and the required minimum number of work hours for pharmacists-in-charge.

Updates for the 2022 *Survey* were provided by the state boards of pharmacy.

As in previous years, all final-year pharmacy students receive the *Survey* free of charge. In addition, board of pharmacy executive directors will receive a complimentary copy for their board.

The *Survey* will also be available for purchase through the NABP e-Profile system.

For more information, contact [help@nabp.pharmacy](mailto:help@nabp.pharmacy). ●



### Massachusetts Board Develops Policy Related to Scope of Practice

The Massachusetts Board of Registration in Pharmacy has developed a policy to capture permitted professional activities that the Board has deemed to be within the scope of practice of pharmacists, pharmacy interns, and pharmacy technicians. Some of the limitations are set by statute or regulation and are outlined in the policy for clarity purposes. For instance, pharmacists and interns may only administer certain vaccines and specific medications for the treatment of mental illness and substance use disorder as defined in 105 Code of Massachusetts Regulations 700.00 and associated guidance documents. No other medications may be administered, including ones used for skin tests. Other nontraditional activities have been specifically permitted by the Board and include the allowance of two certified technicians performing perpetual inventory, remote processing of prescriptions by technicians, and the use of technology to verify certain inventory management functions in a health care facility. As pharmacy practice evolves and laws and regulations change, this policy will continue to be updated to guide pharmacy licensees in their practice.

### Ohio Issues Policy for Use of Contingency Stock License by Institutional Facilities

To promote vaccination storage and administration at long-term care facilities and other institutional facilities, the State of Ohio Board of Pharmacy authorized the following policy:

A long-term care facility or other institutional facility, as defined under agency 4729 of the Ohio Administrative Code, may possess and administer vaccines and other biologics to patients and staff under the terminal distributor of dangerous drugs license issued to the facility's servicing pharmacy (eg, contingency stock license). This policy shall also permit the use of the servicing pharmacy's contingency stock license to maintain dangerous drugs used to treat adverse reactions to vaccines and biologics stored at the facility.

For more information on this policy, visit [www.pharmacy.ohio.gov/ConStock](http://www.pharmacy.ohio.gov/ConStock).

### New Oregon Legislation Impacts Several Areas of Pharmacy Practice

The following are summaries of selected bills, effective January 1, 2022, that will impact Oregon licensees and require rulemaking by the Oregon State Board of Pharmacy.

- **House Bill (HB) 2648:** Allows a pharmacist or pharmacy technician to transfer drugs containing pseudoephedrine or ephedrine without a prescription to a person who is at least 18 years of age and presents the person's valid government-issued photo identification in accordance with Board rules.
- **HB 2958:** Allows a pharmacist to prescribe, dispense, and administer pre-exposure prophylactic antiretroviral therapies and post-exposure prophylactic antiretroviral therapies in accordance with Board rules.
- **Senate Bill 629:** Allows a pharmacist to use telepharmacy to deliver pharmacy services to a patient at a remote location in accordance with Board rules.

More information is available in the Board's August 2021 *Newsletter*, which can be accessed on the NABP website.

### South Carolina Legislation Addresses Renal Dialysis Patients, Naloxone

The following bills were enacted by the South Carolina General Assembly during the 2021 legislative session and may impact the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy and/or its licensees:

- **S427/Act 48:** Allows a renal drug manufacturer to deliver a legend dialysate drug comprised of dextrose or icodextrin

or a device to a patient of a renal dialysis facility, under established circumstances. The act also exempts pharmacists and pharmacy technicians from in-person continuing education attendance.

- **S571/Act 22:** Requires a prescriber to offer a prescription for naloxone hydrochloride or another drug approved by Food and Drug Administration for the complete or partial reversal of opioid depression to a patient if (a) the prescription is 50 or more morphine milligram equivalents of an opioid medication per day; (b) the opioid is prescribed concurrently with a prescription for benzodiazepine; or (c) the patient presents with certain increased risk for overdose. The act also requires a prescriber to offer the same patient, or the parent/guardian of a minor patient, overdose education.

More information is available in the Board's August 2021 *Newsletter*, which can be accessed on the NABP website.

### West Virginia Updates Prescription Monitoring Program Rules

Effective May 31, 2021, a pharmacist licensed by the West Virginia Board of Pharmacy must access the West Virginia Controlled Substance Monitoring Program database for information regarding specific patients upon initially prescribing or dispensing any Schedule II controlled substance (CS), opioid, or benzodiazepine to a patient who is not suffering from a terminal illness, and at least annually thereafter should the practitioner or dispenser continue to treat the patient with a CS. ●



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.

### FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Children Ages 5-11

Food and Drug Administration (FDA) has authorized for emergency use the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine for children ages five through 11. The emergency use authorization (EUA) from FDA is based on a thorough evaluation of data and experts.

On November 2, 2021, the Centers for Disease Control and Prevention (CDC) recommended that all children ages five through 11 get a low-dose COVID-19 vaccine made by Pfizer-BioNTech.

The Pfizer-BioNTech COVID-19 vaccine for children five through 11 years of age is administered in two doses, three weeks apart, and at a lower dose (10 mg) compared to the dose used for individuals 12 years of age and older (30 mg). Vaccines have been widely available for this age group since the week of November 8.

The Pfizer-BioNTech COVID-19 vaccine received EUA for adolescents ages 12 to 15 in May and full approval for children 16 years and older in September.

### Study Shows That Initiating High-Dose Buprenorphine in Emergency Rooms May Improve Opioid Treatment Outcomes

High-dose buprenorphine that is administered in the emergency department is safe for those experiencing opioid withdrawal symptoms, according to a study supported by the National Institutes of Health's National Institute on Drug Abuse (NIDA) through the Helping to End Addiction Long-term Initiative. The study stated that providing the higher dose of buprenorphine potentially can provide an extended period of withdrawal relief for those discharged from the emergency room, giving these patients the support needed to seek care for opioid use disorder treatment.

More information is available in a press release on the NIDA website at [www.drugabuse.gov/news-events/news-releases/2021/07/emergency-department-administered-high-dose-buprenorphine-may-enhance-opioid-use-disorder-treatment-outcomes](http://www.drugabuse.gov/news-events/news-releases/2021/07/emergency-department-administered-high-dose-buprenorphine-may-enhance-opioid-use-disorder-treatment-outcomes).



### New APhA Training Program Helps Pharmacists Provide Diabetes Care

About 34.2 million adults in the United States have diabetes, and one in five do not know they have it, according to CDC. In order to effectively support pharmacists, the American Pharmacists Association (APhA) has developed an intensive training program that focuses on providing pharmacists with the tools needed for effective, evidence-based diabetes care. The program is designed with real-life practice scenarios that pharmacists may encounter. In addition, the program provides comprehensive instruction on concepts and standards that define diabetes care management through case studies and hands-on skills training.

### Study Shows Retail Pharmacies Are Increasingly Becoming a One-Stop Shop for Consumers' Health Needs

A new J.D. Power survey found that just over half of consumers are turning to their local pharmacies for their health care needs. According to the J.D. Power 2021 US Pharmacy Study, this trend has increased over recent years, with customers choosing to use their local retail pharmacy for wellness services. In 2019, about 43% of customers said they used pharmacy health and wellness services compared to about 48% of customers in 2020. The findings from the survey were based on responses

from 12,646 pharmacy customers from September 2020 through May 2021. The full survey results can be found by visiting [www.healthcarefinancenews.com/news/consumers-are-increasingly-turning-their-pharmacies-health-services-survey-says](http://www.healthcarefinancenews.com/news/consumers-are-increasingly-turning-their-pharmacies-health-services-survey-says).

### Second Vaccination Is Safe Even After an Allergic Reaction, Study Finds

There were no reports of complications related to those patients who received a second vaccine dose of a COVID-19 vaccine after having an allergic reaction to their first dose and who were advised by allergy specialists, according to a study published in *JAMA Internal Medicine*. Allergic reactions after mRNA COVID-19 vaccines have been reported in as many as 2% of individuals receiving the vaccine, with anaphylaxis, a possibly fatal allergic reaction, occurring in up to 2.5 of 10,000 people. The study found that 159 participants who received the second dose (of the 189 total, including 19 who suffered a severe allergic reaction to the first dose) tolerated the second dose of the vaccine. Of those who received the second dose, 32 reported mild symptoms. The full study and more information can be found by visiting [www.massgeneral.org/news/press-release/Second-COVID-19-mRNA-vaccine-dose-found-safe-following-allergic-reactions-to-first-dose](http://www.massgeneral.org/news/press-release/Second-COVID-19-mRNA-vaccine-dose-found-safe-following-allergic-reactions-to-first-dose). ●



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## UPCOMING EVENTS

### **Committee on Law Enforcement/Legislation**

January 19-20, 2022 | NABP Headquarters

### **NABP Interactive Member Forum**

January 26-27, 2022

### **Advisory Committee on Examinations**

April 7, 2022 | NABP Headquarters

### **Committee on Constitution and Bylaws**

April 11, 2022 | Virtual Meeting

### **118<sup>th</sup> NABP Annual Meeting**

May 19-21, 2022 | Phoenix, AZ

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