NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS®

Looking Ahead:

Association Prepares for Leadership Changes

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INNOVATIONS®

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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 and jurisdictions for the purpose of protecting the public health.

Interview With a Board Executive Director

Darren J. Covington, JD,
Director,
Indiana Board of Pharmacy

Darren J. Covington, JD, Director,
Indiana Board of Pharmacy

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

I have been with the Indiana Board of Pharmacy for three years and with the Indiana Professional Licensing Agency for four and a half years. I also serve as the director of the Medical Licensing Board of Indiana, along with five other licensing boards. Before joining the Board of Pharmacy, I was a deputy attorney general in the Licensing Enforcement & Homeowner Protection Unit.

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

For the past year or two, we have been implementing new statutory authority regarding telepharmacy. It is a new model for our Board and our inspectors. It has been opening up opportunities for pharmacy services to be provided in rural, underserved areas of the state.

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

We formed a telepharmacy committee and invited various stakeholders, including some from outside of the state that had experience with telepharmacy, to explore the issues surrounding telepharmacy and remote dispensing, in general. This committee helped draft an emergency rule for us, which has been adopted by the Board. The Board is currently working on adopting a final rule. We have had to partner with other agencies, such as Drug Enforcement Administration (DEA), that were not as familiar with the telepharmacy model in this state. We also are working closely with pharmacies interested in adopting this telepharmacy model, both at the Board and inspector level.

What other key issues has the Board been focusing on?

Last fall, we switched vendors for our drug and alcohol abuse monitoring service, which has been a major transition for us. We also have a compounding committee that continues to review changes to United States Pharmacopeia (USP) Chapters <795> and <797> and is looking at USP Chapter <800> to see which portions the Board will adopt. We continue to work on different rulemaking actions, some of which expand the scope of practice, such as permitting technicians to do remote data entry. Our legislature continues to adopt new rules regarding the opioid crisis, such as placing limits on acute prescriptions and increasing query requirements for our state prescription drug monitoring program (PDMP). We will be moving to a mandatory PDMP query, which is being phased in over the next few years. We are going to be requiring electronic prescribing for controlled substances beginning January 1, 2021.

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

While telepharmacy is not new, it is new to us and the Board. Therefore, as we thought about how we were going to implement the telepharmacy model, we found that identifying the key stakeholders early on and getting them involved

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Indiana Board of Pharmacy

Number of Board Members: 6 pharmacist members and 1 public member
Number of Compliance Officers/Inspectors: 7
Rules and Regulations Established by: Board of pharmacy
Number of Pharmacist Licensees: 10,817
Number of Pharmacies: 1,368
Number of Wholesale Distributors: 440

Impact of CBD-Derived Products on State Boards of Pharmacy

Libby Baney, JD,
Faegre Baker Daniels LLP

Kevin P. Boot, JD,
Faegre Baker Daniels LLP

As states have begun legalizing marijuana for recreational use and attention to the potential medicinal benefits of marijuana and its derivatives has increased, states and the federal government are struggling to add a layer of regulation for new classes of products made from cannabis.

History of Federal and State Regulation

Cannabis is a species of plant with a long history of use for its numerous phytochemicals and fibers. Among the 104 identified biologically active chemical compounds, called cannabinoids, the two most commonly known are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).

While both THC and CBD share similar properties, including molecular structure, a slight chemical difference accounts for how each affects the body's cannabinoid receptors. Cannabis' psychoactive effects are associated with THC, which is also responsible for the adverse effects reported from acute or regular cannabis use. On the other hand, CBD has a different chemical structure devoid of psychoactive effects.

Although marijuana has remained illegal under federal law for decades, states contradicted federal laws by creating state laws legalizing medical, and now recreational, use of marijuana. California first legalized medical marijuana in 1996 and 16 years later, Colorado voters approved recreational marijuana in 2012. All but four states (Idaho, Kansas, Nebraska, and South Dakota) allow some form of medical marijuana or CBD with low THC content.

Federal Regulation of Cannabis Products: 2018 Farm Bill

The Agriculture Improvement Act of 2018, Pub. L. 115-334 (the 2018 Farm Bill) dramatically expanded prospective opportunities for hemp and hemp-derived products. Specifically, it expanded the industrial hemp definition to mean "the plant *Cannabis sativa L.* and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."

Carving out the industrial hemp definition from the Controlled Substances Act Schedule I was a major change, but the 2018 Farm Bill did not outright legalize CBD or marijuana. Marijuana and hemp are both encompassed under the umbrella of "cannabis," but with hemp being distinguished as having less than 0.3% THC. Hemp is the only form of cannabis that can be legal under both federal and state law. On October 29, 2019, the United States Department of Agriculture (USDA) announced the establishment of the US Domestic Hemp Program to help states complete their hemp agriculture plans in time for the 2020 planting season. State agriculture plans will address record keeping, testing for THC, disposal procedures for plants having too much THC, and related inspections and certifications. The similarity in appearance between hemp and marijuana are going to be ongoing challenges for law enforcement authorities as they will increasingly need to rely on testing and certification schemes that will need to

be developed. Regulation by USDA does not mean substances made from hemp can be used in food. As is the case for all substances used in food, Food and Drug Administration (FDA) has an essential role in regulating substances made from hemp that will be used in food or dietary supplements.

Federal Regulation of Cannabis and Cannabis-Derived Products: FDA

Excitement about substances made from cannabis does not change FDA responsibility to regulate all substances added to food. The FDA authority to regulate products containing hemp-derived substances presents more complex issues that will take longer to resolve. Certain hemp-related ingredients that are derived from plant parts lacking THC or CBD already may be lawfully added to food and dietary supplements (eg, hemp seed oil, which is the subject of a 2018 notification to FDA that the substance is generally recognized as safe).

Not all substances that may be derived from hemp can be used in food or dietary supplements. **It is unlawful to sell food or dietary supplements containing added CBD regardless of whether the substances are hemp-derived.** This is because CBD and THC are active ingredients in FDA-approved drugs and were the subject of clinical investigations before they were marketed as foods or dietary supplements. When a substance is excluded from the dietary supplement definition under section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act, the exclusion applies unless FDA uses a "never-before-used option" to issue a regulation making it lawful to use a prior-approved active ingredient as a dietary supplement or food.

FDA has approved Epidiolex®, which contains a purified form of CBD. In addition, FDA has approved three cannabis-related drug products – Marinol® and Syndros® that include the active ingredient dronabinol, a synthetic THC, and Cesamet™ that contains the synthetically derived active ingredient nabilone, which has a chemical structure similar to THC. These approved products are only available with a prescription from a licensed health care provider.

Before food and dietary supplements can lawfully contain hemp-derived ingredients like CBD, FDA must first resolve the complicated issues caused by the prior approval of CBD as a drug ingredient. FDA has sent mixed messages about whether this will be done through the regular rulemaking processes. Despite the typical regulatory process taking years, FDA has said consumer interest in cannabis-related products compels the agency to move quickly. FDA sought input from the scientific community and industry at a heavily attended public meeting in May 2019 and has promised to provide a framework for future regulatory activities before the end of 2019.

In the meantime, an increasing number of dietary supplement and food products are being marketed under the belief that FDA is exercising "enforcement discretion" by tacitly allowing dietary supplement or food products that contain CBD or related ingredients to be marketed as long as claims are not the type considered "over-the-line" by former FDA Commissioner Scott Gottlieb during a March 2019 subcommittee hearing before a US Senate Committee on Appropriations. Consistent with that approach, in 2019, FDA sent four warning letters to dietary supplement companies that focus on claims not allowed for supplements (eg, related to Alzheimer's, cancer, depression, arthritis, etc), while making a relatively lighter mention about the illegality of the CBD ingredient. There have been no FDA enforcement actions based solely on the presence or use of CBD.

In the short term, regulatory developments for food and dietary supplements will continue to affect the operations of pharmacies that are already selling or intend to sell cannabis-derived products. Further, we anticipate that state boards of pharmacy will increasingly be looked to as a resource on issues of CBD sales and safety. As such, it will be important to actively track developments from FDA, USDA, and state governments. This includes confirming whether and how states are updating their own controlled substance laws to reflect the federal-level changes that already occurred in the 2018 Farm Bill.

In the long term, FDA's policy decisions about possible CBD use in food and dietary supplements will have strategy implications for the research and development of FDA-approved prescription drugs. Once FDA provides a framework for cannabis products used in drugs, food, and dietary supplements, it is anticipated that FDA's enforcement strategy for food and supplements will broaden beyond claims enforcement to more forcefully prevent food and supplement products from containing ingredients that FDA determines are for use only in drugs. This FDA enforcement and guidance will be useful for boards of pharmacy as they protect the health and safety of patients who encounter cannabis products in circumstances beyond the current use in drugs. NABP will continue to monitor policies that help state boards of pharmacy to fulfill their public health missions and will seek ways to work together with relevant stakeholders to benefit patient health and consumer safety.

This article was written by Libby Baney, JD, and Kevin P. Boot, JD, with Faegre Baker Daniels LLP. Please note, the opinions and views expressed by Faegre Baker Daniels LLP do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated. ■

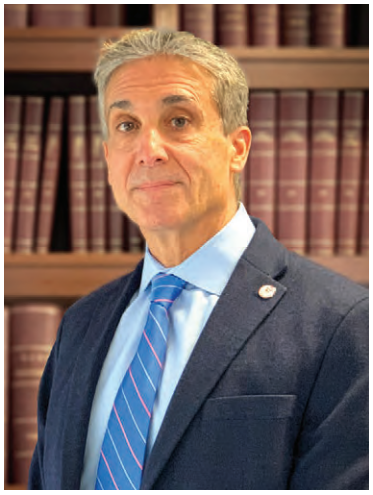
From the Executive Director/Secretary

Blessed With Caring People on an Unexpected Journey

By Carmen A. Catizone, MS, RPh, DPh

Friends and Colleagues:

Sometimes our travels through life place us on paths and provide us with gifts and memories never imagined. Such has been my good fortune. Because of NABP, I traveled a path that was unimaginable for a kid from the South Side of Chicago!



When I first began my career at NABP, I was excited and intimidated by what was ahead and wondered how I was going to keep NABP strong and dynamic. Luckily for me, one of the Association's greatest strengths are the people who were and are NABP. From my first day with NABP, I have been blessed with mentors, guardians, and caring people who looked out for NABP and, in doing so, also placed me under their protective wings. Over the more than three decades of my service with NABP, my fondest memories are the words of encouragement, comforting smiles, and boundless laughter of all of those people who shared some of their precious time with me because of NABP.

As NABP moves forward into a new time with a new executive director, I am excited for the Association and the continued impact it is going to have on protecting patients every single day. In reflecting back on what I have been able to be a part of while here at NABP, it is my hope that someone I helped is able to help someone else and, in doing so, remembers me.

Thanks to so many people for an incredible path never imagined, but forever thankful that I was fortunate to walk!

Carmen

> **"It is my hope that someone I helped is able to help someone else."**

Looking Ahead:

Association Prepares for Leadership Changes

The NABP Executive Committee and Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, have announced Catizone's planned retirement from the Association after 35 years of service. Catizone will formally retire from NABP at the end of 2020, following the selection of a new executive director and a transition period of leadership.

Filling the Shoes of a 'Living Legend'

Catizone began his career at NABP in 1985, when he was hired as the test and measurement director, overseeing the Association's examination programs, and served as national news director for the State Newsletter Program. As the test and measurement director, Catizone oversaw the transition of the NABPLEX®, which is now known as the North American Pharmacist Licensure Examination® (NAPLEX®), from five separate examinations to an integrated examination more accurately reflecting the practice of pharmacy.

In November 1987, then NABP President Henry Cade announced the appointment of Catizone as the Association's new executive director, effective January 1, 1988. In this role, he would be following the legendary steps of Fred T. Mahaffey.

"If I had to set a theme for what lies ahead, it would flow from just a few words – communication, cooperation, and leadership," said Catizone in his first official communication to member boards of pharmacy in 1988. "Staff and resources of your Association stand ready for a revitalization, a move to a more proactive NABP."

> **"If I had to set a theme for what lies ahead, it would flow from just a few words – communication, cooperation, and leadership."**

Catizone's long-range plans for the Association included a number of proposals and projects to position NABP at the center of pharmacy regulation and earn the Association a reputation as a motivating force in the practice of pharmacy. Keeping to this promise, in his early years of leading NABP, he oversaw the restructuring of the National Clearinghouse of Pharmacist Disciplinary Data (now the NABP Clearinghouse) and the consolidation of the NABPLEX and the Federal Drug Law Examination™ (FDLE®). The changes to the FDLE paved the way for the development and launch of the Multistate Pharmacy Jurisprudence Examination® several years later.

In the early 1990s, working with the NABP Executive Committee, Catizone led the Association and its member boards through the tumultuous legislative changes affecting the practice of pharmacy at the time – specifically, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) – which would heighten the pharmacist's responsibility to provide patient counseling. During this time, the Association gained national attention for its "Model Regulations on Patient Counseling," which were adopted verbatim into OBRA '90.

Catizone's early years with the Association also brought about change in the overall approach to addressing issues impacting member boards. In 1992, under President

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NABP Leadership Changes

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Llyn A. Lloyd's leadership, the development of task forces began, giving state boards of pharmacy an active voice in the driving changes of the Association. Interestingly, one such task force was the 1993 Task Force on Pharmacy Technicians, a topic that continues to be debated to this day!

Leading NABP Into the Digital World

Under Catizone's leadership, the Association, like much of the rest of the world, embarked on a new journey through the digital world. In 1996, the Association began verifying licensure transfer applications through email with the Electronic Licensure Transfer Program® (e-LTP™) and transitioning the NAPLEX from a paper-and-pencil format to a computer-adaptive assessment. In 1998, the Association debuted *www.nabp.net*, giving its members access to a number of resources and information about NABP, including the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, the NAPLEX *Registration Bulletin*, the *NABP Newsletter*, licensure transfer applications and forms, and over 35 state newsletters, to name a few.

Additionally, to further recognize NABP as an expert and resource to its member boards, Catizone led the Association through the development of the Customer Service Call Center (known now as Customer Engagement) to better respond to member boards and individuals who utilized NABP's growing number of programs and services.

With the internet in full bloom, the need to protect patients online from bad actors became paramount. In 1999, Catizone led the Association through the development of the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, awarding the first VIPPS Seal in September of that year.

Protecting Patients

With the opioid epidemic reaching its "second wave" in 2010 due to rapid increases in overdose deaths involving heroin – the "first wave" began in 1999 due to the rise in prescription opioid overdose deaths – member boards of pharmacy were proactively searching for solutions. Although state prescription monitoring programs (PMPs) were being utilized throughout the country, NABP recognized the need for interoperability among them. Under Catizone's leadership, the Association developed an interconnected communications hub for state PMPs to share and exchange prescription data among PMP systems. Fully operational in 2011, NABP PMP InterConnect® now securely connects 51 of the 54 PMPs in the US.

In 2010, NABP also sought a different approach to dealing with prescription drug abuse – going directly to consumers. During that time, NABP acquired from the Minnesota Pharmacists Association, and relaunched, the AWAR$_x$E® Prescription Drug Safety Program, which aimed to educate and raise public awareness about rogue internet drug outlets, counterfeit medications, and prescription drug abuse. The program was also expanded to reach national attention through a number of public service announcements (PSAs), radio and video PSAs, and web banner ads.

As online safety and security challenges evolved, Catizone also led the Association in evolving its verification program for pharmacy-related entities with an online presence. In June 2014, NABP became the registry operator of the .pharmacy domain name, which launched the .Pharmacy Verified Websites Program. The .Pharmacy Program allows consumers to identify legitimately operating pharmacies and pharmacy-related entities.

Big Data, Big Future

Under Catizone's leadership, in April 2018, NABP relaunched its e-Profile system to allow the Association to begin offering more services to its member boards. As part of the upgrades to the system, several enhancements have benefited the boards, including eliminating all paper applications for e-LTP, enhancing the CPE Monitor® service to support board continuing pharmacy education (CPE) audits, expanding examination eligibility services to all boards, and adding more data and reporting features to NABP e-Profile Connect.

Moving on Up

Over the years, as the Association grew and more and more programs were developed, Catizone has seen NABP through multiple office relocations to better serve its member boards. Under Catizone's leadership, the Association moved from 1300 Higgins Rd in Park Ridge, IL, to 700 Busse Hwy in Park Ridge, tripling its space from over 5,000 square feet to 16,000 square feet. By 2004, the Association announced plans to once again move its headquarters to a 51,000-square-foot building at 1600 Feehanville Dr in Mount Prospect, IL, which remains NABP's Headquarters today.

In October 2016, the Association began an extensive renovation at its Mount Prospect headquarters to reconfigure and update the building to better provide efficiencies and resources that enable staff to better address member boards' needs.

A New Era

Keeping the Association's legacy and best interest at the forefront, a search committee was organized in fall 2019 and is working diligently to begin the search and selection of NABP's new executive director. The final selection will be made sometime in 2020, with a leadership transition occurring over the final months of the year. The Executive Committee and search committee are working closely together to secure new leadership for NABP that will elevate the Association to even more advanced heights. More information about the transition will be provided in future NABP communications. ■

Interactive Member Forum
NABP Headquarters
Mount Prospect, IL
January 28-29, 2020

The forum provides attendees a unique opportunity to discuss issues facing their boards with fellow pharmacy regulation experts. Highlights of the forum include:

- **Networking with colleagues**
- **Discussing topics submitted by fellow attendees**
- **Discovering solutions for shared challenges**
- **No registration fees**
- **Travel, hotel, and meal expenses paid by NABP**

Members received registration information in October. One member per board may attend the Interactive Member Forum at no charge.

Past Interactive Forum participants shared their experiences with NABP:

- "Great learning from other states."
- "Timely topics. Good info. Short/focused presentations."
- "Enjoyed the conversation and different viewpoints presented."
- "These meetings give so much good information that we can take back to our state."

NABP Interactive Forum Provides Executive Officers Opportunity to Discuss Regulatory Challenges

Thirty-four board of pharmacy executive officers gathered for the annual NABP Interactive Executive Officer Forum, held October 1-2, 2019, at NABP Headquarters. Themed "Turning Data Into Information, and Information Into Insight," the event offered attendees an opportunity to discuss challenges faced by the state boards, as well as reinforced the partnership between the boards of pharmacy and NABP and their shared mission to protect the public health. The meeting format featured two days of sessions to provide executive officers an opportunity to discuss specific topics and issues of special interest provided by invitees via a pre-meeting survey. Prior to the events of the Interactive Executive Officer Forum, the New Executive Officer Orientation Program was held the afternoon of Monday, September 30, 2019. The orientation enabled seven newly appointed executive officers to become acquainted with NABP membership and governance.

(Above) The session "ARCOS Data – If We Had Only Known . . ." focused on the impact of Automation of Reports and Consolidated Orders System (ARCOS) data on boards of pharmacy and examined possible changes to the system in the future. Pictured are (left to right) Darren J. Covington, JD, director, Indiana Board of Pharmacy; Reginald B. "Reggie" Dilliard, DPh, executive director, Tennessee Board of Pharmacy; Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee, and executive director, Idaho State Board of Pharmacy, who moderated the Shared Discussion Topics session that followed; session moderator Caroline D. Juran, RPh, DPh, NABP treasurer, and executive director, Virginia Board of Pharmacy; John Clay Kirtley, PharmD, RPh, executive director, Arkansas State Board of Pharmacy; and Steven W. Schierholt, Esq, executive director, State of Ohio Board of Pharmacy.

(Above) The session "Important Information About What's Wrong With Importation" featured litigation and state and provincial updates as well as a look at using facts to protect the integrity of the drug supply. Pictured are (left to right) Michael L. Goff, executive director and CSMP administrator, West Virginia Board of Pharmacy; Beverley Zwicker, BSc Pharm, registrar, Nova Scotia College of Pharmacists; session moderator Jack W. "Jay" Campbell IV, JD, RPh, NABP president, and executive director, North Carolina Board of Pharmacy; Justin Macy, PharmD, JD, digital health senior manager, NABP; and Kevin McGlynn, accreditation and inspection programs director, NABP.

(Above) The session "Member Collaborations — Byte by Byte" provided updates from the NABP Work Group on the Development of an Interstate Endorsement Credential and the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment. Pictured are (left to right) Bradley S. Hamilton, RPh, member, NABP Executive Committee; session moderator Susan Ksiazek, RPh, DPh, NABP chairperson; Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy; and Mark J. Hardy, PharmD, RPh, executive director, North Dakota State Board of Pharmacy.

(Above) The session "Compounding by the Numbers — Unlocking the Data of the MOU" provided information about a Food and Drug Administration grant to develop a data sharing system for improved oversight of compounding pharmacies and other compounding updates from the boards. Pictured are (left to right) Richard B. Mazzoni, RPh, member, NABP Executive Committee, who moderated the Shared Discussion Topics session that followed; Anthony Rubinaccio, RPh, executive director, New Jersey State Board of Pharmacy; Kamlesh "Kam" Gandhi, PharmD, RPh, executive director, Arizona State Board of Pharmacy; Melissa A. Madigan, PharmD, JD, policy and communications director, NABP; and session moderator Shane R. Wendel, PharmD, RPh, member, NABP Executive Committee.

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Interactive Forum

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(Above) The session "Just the Data — Informed Regulatory Decisions!" offered attendees competency assessment insights and Electronic Licensure Transfer Program® (e-LTP™) trends. Pictured are (left to right) Lawana Lyons, licensure programs senior manager, NABP; session moderator Lenora S. Newsome, PD, member, NABP Executive Committee; and Maureen Garrity, PharmD, competency assessment director, NABP.

(Above) The session "Connection Overload – Path to Sanity" discussed data collection challenges and NABP data exchange projects. Pictured are (left to right) session moderator Bradley S. Hamilton, RPh, member, NABP Executive Committee; Praseed Thapparambil, chief information officer, NABP; and Jeffrey J. Mesaros, PharmD, JD, RPh, member, NABP Executive Committee, who moderated the Shared Discussion Topics session that followed.

NABP Launches the Supply Chain Inspection Program

In August 2019, NABP began accepting applications for inspections from businesses engaged in prescription drug/device distribution. The inspection service is currently being piloted by the state of Michigan as part of its efforts to protect the prescription drug supply chain in its jurisdiction.

The inspections will follow a timeline similar to that of Verified Pharmacy Program® (VPP®) inspections. Each inspection will take place approximately eight weeks after NABP receives and reviews a facility's complete application; the inspection is unannounced. In addition, the inspection may take up to two days, depending on the facility's activities. As with VPP, applicants will not be able to choose the areas they would like inspected.

Each inspection will offer a "snapshot in time" of a facility, with the inspector reporting what he or she finds on the day of the inspection. The inspection report and other supporting materials submitted by the applicant will be available to state and federal regulators via NABP e-Profile Connect.

Inspection Service Benefits

The inspection service offers several benefits to state and federal regulatory agencies, eligible businesses, and NABP. States requiring wholesale distributors to undergo inspections for licensure will find that NABP inspections supplement their own inspections. In addition, the inspections will give regulators an additional tool to help protect the public health and potentially another "set of eyes" when it comes to facility inspections. The NABP inspection service will also offer non-Verified-Accredited Wholesale Distributors® facilities an audit that may help better prepare their facility for accreditation in the future should they choose to apply.

Under the Drug Supply Chain Security Act, from the submission of their initial licensing application, wholesale distributors must be inspected within a reasonable amount of time by the state, the federal licensing authority, or by a third-party accreditation or inspection service approved by Food and Drug Administration or by the state licensing the wholesale distributor. To assist states, NABP can serve as the third-party inspection service ensuring compliance with this requirement. States interested in utilizing this inspection service to meet a particular state licensing and regulatory need may contact the Member Relations and Government Affairs department at GovernmentAffairs@nabp.pharmacy.

NABP is now accepting applications via the NABP website for this inspection service on a special request-only basis when facilities have a particular state licensing and regulatory need. The full launch of the inspection service will take place in early 2020. NABP anticipates a separate inspection service for third-party logistics providers to launch shortly thereafter.

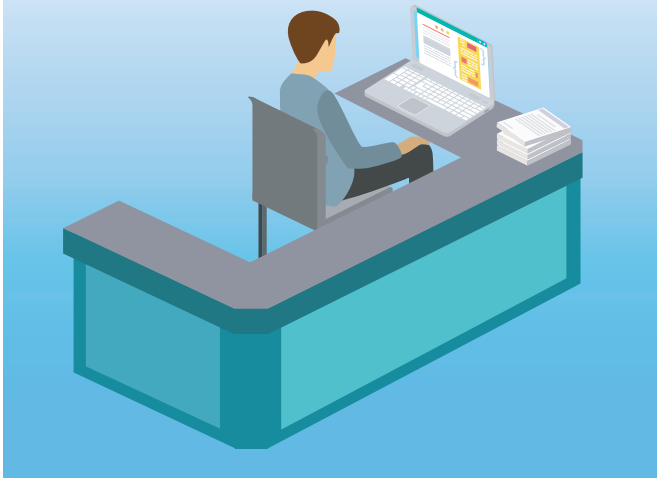
More information about NABP's new inspection service for wholesale distributors will be provided in future NABP communications. ■

> **"... the inspections will give regulators an additional tool to help protect the public health and potentially another 'set of eyes' when it comes to facility inspections."**

NABP **e-Profile Connect**: The Access Point for Board Staff and Schools and Colleges

What is NABP e-Profile Connect?

NABP e-Profile Connect is a secure online workspace that allows authorized board of pharmacy staff to access pharmacy, pharmacist, technician, and facility e-Profile information in support of licensure responsibilities. In addition, some information is available to authorized users at schools and colleges of pharmacy.



What actions can be taken by boards through e-Profile Connect?

- View NABP Clearinghouse data, which is uploaded and available in real time.
- Process licensure transfer applications and supporting documentation.
- Download North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®) official candidate and summary score transfer reports.
- Approve NAPLEX and MPJE eligibility.
- Check the certification status of Foreign Pharmacy Graduate Examination Committee™ certification candidates.
- View Verified Pharmacy Program® inspection reports and upload state inspection reports.
- Process exam eligibility and score reports.

What services are available to schools and colleges of pharmacy?

Schools and colleges of pharmacy receive access to summary score reports, and can also view and manage Pharmacy Curriculum Outcomes Assessment® rosters and purchase Pre-NAPLEX and Pre-MPJE™ vouchers.

How do I get access?

Board of pharmacy executive directors and college of pharmacy deans or administrators select and submit users to NABP. NABP staff customizes user access by assigning certain responsibilities and functions for use only by designated board staff or college staff, as directed by the board executive director or dean. Each staff person is assigned a unique username and password that grants access to the designated area.

If you are a board staff member or college of pharmacy administrator, contact your executive director or dean, respectively, to request access to the system. If you are an executive director or dean, contact eProfileAccess@nabp.pharmacy to obtain accounts for new staff members and to designate their roles.

If I have other questions, who should I talk to?

Contact GovernmentAffairs@nabp.pharmacy or 847/391-4406. ■

VPP Continues to Provide Valuable Inspection Findings for Member Boards of Pharmacy

The Verified Pharmacy Program® (VPP®) continues to provide member boards of pharmacy with valuable information on pharmacies operating in multiple states. Through NABP e-Profile Connect, member boards may access inspection findings, documents collected during the application process, licensure verification, and any available disciplinary history in a facility's e-Profile. In an effort to support the boards in making informed licensing decisions, VPP delivers the boards a quality uniform inspection report that is broken down into several sections and provides an assessment of compliance with the published United States Pharmacopeia (USP) Chapters <795> and/or <797> as well as other referenced chapters. As an additional service to its members, VPP inspections are also available to be performed at the state's request.

From May 2018 to May 2019, 330 pharmacies underwent VPP inspections (see chart on this page). Findings from inspections conducted from May 2018 to May 2019 were compiled for each pharmacy group. Some findings related to general practice, nonsterile compounding, and sterile compounding are as follows:

General practice:

- 72% mail/deliver out-of-state
- 58% hold an accreditation or certification
- 56% do not, or do not know if they determine that all sources listed on transaction histories have reported to Food and Drug Administration's wholesale distributor database

Nonsterile compounding:

- 66% perform nonsterile compounding
- 65% perform compounding with hazardous drugs
- 42% do not perform hazardous nonsterile compounding in a ventilated cabinet, such as a biosafety cabinet, compounding aseptic isolator, or compounding aseptic containment isolator

Sterile compounding pharmacies:

- 49% perform sterile compounding
- 37% perform high-risk sterile compounding
- 28% perform high-risk sterile compounding without assigning beyond-use dates within USP guidelines (24 hours at controlled room temperature, three days refrigerated, 45 days frozen)

NABP member boards of pharmacy and the Association remain committed to developing a robust inspection network. NABP continues to be in close discussions with the state boards to further develop VPP so that it meets their needs. For information about participating in VPP, contact NABP at VPP@nabp.pharmacy.

VPP Inspections*	May 2018 – May 2019
Nonsterile Compounding Only	104
Nonsterile and Sterile Compounding	96
Non-compounding	48
Sterile Compounding Only	46
Nuclear	23
Outsourcing	13

* The totals above represent pharmacies whose inspections have already been completed and do not include applicants who are awaiting an inspection or who recently submitted an application.

Pharmacists Invited to Participate in NAPLEX Practice Analysis Survey

In early November 2019, NABP sent email invitations to randomly selected pharmacists in all areas of practice encouraging them to participate in the North American Pharmacist Licensure Examination® (NAPLEX®) Practice Analysis Survey. Pharmacists who receive the email invitation are encouraged to participate. Analysis of the survey results will be used to validate the NAPLEX competency statements.

Survey responses will be carefully analyzed and weighted, and the results of the analysis will be presented to the NAPLEX Review Committee, the Advisory Committee on Examinations, and the NABP Executive Committee for policy recommendations and final approval. The resulting approved competencies and blueprint are expected to be implemented in the NAPLEX beginning in 2021. All schools and colleges of pharmacy, as well as the state boards of pharmacy, will be notified of these revisions.

The current version of the NAPLEX blueprint is in the *NAPLEX/MPJE 2019 Candidate Application Bulletin*, which can be downloaded at *https://nabp.pharmacy/programs/naplex/#bulletin.*

Despite Popular Support, Prescription Drug Importation Remains Risky

As the buildup to the 2020 election continues, the issue of prescription drug importation – that is, whether regulations should be changed to allow legal importation of medications from foreign countries – is once again in the national spotlight. With some leaders demanding prescription drug importation, some consumers may be unaware that the law does not allow foreign online drug outlets to ship medications into the United States. In addition to being unlawful, many of these organizations endanger US patients by providing adulterated, unsafe, or substandard medications.

Political Leaders Appear to Support Drug Importation

In late July 2019, the US Department of Health and Human Services and Food and Drug Administration (FDA) published their Safe Importation Action Plan that includes two possible pathways to allow importation of drugs from foreign markets. The first pathway would use provisions in the Federal Food, Drug, and Cosmetic Act to allow importation of certain drugs from Canada that are versions of FDA-approved drugs, if manufactured consistent with FDA approval. This pathway requires that there be no additional risk to the public's health and safety and that the importation result in significant cost savings to the American consumer. The second pathway would allow manufacturers to import "versions of FDA-approved" drug products that are sold in foreign countries, where the foreign versions are the same as US versions. These drugs would be relabeled for US sale.

> **"...importation presents many risks that most consumers do not fully understand."**

Meanwhile, leaders in Congress have proposed more ambitious drug importation legislation. The most prominent example is the Affordable and Safe Prescription Drug Importation Act, which would allow patients, pharmacists, and wholesalers to import "safe, affordable medicine from Canada and other major countries," according to an FDA press release. While it seems unlikely that the proposed legislation will gain traction in the current Congress, it should be noted that it is backed by prominent leaders in both the House and Senate, including Democratic presidential candidates Senators Bernie Sanders (VT), Elizabeth Warren (MA), and Amy Klobuchar (MN).

In addition to these national efforts, legislators at the state level have also considered and, in some cases, approved measures to allow drug importation.

On the whole, the concept of drug importation is popular among Americans. A February 2019 poll conducted by the Kaiser Family Foundation found that nearly 80% of Americans, regardless of political affiliation, support such a policy change. Nevertheless, importation

presents many risks that most consumers do not fully understand.

Consumer and Pharmacy Organizations Warn Against Importation

Consumer Reports, a nonprofit organization that uses "rigorous research, investigative journalism, and consumer advocacy" to inform purchase decisions, has advocated that patients avoid buying medication from overseas. In an August 2019 article, the organization noted that while it supports efforts to lower drug costs, it "is and will remain illegal for consumers" to mail order drugs from outside the US. Consumer Reports notes that buying drugs this way can be risky. It cites NABP's research, as well as a US Department of Justice settlement involving Canada Drugs, a Canadian wholesaler and pharmacy that admitted to distributing counterfeit cancer medications in the US. Because these falsified medicines contained no active ingredient, vulnerable US cancer patients did not receive the care they needed and suffered direct harm from illegal importation.

In March 2019, the Canadian Pharmacists Association (CPhA) and the American Pharmacists Association (APhA) issued a joint statement summarizing the risks of importation. The statement acknowledges the desire to address affordability issues related to prescription medications but opposes federal legislation that would authorize personal and commercial importation of prescription drugs from Canada to the US. Because Canadian pharmacies can only dispense medications prescribed by a Canadian health care provider, the statement expressed concerns about the possibility of fragmented care in the form of American patients receiving medications from Canadian providers without the providers having full access to the patients or their health care records. The statement also noted that authorizing importation could exacerbate legitimate supply chain issues that impact safety and security, including Canadian drug shortages and recalls.

Additionally, APhA and CPhA expressed concern for patients who may wish to purchase and import medications online. "Some online pharmacies are entities selling counterfeit drugs and operating outside Canadian and American laws," the associations said. "These entities are difficult to detect and control due [to] their sophistication and the large number in operation."

In February 2019, NABP released a statement detailing its concerns about prescription drug importation. "While [NABP] appreciates these important efforts to increase patient access to affordable medications, we must also ensure that those medications are safe. Allowing Americans to import foreign medicines would put patients in this country at risk of harm from the infiltration of unapproved, substandard, falsified and counterfeit medicines into the US supply chain," the statement reads.

In explaining this position, NABP notes importation without appropriate safeguards may make consumers more vulnerable to the "continuous and growing public health threat" of illicit and dangerous drug sellers shipping counterfeit and substandard medications into the US, even with the full force of US law enforcement opposing their activity. The full statement is available in the Position Papers section of the NABP website.

While drug importation policies continue to be debated, NABP maintains its long-standing efforts to protect the public health and support its member boards of pharmacy through programs intended to help consumers recognize safe and legal online pharmacies.

These programs include the .Pharmacy Verified Websites Program, which provides a .pharmacy domain to medication-related websites that are reviewed to ensure they comply with all applicable laws and business best practices. Receiving a .pharmacy domain gives these organizations the ability to set themselves apart from the websites operating out of compliance with laws and standards.

NABP also continues to maintain a database of pharmacy websites. By visiting NABP's consumer website, *www.safe.pharmacy*, and entering a URL into the "Buy Safely" tool, consumers can quickly identify whether the online pharmacy they want to buy from is safe, or if it is on the Association's Not Recommended List. Of the almost 12,000 websites reviewed by NABP, nearly 95% operate out of compliance with NABP patient safety and pharmacy practice standards, or applicable laws. The consumer website also gives users the ability to report suspicious websites, which NABP can examine and add to the Not Recommended List, if needed.

In accordance with NABP's mission to support its member boards and jurisdictions in protecting the public health, NABP remains committed to upholding the integrity of the practice of pharmacy – in any practice setting or location – and ensuring patients have access to safe and effective prescription medications. For additional information about NABP's efforts to enhance online safety for consumers, visit the Initiatives section of the NABP website. ■

2020 *Survey of Pharmacy Law* Available Soon

The 2020 edition of the *Survey of Pharmacy Law*, which will become available this December, is 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*, which is published in a downloadable pdf format, consists of four chapters: a state-by-state overview of organization law, licensing law, drug law, and census data. The 2020 *Survey* includes five new questions addressing:

- board membership as it pertains to pharmacy technicians;
- Foreign Pharmacy Graduate Examination Committee™ certification requirements for licensure;
- nonprescription device dispenser licensure requirements;
- pharmacists' independent prescribing authority; and
- requirements for electronic transmission of prescriptions.

In addition, questions related to device wholesale distributor and dispenser requirements have been revised to better address pharmacy practice topics. Also, Section 12, Discipline of Pharmacist Licenses and Section 23, Electronic Transmission of Prescriptions: Computer-to-Computer have been removed.

Updates for the 2020 *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 receive a complimentary copy for their board.

The *Survey* will be available for purchase online for $195 by visiting the Publications and Reports section of the NABP website at *www.nabp.pharmacy.*

New NABP Verifications

The following entities were recently granted NABP verification through the .Pharmacy Verified Websites Program noted below. A full listing of .Pharmacy Verified Websites can be found in the Programs section at *www.nabp.pharmacy.*

.Pharmacy Verified Websites

Amber Enterprises, Inc
www.amberpharmacy.pharmacy
www.amberpharmacy.com

Apotheco, LLC
www.apotheco.pharmacy
www.apothecopharmacy.com

Ardon Health, LLC
www.ardonspecialtyrx.pharmacy
www.ardonhealth.com

AV Pharma LLC
www.citizen.pharmacy
www.citizenpharmacy.com

Boston Medical Center Corporation
www.cornerstonehealthsolutions.pharmacy
www.cornerstonehealthsolutions.org

CD Pharmacy
www.redrockhome.pharmacy
www.redrockhomepharmacy.com

Center City Pharmacy
www.zoomeds.pharmacy
www.zoomeds.com

Connected Health Pharmacy
www.connectedhealth.pharmacy
www.connectedhealthrx.com

Devron System Inc
www.simplerx.pharmacy
www.simplerxpharmacy.com

Enclara Pharmacia, Inc
www.enclarapharmacia.pharmacy
www.enclarapharmacia.com

Entourage MD Skin & Wellness Medical Corporation
www.entouragemd.pharmacy
www.entouragemd.com

Gwinnett Drugs LLC
http://gwinnettdrugs.pharmacy
www.gwinnettdrugs.com

Hope Specialty Pharmacy (hopesp.com)
http://hopesp.pharmacy
www.hopesp.com

HYVACS, LLC
www.hvrxsolutions.pharmacy
www.hvrxsolutions.com

JMC Pharmacy
www.abc.pharmacy
www.iepharmacy.com

Jolly's Pharmacy Inc
www.readymedspharmacy.pharmacy
www.readymedspharmacy.com

Kamran Pharmacy Inc
http://thefamilypharmacy.pharmacy
www.thefamilypharmacy.com

Lee's Marketplace
www.leesmarketplace.pharmacy
www.leesmarketplace.com

Ostrom Enterprises Inc
www.ostroms.pharmacy
www.ostroms.com

Pathema RX, LLC
www.pathemarx.pharmacy
www.pathemarx.sbx.itsupportme.by

Pharmaneek, Inc
www.pharmaneek.pharmacy
www.pharmaneek.com

Pope Shenouda LLC
https://firstchoicepharmacy.pharmacy
www.1stchoicepharmacy.net

Prescription Hope, Inc
www.prescriptionhope.pharmacy
www.prescriptionhope.com

Schraft's 2.0
www.fertilityrx.pharmacy
www.schrafts2.pharmacy
www.schrafts2.com

SP2, LLC
www.smrtrx.pharmacy
www.smrtrx.net

Symptos LLC
www.symptos.pharmacy
https://v1.symptos.com

Vedas Medical Spa & Wellness Center
www.vedasmedspa.pharmacy
www.vedasmedspa.com

Proposed Amendments to the NABP Constitution and Bylaws Must Be Submitted by March 30

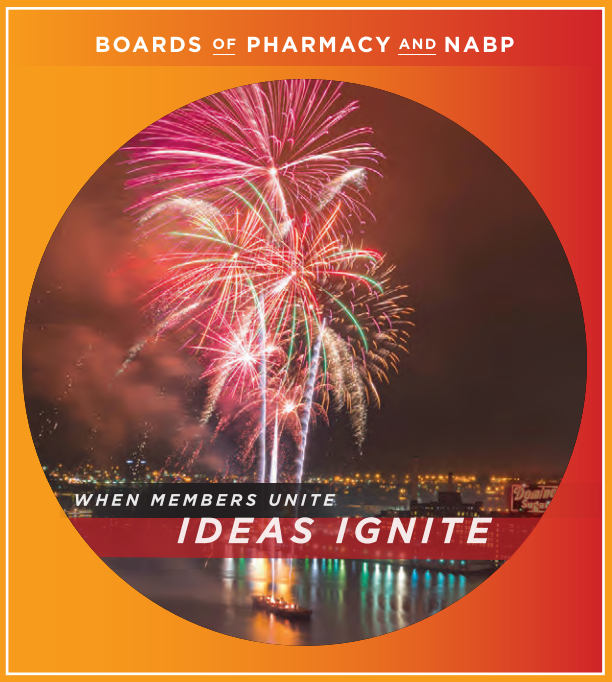
To be considered during the 116th Annual Meeting, proposed amendments to the NABP Constitution and Bylaws (CBL):

- must be submitted between Friday, February 14, 2020, and Monday, March 30, 2020. 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 Carmen A. Catizone.

  by email:
  ExecOffice@nabp.pharmacy

  by mail:
  NABP Headquarters
  1600 Feehanville Dr
  Mount Prospect, IL 60056 ■



Save the Date!

116th NABP Annual Meeting

May 14-16, 2020 • Baltimore, MD

More information will be available in future issues of *Innovations* as well as on the NABP Annual Meeting website.

Interview With a Board Member

Lemrey "Al" Carter, MS, PharmD, RPh, Member, Illinois State Board of Pharmacy

Lemrey "Al" Carter, MS, PharmD, RPh,

Member, Illinois State 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 appointed by former Governor Bruce Rauner to the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy on May 27, 2015. I am a pharmacist member.

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

One of the first things a board member should do to be successful is learn about all the different practice settings. I have always practiced in community pharmacy and, outside of my rotations in my sixth year of pharmacy school, was not exposed to compounding pharmacies, institutional settings, etc. It benefited me to talk to pharmacists in those practice settings and learn how they operate and what some of the challenges are that they deal with in providing patient care. Second, I think it is important to become engaged and stay engaged with pharmacy practice, and volunteer in NABP activities and board of pharmacy committees and task forces when opportunities arise. I learned a lot from participating in task forces and writing and analyzing questions for the Multistate Pharmacy Jurisprudence Examination®, etc.

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

A legislative action set up the Illinois Collaborative Pharmaceutical Task Force, to which I was appointed. It is responsible for addressing how to further advance the practice of pharmacy and workforce conditions. The task force has been charged with looking at pharmacist work conditions and changes that need to be made to the Illinois Pharmacy Practice Act. Some of the recommendations that the Board is currently working on would mandate uninterrupted meal breaks, expand pharmacy technician duties to allow for such things as administering immunizations, and change the pharmacy technician education and training requirements.

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

Due to the nature of the task force and having members from all areas of pharmacy practice and other professional groups such as labor unions, medical societies, and colleges of pharmacy, you will encounter some challenges along the way. We have had our share of challenges. However, our Board members have all come together to learn and understand one another's positions and made decisions that will incorporate the appropriate recommendations to address each member's concerns and provide a complete recommendation to the state.

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Illinois State Board of Pharmacy

Number of Board Members: 7 pharmacist members and 2 public members
Number of Compliance Officers/Inspectors: 6
Rules and Regulations Established by: Illinois Department of Financial and Professional Regulation, Division of Professional Regulation
Number of Pharmacist Licensees: 18,184
Number of Pharmacies: 3,677
Number of Wholesale Distributors: 1,436

Around the Association

Board Member Reappointments

- **Claudia Alexander** has been reappointed a public member of the New York State Board of Pharmacy. Alexander's appointment will expire March 31, 2022.
- **Joseph J. Bova, MS,** has been reappointed an extended member of the New York State Board of Pharmacy. Bova's term expires July 31, 2020.
- **John L. Croce, RPh,** has been reappointed an extended member of the New York State Board of Pharmacy. Croce's term expires January 31, 2022.
- **Patricia Donato, BSPharm, RPh-1, DPh (Hon),** has been reappointed an extended member of the New York State Board of Pharmacy. Donato's term expires September 30, 2022.
- **Rocco F. Giruzzi, Jr, BS,** has been reappointed an extended member of the New York State Board of Pharmacy. Giruzzi's term expires June 30, 2021.
- **Fernando Gonzalez, RPh,** has been reappointed an extended member of the New York State Board of Pharmacy. Gonzalez's term expires January 31, 2022.
- **Heather King, RPh,** has been reappointed a member of the New York State Board of Pharmacy. King's appointment will expire October 31, 2022.
- **Susan Ksiazek, RPh, DPh,** has been reappointed an extended member of the New York State Board of Pharmacy. Ksiazek's term expires November 30, 2023.
- **Brendan Lawler, BS,** has been reappointed an extended member of the New York State Board of Pharmacy. Lawler's term expires July 31, 2020.
- **Nasir Mahmood, MBA, RPh,** has been reappointed a member of the New York State Board of Pharmacy. Mahmood's appointment will expire April 30, 2024.
- **Carolyn Reres** has been reappointed an extended member of the New York State Board of Pharmacy. Reres' term expires November 30, 2023.
- **David J. Schaff, PharmD, RPh,** has been reappointed an extended member of the New York State Board of Pharmacy. Schaff's term expires July 31, 2020.

Interview With an Executive Director

continued from page 3

early on in the process was very important. Having frequent communication with them helps limit the number of surprises that we have as we implement this. For instance, we have a law that requires constant audio communication between the telepharmacy and the supervising pharmacy. The Board and its inspectors implemented the law one way, while DEA interpreted it a different way. That was an instance where we had to reconcile two different interpretations that were not expected at first. We have had hiccups along the way, but we have been able to find solutions as we work with each other. We have taken a slower approach to implementing the telepharmacy model because we want to make sure that we get it right, as opposed to getting it done quickly.

Interview With a Board Member

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What advice would you give a new board member?

My recommendation for new board members is to read their state's pharmacy practice act and rules and become very familiar with it. I would also spend some time with experienced board members to learn from them how to be prepared for and proceed in board meetings. Finally, I would advise new board members to get engaged early and often, while being fully committed to providing quality care to the citizens and patients of their 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 NABP task forces and committees. I participated on the NABP Committee on Resolutions for two years, the Committee on Law Enforcement/Legislation, and the NABP Task Force to Develop Regulations Based on Standards of Care. In addition, I was chair of the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment. It is always fascinating to understand the differences and similarities between state board of pharmacy regulations. I benefited by having the opportunity to network and learn how some board members dealt with specific issues and/or different initiatives in their states. Also, I have been going to the NABP Annual Meeting since 2009 and have attended several district meetings as well. These meetings are extremely beneficial and are where I learn about a lot of initiatives and challenges in pharmacy practice. I don't think any other meetings provide attendees with the opportunity to network and hear from all 50 state boards of pharmacy. I hope that I am able to attend and participate in NABP meetings for years to come.

Massachusetts to Only Accept Electronic Prescriptions for CS

In Massachusetts, beginning January 1, 2020, only electronic prescriptions will be accepted at pharmacies for all controlled substances (CS) in Schedules II through VI. The Massachusetts Board of Registration in Pharmacy noted that the change was implemented to help combat the opioid epidemic via paper-based prescriptions.

Exceptions to the new law include veterinary prescriptions, out-of-state prescriptions, instances where electronic prescribing is not available due to temporary technological or electrical failure, emergency prescriptions as defined by the commissioner of the Massachusetts Department of Public Health, and in cases where the prescriber has been issued a temporary waiver. More information is available in the Board's August 2019 *Newsletter*.

Ohio Requires Pharmacy Technicians to Obtain Criminal Background Check

All pharmacy technician applicants in Ohio are required to obtain a criminal record check by submitting fingerprints to the Ohio Bureau of Criminal Identification and Investigation and the Federal Bureau of Investigation via a WebCheck provider located in Ohio. The new rule went into effect on April 6, 2019.

More information about criminal background checks for pharmacy technicians can be found by viewing the Board's criminal records check document for pharmacy technicians.

Virginia Updates Processes for Issuing Licenses, Registrations, and Permits

The Virginia Board of Pharmacy is implementing a process to cease mailing out, on an annual basis, hard copy licenses, registrations, and permits that bear an expiration date. A final hard copy that contains no expiration date will be issued. Licensees must still continue to renew their licenses annually or as required, submit payment, and attest to compliance while obtaining any required continuing education. More information is available at *www.dhp.virginia.gov/pharmacy/newsletters/2019/PhamacyNews06262019.pdf.*

Washington Board Requires Nonresident Pharmacies to Submit Inspection Reports With Substantially Equivalent Standards

During the 2019 Washington Legislative Session, the legislature passed House Bill (HB) 1412, an act relating to nonresident pharmacies. HB 1412 amends Revised Code of Washington (RCW) 18.64.360 to require a nonresident pharmacy to submit a copy of an inspection report that has substantially equivalent standards to those of the Washington State Pharmacy Quality Assurance Commission and was issued within the last two years of application for, or renewal of, a license. This change in law aligns Washington's standards for nonresident pharmacies with those of resident pharmacies, continuing the Commission's efforts to ensure patient safety.

If a state inspection does not qualify, a pharmacy can get an inspection report done through an approved third-party inspection program, such as the Verified Pharmacy Program®. This law became effective July 28, 2019. More information is available in the Board's August 2019 *Newsletter*.

Washington's New Opioid Bill Impacts the Practice of Pharmacy

Governor Jay Inslee proposed a bill aimed at addressing many of the issues that involve the ongoing opioid epidemic. While the bill has many aspects, several will directly or indirectly affect the practice of pharmacy in Washington.

A new section is added to RCW Chapter 18.64 to allow the partial fill of opioid prescriptions. The law expands the ability of a pharmacist to dispense an opioid overdose reversal medication pursuant to a collaborative drug therapy agreement, standing order, or protocol. The law requires pharmacists to provide written instructions at the time of dispensing on the proper response to an overdose, including instructions for seeking immediate medical attention. It also amends RCW 70.41.480 to permit practitioners to use their professional judgment to dispense prepackaged emergency opioid overdose reversal medication to patients at risk of an opioid overdose from an emergency department. The prepackaged emergency overdose reversal medication is exempt from the labeling requirements of RCW 18.64.246 and RCW 69.41.050.

In addition, the law removes the requirement for the Washington State Pharmacy Quality Assurance Commission to approve electronic prescription communication systems. All systems must comply with state and federal laws and rules.

Many other aspects of the law are aimed at addressing and preventing opioid misuse and overdose, including a requirement that the prescriber notify the patient of the risks associated with opiates, and expanded medication-assisted treatments, education, and treatment. All parts of the law have been effective since July 28, 2019, except the one mandating electronic prescribing for all CS, which begins January 1, 2021. This date aligns with the federal requirement of electronic prescribing for CS prescriptions covered by Medicare Part D. More information is available in the Board's August 2019 *Newsletter*.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following revisions to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding — Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding — Sterile Preparations
- General Chapter <825> Radiopharmaceuticals — Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of USP Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official.

Revisions to *USP General Chapter <800> Hazardous Drugs — Handling in Healthcare Settings* are not subject to pending appeals and will become official on December 1, 2019. During this interim period, USP Chapter <800> is "informational and not compendially applicable." However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of USP Chapter <800>. More information is available at *www.uspnf.com*.

DEA Proposes to Reduce the Number of Opioids Manufactured in 2020

In accordance with the SUPPORT for Patients and Communities Act, US Drug Enforcement Administration (DEA) has proposed to reduce the amount of five prescription opioids that can be manufactured in the US next year. If adopted, the proposal would affect the following controlled substances (CS) as compared to production in 2019:

- Fentanyl production to be reduced by 31%
- Hydrocodone to be reduced by 19%
- Hydromorphone to be reduced by 25%
- Oxycodone to be reduced by 9%
- Oxymorphone to be reduced by 55%

The proposal would result in a 53% reduction in the allowable production of CS opioids since 2016 and would also increase the amount of marijuana that can be produced for research by almost a third compared to 2019.

The proposal was published in the *Federal Register* on September 12, 2019.

DEA Proposes to Control Three Precursor Chemicals Used to Illegally Manufacture Fentanyl

DEA has issued a proposal to begin controlling three substances used to illicitly manufacture fentanyl. Two notices of proposed rulemaking were published in the *Federal Register*:

- **On September 13, 2019**, DEA proposed that benzylfentanyl and 4-anilinopiperidine be controlled as list I chemicals under the Controlled Substances Act (CSA).
- **On September 17, 2019**, DEA proposed to designate norfentanyl as an immediate precursor (a substance from which another is formed) for fentanyl and to make it a Schedule II CS under the CSA.

The DEA notice is available at *www.dea.gov/press-releases/2019/09/17/dea-proposes-control-three-precursor-chemicals-used-illicitly-manufacture.*

FDA Issues Statement on Improving Adverse Event Reporting of Compounded Drugs

Acknowledging that compounded drugs serve an important medical need for patients, while also presenting certain risks, Janet Woodcock, MD, director of Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research, emphasizes the need to improve regular reporting of issues related to these products that may potentially affect patient health in an FDA statement.

Woodcock specifically cites a recent case involving hormone pellets compounded at an outsourcing facility that were associated with 4,202 adverse events that occurred, including cancers, strokes, and heart attacks, that were never reported to FDA during the five-year period (2013-2018) in which they occurred.

FDA will continue to work with outsourcing facilities to improve on how they obtain reports of adverse events related to their products and on providing adverse event reports to FDA. In addition, the statement cites ongoing work to finalize a memorandum of understanding (MOU). States that sign the MOU will, among other things, agree to investigate reports of adverse events associated with certain compounded drugs and report "serious adverse events" to FDA. The MOU is expected to be finalized later in 2019.

NABP was awarded funding from FDA to create a data system to enable the collection, management, and sharing of information regarding compounding pharmacies in the US. The new system will provide boards of pharmacy with a tool to report interstate compounding information to other boards and FDA. More information is available in an October 2, 2019 news release at *www.nabp.pharmacy/newsroom/news*. More information will also be available in the January 2020 edition of *Innovations.* ■

INNOVATIONS®
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

UPCOMING EVENTS

Committee on Law Enforcement/Legislation
January 14-15, 2020
NABP Headquarters

NABP Interactive Member Forum
January 28-29, 2020
NABP Headquarters

FPGEE Administration
April 2, 2020

Committee on Constitution and Bylaws
April 6, 2020
Teleconference

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

NEVER MISS A MINUTE. FOLLOW US ON SOCIAL.