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WHOLESALE DRUG IMPORTATION UNDER THE SPOTLIGHT

as NABP, Member Boards Act to Ensure Patient Safety

NABP
National Association of Boards of Pharmacy

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Feature News
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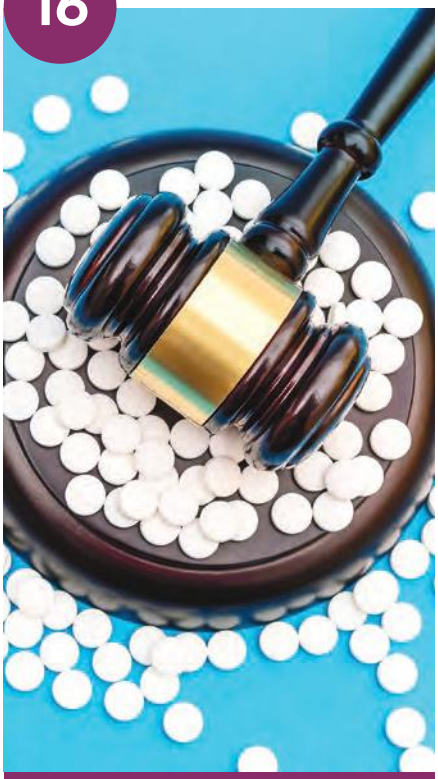

Association News
NABP Clearinghouse Records Over 1,000 Disciplinary Actions in First Quarter 2021

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.

NABP
National Association of Boards of Pharmacy

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

Fellow Members,

As we see real progress against COVID-19 in the form of decreased hospitalizations and fatalities and increased access to vaccinations, it feels like life is finally starting to get back to normal. Reflecting on the pandemic, the road before us, and the opportunities to focus on other priorities, I feel recharged with a new sense of purpose and drive in my mission of protecting the public health, especially as I begin my new term as NABP chairperson.

This perspective was especially helpful during this year's Annual Meeting. Although virtual, it was great to be able to connect with so many of you on important NABP business. We elected a new Executive Committee, approved six resolutions, and offered several continuing pharmacy education sessions on a variety of topics. I would also like to give a shout-out to all the pharmacy schools that participated in the Educational Poster Session. I commend the deans of these schools and colleges for encouraging students to participate and play an active role in public health protection as future pharmacists! You can learn more about the 117th NABP Annual Meeting in the digital Annual Meeting issue of *Innovations*.

As board operations return to a more normal routine, I would also like to encourage each board to resume reporting disciplinary, licensure, and inspection information to the NABP Clearinghouse. As Reginald B. "Reggie" Dilliard, our new president-elect, reported during the Annual Meeting, we saw a nearly 25% decrease in records submitted to the Clearinghouse during 2020. The Clearinghouse data is used to support NABP accreditation programs as well as the Electronic Licensure Transfer Program®, so ensuring that this information is kept up to date is crucial to the effectiveness of these programs, and to ensuring the safety of the patients.

Another important topic discussed at the meeting was drug importation. This topic will be the focus of NABP President Caroline D. Juran's initiative for her 2021-2022 term. As Caroline noted when she addressed the membership at the Annual Meeting, she will be working with all of you to help mitigate risks to the global supply chain and ensure the safety and integrity of prescription medications that may be imported into the United States. This topic is rather complex and one that requires a great deal of responsibility and oversight from the boards of pharmacy as we work to keep the main priority of safety at the forefront. In this issue of *Innovations,* we feature an overview of how federal actions have opened pathways for drug importation that several states are working to navigate, along with key points from Caroline's initiative.

NABP task forces and committees will play an essential role in this endeavor and ensure that a range of member and expert voices are part of the discussion. Member voices will also make up the newly developed *Model Act* Review Committee that will perform periodic reviews of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).* More information on this new committee is available on page 12 of this newsletter. Although the deadline for the 2021-2022 task force and committee applications has passed, I encourage all board of pharmacy members to watch the Members section of the NABP website for future opportunities to be involved.

I look forward to serving all of you in the year ahead as chairperson of the Executive Committee, and working with you on current and new initiatives. Let's get to work!

Sincerely,

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

Non-Dispensing Pharmacies: Does My Company Need a License?

Libby Baney, JD
Faegre Drinker Biddle & Reath LLP

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

The role of pharmacists in patient care has expanded beyond the traditional tasks of dispensing medications and providing basic medication counseling to working with other health professionals and the general public. As the role of pharmacists continues to evolve, we are beginning to see a new class of pharmacy entities emerge: **non-dispensing pharmacies**. This type of pharmacy entity has presented a unique challenge to the boards of pharmacy as it is often unclear whether such activities fall within the board's regulatory scheme governing pharmacies, which have traditionally focused on the processing and dispensing of prescription drugs and devices. This uncertainty is especially apparent for non-dispensing entities seeking to provide pharmacy services to patients residing outside their resident state.

This article will discuss the types of services provided by a non-dispensing pharmacy, provide examples of how certain states license entities providing non-dispensing pharmacy activities, provide a summary of our discussions with the various boards of pharmacy regarding licensure of non-dispensing pharmacies, and conclude with what you should consider when evaluating licensure of a non-dispensing pharmacy entity.

What Is a Non-Dispensing Pharmacy?

A non-dispensing pharmacy typically means an entity that provides, through its pharmacists, services such as medication therapy management (MTM), drug therapy assessment and monitoring, drug regimen review, disease management, coordination of patient care with other health care providers, and other related patient care services. The goal of these services is to optimize a patient's individual pharmacotherapy through collaboration with the patient and oftentimes their primary care physician.

As the name suggests, a non-dispensing pharmacy does not order, stock, receive, dispense, distribute, or ship prescription drugs or devices of any kind. Rather, the role of the pharmacist is to provide clinical pharmacy services to patients in an outpatient setting. This often presents a challenge when evaluating whether the entity providing the non-dispensing pharmacy services should obtain a pharmacy license, especially for entities providing services outside of their resident state.

Regulation of Non-Dispensing, Nonresident Pharmacies

Every board of pharmacy's definition of the "practice of pharmacy" includes the provision of MTM or a similar patient care service provided by a pharmacist. However, simply because a pharmacist is engaging in the practice of pharmacy and providing pharmacy services, does not necessarily mean the entity that employs the pharmacist must also be licensed as a pharmacy.

We reviewed the rules and regulations governing licensure for non-dispensing, nonresident pharmacies in an attempt to understand the licensure requirements for these entities nationally. The results revealed a lack of uniformity around the licensure requirements for such non-dispensing facilities providing pharmacy services outside of their state. Several states clearly contemplate licensure, some states do not, while the regulations for a majority of the states are ambiguous.

- **Board of Pharmacy Regulations Providing for Licensure of Non-Dispensing Pharmacies:** The pharmacy regulations of Oregon, South Carolina, and Vermont allow for licensure of non-dispensing, nonresident pharmacies. Oregon requires a consulting pharmacy, defined as a physical location where pharmaceutical care services are performed, to be registered by the board of pharmacy:[1] South Carolina has a facility permit classification specifically for non-dispensing, nonresident pharmacies:[2] and Vermont defines a

nonresident pharmacy as any business located outside of Vermont that provides pharmacy services, including consulting and MTM services.[3]

- **Board of Pharmacy Regulations That Do Not Appear to Require Licensure of Non-Dispensing Pharmacies:** Conversely, several other states, such as Alaska,[4] Colorado,[5] Connecticut,[6] and Delaware,[7] do not appear to provide for licensure of non-dispensing, nonresident entities as the regulations in those states tie pharmacy licensure to whether the entity ships, mails, dispenses, or delivers prescription drugs or devices into the nonresident state – activities that a non-dispensing pharmacy does not perform.

Guidance From the Boards of Pharmacy

Given the lack of uniformity around licensure requirements, including the terminology used to define a nonresident pharmacy, we surveyed the boards of pharmacy to better understand the status of non-dispensing, nonresident pharmacy licensing in the United States. Key findings:

- 32 states likely allow for the licensing of non-dispensing, nonresident facilities.
- 18 states likely do *not* issue a license to non-dispensing, nonresident facilities.

Corresponding Pharmacist Licensure Rules

In addition to determining whether the non-dispensing, nonresident *entity* should obtain licensure, you must also consider *pharmacist* licensure as well. As mentioned previously in this article, a pharmacist providing non-dispensing pharmacy services, such as MTM, would be "practicing pharmacy" and, depending on whether the entity obtained licensure as a pharmacy, the pharmacist providing such services may need to be licensed as a pharmacist in the nonresident state where they are providing the pharmacy services. For example, if a pharmacist is providing MTM services to a patient in a state that does not license a non-dispensing entity, then each pharmacist providing services to patients in that state should hold a pharmacist license from that state.

. . . simply because a pharmacist is engaging in the practice of pharmacy and providing pharmacy services, does not necessarily mean the entity that employs the pharmacist must also be licensed as a pharmacy.

One of the major advantages for a non-dispensing, nonresident entity obtaining pharmacy licensure is that it generally alleviates the requirement that each individual pharmacist must obtain a pharmacist license in the states where the pharmacist engages in the practice of pharmacy. The one exception to this general rule is that there appear to be 19 states that, in addition to requiring the entity to hold a pharmacy license, *also* require the pharmacist-in-charge (PIC) to hold a pharmacist license for the nonresident state.

Lastly, through our discussions with the various boards of pharmacy, we learned that three states – Nevada, New York, and South Carolina – also require all pharmacists who provide MTM services to patients located in their states to hold a pharmacist license in their jurisdiction.

Final Considerations

When you are evaluating whether a non-dispensing entity should register as a pharmacy, there are several considerations to keep in mind:

- Determine whether the resident state will issue a pharmacy license to the non-dispensing entity. This resident license will serve as the basis upon which the entity can seek to obtain nonresident licenses.
- Determine which nonresident states (assuming the entity will provide pharmacy services outside of its resident state) will issue a nonresident pharmacy license to the non-dispensing entity.
- Determine in which nonresident states the PIC will be required to hold a pharmacist license.
- Determine in which nonresident states the pharmacists providing the non-dispensing pharmacy services will be required to hold a pharmacist license.

It will be interesting to see how non-dispensing pharmacies continue to grow and what impact this may have on the pharmacy licensing scheme, especially for states that do not currently license such entities. ●

This article was written by Libby Baney, JD, and Jonathan A. Keller, PharmD, JD, RPh, with Faegre Drinker Biddle & Reath LLP. Please note, the opinions and views expressed by Faegre Drinker Biddle & Reath do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated.

Hyperlinks to footnoted references are available in the June/July 2021 *Innovations* pdf on *www.nabp.pharmacy.*

[1] OAR 855-041-3305, -3310.

[2] S.C. Code of Regulations R. 99-43(C).

[3] VT Rule 20-4-1400:16.1.

[4] AS § 08.80.158.

[5] C.R.S. § 12-280-103(43).

[6] C.G.S.A. § 20-628

[7] 24 Del. C. § 2535.

California State Board of Pharmacy

Number of Board Members
7 pharmacist members and 6 public (The governor appoints 4 public members; the senate and assembly each appoint 1 public member.)

Number of Compliance Officers/Inspectors
55

Rules & Regulations Established by
State Board of Pharmacy

Number of Pharmacist Licensees
47,926

Number of Pharmacies
7,620

Number of Wholesale Distributors
592 (includes manufacturers, wholesale distributors, and third-party logistics providers)

Anne Sodergren

Executive Officer, California State Board of Pharmacy

How long have you served as executive officer?

I was appointed to serve as executive officer in January 2020. Prior to this appointment, I served as assistant executive officer.

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

Navigating and responding to the coronavirus disease 2019 (COVID-19) pandemic. The Board focused on steps it could take to ensure continuity of patient care under very dynamic conditions. This included looking at the practice of pharmacy and, given the climate and transmission ability of COVID-19, the identification of meaningful steps to address patient and pharmacy staff safety concerns, while still providing safe patient care.

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

Since early March 2020, the Board has relied heavily on its authority to issue waivers to provisions of its pharmacy laws and regulations that, in the Board's opinion, will aid in the protection of the public and the provision of patient care. The Board has taken quick and meaningful actions, including approving about 25 broad and over 300 site-specific waivers. We also transitioned to a remote desk audit inspection process, allowing us to continue to evaluate portions of pharmacy practice to ensure consumer protection and continuity of patient care.

The Board used its waiver authority in several areas to promote physical distancing, including approving waivers to expand conditions for remote order entry, allow for the receipt of wholesaler deliveries without requiring a physical signature from the pharmacist, and create different requirements for patient consultations to ensure that patients still receive quality care, which may be delivered through different means. Pharmacists in California already have the authority to administer vaccines, but they can now administer COVID-19 vaccines without having to notify a patient's primary care provider. In addition, the Board issued a number of temporary licenses for alternative care sites to build capacity, as well as temporary licenses to facilitate the distribution of personal protective equipment, ventilators, vaccines, and so on.

What other key issues has the Board been focusing on?

The Board is balancing these efforts with other essential functions, including implementation of community pharmacy staffing regulations with provisions to ensure that a pharmacist working alone has ready access to assistance; regulations to expand access to HIV preexposure and postexposure prophylaxis; and pursuing legislation to expand authority for pharmacist-provided Clinical Laboratory Improvement Amendments-waived testing. Under existing law, pharmacists in California have limited testing authority within their scope.

What insights do you have for states facing similar challenges?

Under provisions of pharmacy law, all licensees are required to enroll in the Board's subscriber alert system, which allows the Board to quickly disseminate information. The Board has used this tool to convey information from the Board and other regulators, ensuring that licensees have up-to-date information, which has proved especially important during the pandemic.

Also, the NABP Interactive Executive Officer Forum provides an easy forum in which to interact with other executive officers. Because it is a different dynamic from one where there are also industry representatives, it allows for a better flow of information and for benchmarking and understanding the challenges and successes of other states. ●

New Department Monitors Federal Affairs on Behalf of Boards, Member Relations Continues to Provide Support

As members of NABP, boards of pharmacy have access to several innovative services, programs, and resources that support and strengthen their efforts to protect the public health. Specific professional services are offered to NABP members through two departments: the Federal Affairs department, which was formed in 2020, and the Member Relations and Government Affairs department.

NABP Federal Affairs

The NABP Federal Affairs department monitors specific issues and legislation, providing education to lawmakers on NABP's positions and the Association's mission of protecting the public health. The department partners with other organizations and stakeholders and gives testimony before Congress on behalf of boards. Federal Affairs staff can also support the boards of pharmacy on state-based initiatives.

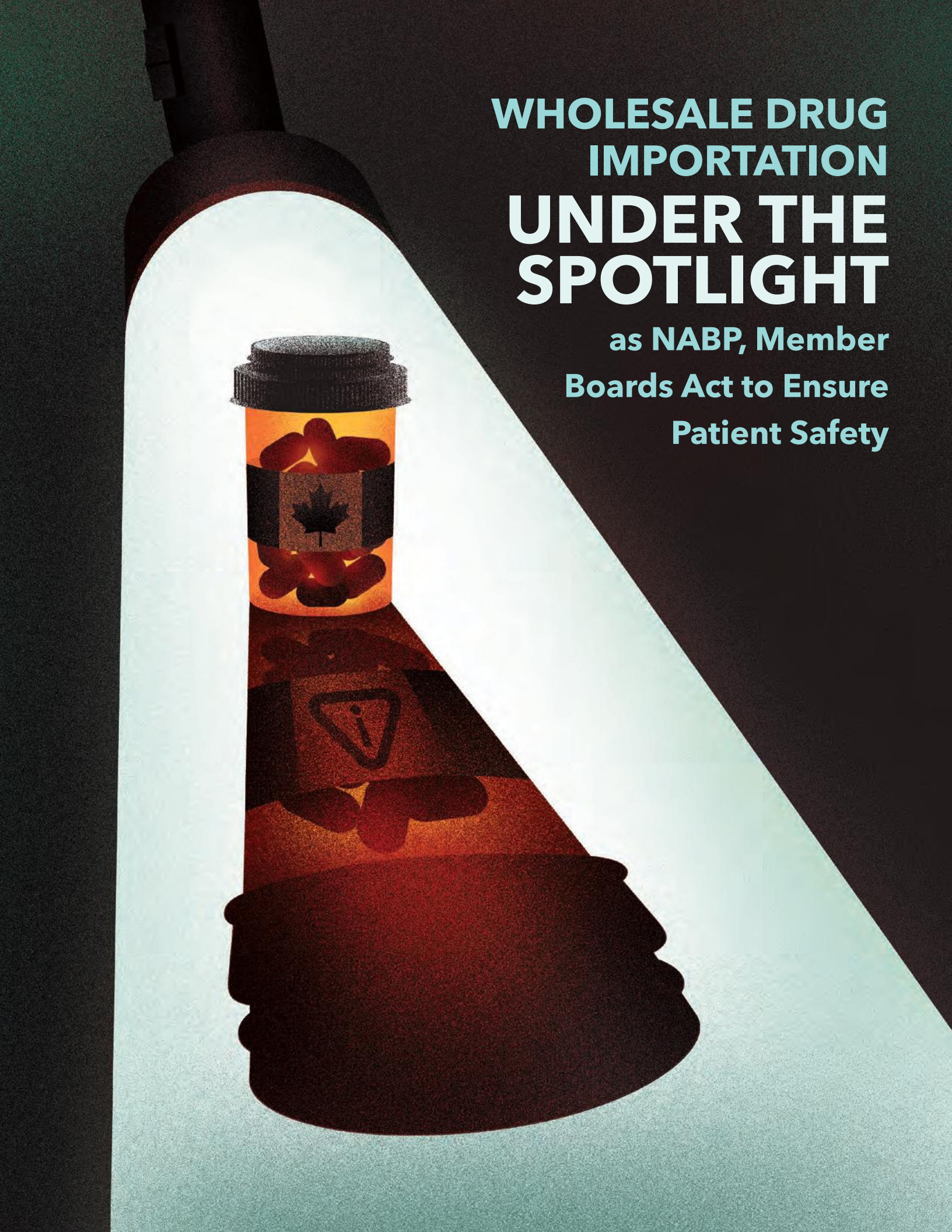
With the coronavirus disease 2019 pandemic bringing pharmacy practice and regulation to the forefront of many federal issues, Federal Affairs staff has been dedicated to monitoring these issues for the boards of pharmacy. Federal Affairs is also currently focused on legislation related to medication-assisted treatment (MAT), which was part of the 2020-2021 presidential initiative of former NABP President Timothy D. Fensky, RPh, DPh, FACA. NABP continues urging Congress to pass the Mainstreaming Addiction Treatment Act, which would allow states to recognize pharmacists as MAT providers. In addition, Federal Affairs is monitoring the progress on the Temporary Reciprocity to Ensure Access to Treatment Act, which if passed, could potentially impact licensing. As NABP President Caroline D. Juran, BSPharm, DPh (Hon), begins her 2021-2022 presidential term, Federal Affairs will also be monitoring issues related to drug importation.

With the coronavirus disease 2019 pandemic bringing pharmacy practice and regulation to the forefront of many federal issues, Federal Affairs staff has been dedicated to monitoring these issues for the boards of pharmacy.

NABP Member Relations and Government Affairs

The NABP Member Relations and Government Affairs department is responsible for working to understand and meet the unique needs of each member board of pharmacy. The department conducts regular outreach to member boards of pharmacy to stay in tune with the emerging issues in each state and ensure that the Association continues to provide resources that are of value to the membership. The department is a primary connection between the boards and NABP. The Member Relations and Government Affairs team members are the NABP subject matter experts for the boards, and also make sure that any issues with NABP programs are resolved quickly and proactively. The department also introduces new NABP programs to boards and tracks state legislation and trends. Current initiatives they are focused on include adoption of Food and Drug Administration memorandum of understanding, supply chain inspections, and working with states to leverage NABP's e-Profile system data-sharing capabilities.

Both teams work closely with one another, ensuring that individual board requests are met. For questions or more information, contact GovernmentAffairs@nabp.pharmacy. ●



WHOLESALE DRUG IMPORTATION UNDER THE SPOTLIGHT

as NABP, Member Boards Act to Ensure Patient Safety

For the first time in the modern history of pharmacy, the doors are opening for wholesale prescription drug importation at the federal level.

Although the Safe Importation Action Plan only allows for importation of some prescription drugs from Canada into the United States under specific circumstances and by certain entities, many stakeholders, including NABP, have serious reservations. Nevertheless, the Safe Importation Action Plan, released by the US Department of Health and Human Services (HHS) and Food and Drug Administration (FDA), went into effect in November 2020.

With this new law, when combined with a new wave of state legislative actions, it may only be a matter of time before importing prescription drugs from Canada or other countries into the US begins in multiple states. NABP remains concerned that this change may put drug supply chain security (and therefore patients) at risk due to the possible infiltration of substandard or counterfeit medications. Through the initiative of NABP President Caroline D. Juran, BSPharm, DPh (Hon), the Association is taking several steps to mitigate risk to the prescription drug supply chain and support state boards of pharmacy tasked with implementing safe importation plans, aiming to continue ensuring patient safety.

Shortly after the announcement that the Safe Importation Action Plan would become a final rule, NABP released a position statement to reiterate its long-standing concerns about how prescription drug importation programs may put patients at risk.

The Two Pathways

For at least two decades, prescription drug importation has been floated by politicians as a possible method of reducing consumer prices for prescription drugs. In 2003, Congress passed the Medicare Modernization Act, which contained a provision allowing certain drugs to be imported from Canada, but only if HHS deemed that importation could be done safely. Under Presidents George W. Bush and Barack Obama, HHS did not take this action. However, former HHS Secretary Alex Azar, who served under President Donald J. Trump, announced the final version of the Safe Importation Action Plan in September 2020.

In November 2020, the Safe Importation Action Plan went into effect. The rule outlines two pathways for legal prescription drug importation.

- **Pathway 1** provides states, wholesalers, pharmacists, and other nongovernmental groups with the ability to import specific drugs from Canada under Section 804 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).
- **Pathway 2** provides pharmaceutical manufacturers an opportunity to reimport prescription drugs destined for other countries under a new national drug code with requisite relabeling and testing to ensure pharmaco-equivalence.

Notably, other forms of prescription drug importation, including personal importation by individual patients, in most cases, remain illegal under the new rule. On its website, FDA states that the agency remains concerned that medications imported by individual patients are often not approved by the agency for use within the US.

It remains unclear whether President Joseph R. Biden, Jr, will move forward with the plan, but Biden is on record expressing support for the concept while running for office. Further, Xavier Becerra, HHS secretary under Biden, voted for the 2003 Canadian drug importation proposal as a member of Congress, which may indicate general support for prescription drug importation. Although legislation has been introduced to further expand drug importation, as of this writing, no final legislative or executive action has been taken on this issue in 2021.

In response to the finalization of the Safe Importation Action Plan, industry groups filed a lawsuit in the US District Court for the District of Columbia against HHS and FDA. The complaint alleges that the Safe Importation Action Plan disregards key protections of the FD&C Act and puts patient safety at risk.

States Are Passing Bills, Submitting Importation Plans for Approval

Several states have enacted laws that would establish importation programs for prescription drugs from Canada, including Colorado, Florida, Maine, New Hampshire, and New Mexico. However, for any of these importation plans to go into effect, the HHS secretary must certify that it meets the safety and cost-saving requirements set forth in Section 804 of the FD&C Act. Each law that has been enacted requires a proposal submitted to HHS, demonstrating how the program will meet those requirements. Thus far, HHS has not certified any of the submitted plans.

At least two states have passed laws that may allow imports of prescription drugs from additional countries. In Colorado, the state legislature passed an importation bill in 2019 that allows the state's Department of Health Care Policy and Financing (HCPF) to purchase drugs from Canada. In April 2021, Governor Jared Polis signed into law an expansion of the program that would allow HCPF to purchase drugs from additional countries.

A similar effort has also received legislative support in Florida. In November 2020, Governor Ron DeSantis signed a bill into law that would allow prescription drug importation and announced that the state had submitted its application to HHS for permission to run an importation program. In addition to permitting drug importation from Canada, Florida's law (CS/HB19) also leaves the door open for a second program to be created that would allow for drugs to be brought in from additional unspecified countries.

Other states have also attempted to implement some form of importation law over the last two decades. For example, Maine enacted a law in 2013 that would facilitate personal importation of prescription drugs for Maine residents utilizing a company called CanaRx. Citing concerns related to patient safety and contradictions with federal regulation, a lawsuit was filed by several stakeholders, including the Maine Pharmacy Association. A federal court ultimately found that the law was not supported by federal law because it had not received federal approval. Maine Governor Janet Mills signed a four-bill prescription drug reform package into law on June 24, 2019. Among the provisions in the legislation was LD 1272, which was modeled after a Vermont law. Vermont was the first state to enact a prescription drug importation law, but it has not yet submitted an application to HHS. LD 1272 includes language directing the state's health department to consider whether the program may be developed in conjunction in other states. The legislation also directed the department to submit the program to HHS, which it did on May 1, 2020.

In New Hampshire, a similar bill requiring the state to submit an importation plan to HHS for approval, Senate Bill (SB) 685, was signed into law by Governor Chris Sununu in July 2020. New Mexico's drug importation legislation, SB 1, was signed into law by Governor Michelle Lujan Grisham on March 4, 2020. A final version of the state's plan was submitted to HHS in December 2020.

NABP Position and Stakeholder Opposition

Shortly after the announcement that the Safe Importation Action Plan would become a final rule, NABP released a position statement to reiterate its long-standing concerns about how prescription drug importation programs may put patients at risk. The position statement noted that the lucrative counterfeit drug trade could more easily

compromise the US market due to vulnerabilities created in the supply chain by drug importation. "Specifically, each separate proposal effectively creates a new and distinct prescription drug supply chain that will require state regulatory oversight and monitoring, only with fewer protections," NABP stated. "This patchwork approach is a step away from the tightly regulated supply chain and safeguards currently in place to ensure the efficacy and safety of prescription medications."

As highlighted by the increase in fraudulent behaviors during the coronavirus disease 2019 pandemic, rogue online drug sellers are opportunistic in nature, and are likely to take advantage of and prey on vulnerable patients as a result of policy changes.

Many other stakeholders have also expressed concerns related to drug importation policies. Notably, the American Pharmacists Association and the Canadian Pharmacists Association issued a joint statement in early 2019; the statement acknowledged the issue of prescription drug prices in the US, but opposed prescription drug importation due to the risks to patient safety and continuity of care. The statement also expressed concern about worsening patient access issues in Canada by creating or worsening drug shortages.

Despite concerns from NABP and other stakeholders, the concept of prescription drug importation is growing in popularity among consumers regardless of political affiliation. A 2019 Kaiser Health Tracking Poll found that approximately 80% of respondents were in favor of allowing Americans to buy prescription drugs imported from Canada. The level of support remained stable among respondents identifying as Democrats, Republicans, and Independents. The overall figure represents an 8% increase from the results of a similar poll conducted by Kaiser in 2017.

Taking Action to Support and Inform the Boards of Pharmacy

NABP has recognized that prescription drug importation may soon become a reality in the US. As such, NABP is taking steps to help states keep the supply chain secure while ensuring that patients can get safe access to the medications they need. NABP and its member boards have decades of experience with drug distributor accreditations and inspections, and the Association brings that expertise to the table when considering the future of drug importation.

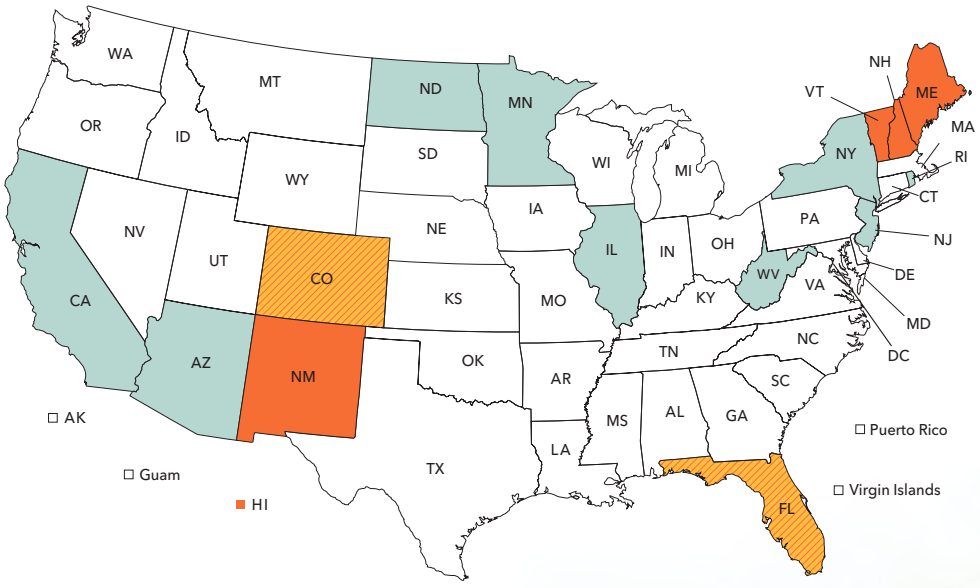
At the 117th NABP Annual Meeting, Juran announced that her presidential initiative during her 2021-2022 term would focus on drug importation. Specifically, Juran announced that NABP would work to provide guidance to states, the federal government, and boards of pharmacy in developing and navigating a regulatory oversight process that will help mitigate risks in the global supply chain and ensure the safety and integrity of imported prescription medications.

Juran's initiative has several areas of focus, including:

- providing guidance to state and federal governments and other policymakers on the risks associated with prescription drug importation and the necessary regulatory oversight process to help mitigate those risks;
- working with state and federal regulators to implement the Drug Supply Chain Security Act, including providing education and other tools to regulators and supply chain participants to assist in implementation; and
- educating the public about the risks associated with purchasing prescription drugs from unknown sources online and through social media.

Juran also committed to emphasizing the responsibility of the boards of pharmacy and the states in overseeing the distribution and dispensing of safe, quality drugs for optimal patient care. NABP intends to develop tools and programming to assist member boards of pharmacy in navigating this challenging issue.

NABP has long been at the forefront of discussions about prescription drug importation and the related complications. NABP will continue to prioritize this issue as state and federal laws and regulations take shape. ●



States with laws that allow Canadian drug importation

States with active legislation to create a Canadian drug importation program

States with laws that allow importation of prescription drugs from Canada and other countries

Task Force on Medication Reuse Recommends Amending Select *Model Act* Sections Pertaining to Prescription Drugs

During the Task Force on Medication Reuse meeting, members reviewed current state laws and regulations related to the reuse of medications as well as existing sections of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) pertaining to the return and reuse of medications and to repository programs.

Task force members noted that a vast number of medications, many of which are expensive, are discarded every year and addressed the question of whether medications could be reused and, if so, how to best accomplish this in the interest of patient care and public protection. Task force members concurred that there is a very delicate balance between deciding if a patient in need of a possibly lifesaving medication should receive a previously dispensed product, realizing that it is impossible to guarantee the product's integrity, versus the patient not receiving it at all.

In attempting to develop minimum standards, the task force agreed that such standards must incorporate the pharmacist's professional judgment when determining a medication's integrity and whether it is appropriate for reuse. Furthermore, members recognized that, if a medication has been determined to be unadulterated based on a pharmacist's professional judgment, it could be obtained from any practice setting.

While discussing fraud prevention, the task force determined that any charges to third-party payers should be reversed prior to reuse of a medication and that donated drugs must not be allowed to reenter the commercial supply chain.

Lastly, the task force agreed that patients who receive medications from a repository program should be fully informed that their medications had been previously dispensed and acknowledge that they have been provided with the repository program's qualifications for acceptable medications for reuse.

The Committee on Law Enforcement/Legislation, however, removed the acknowledgment requirement and instead required patient notification that the medication is being dispensed by a repository program.

After careful review and deliberation, the task force recommended that NABP retain the current *Model Act* definition of "repository program." It also recommended that the Association amend Section 10. Return and Reuse of Prescription Drugs by removing language pertaining to delivery attempts.

The Task Force on Medication Reuse was established in response to Resolution 116-4-20, which was approved by the NABP membership during the Association's 116th Annual Meeting, held virtually in May 2020. Task force members included:

- **Brenda McCrady, PD (chair)**
- **Mike Bertagnolli, MBA, RPh, FACHE**
- **N. Katie Busroe, RPh, BCSCP**
- **Kim Caldwell, RPh**
- **Traci Collier, PharmD, RPh**
- **Donna M. Horn, MS, RPh, DPh, CHC**
- **John Marraffa, Jr, RPh**
- **Dennis McAllister, RPh, FASHP**
- **Rich Palombo, RPh, DPh**
- **Ed Taglieri, MSM, RPh, NHA**
- **Cynthia "Cindy" Warriner, RPh, CDE**
- **Linda Witzal, RPh**
- **Fred M. Weaver, RPh, Executive Committee liaison**

The task force report was approved by the Executive Committee during its October 2020 virtual meeting and is available in the Reports section at *www.nabp.pharmacy/resources.* ●

Task Force Charge

1. Review current state laws and regulations related to the reuse of medications
2. Review existing NABP policy on the reuse of medications
3. Recommend the best mechanisms to enable the transfer of unused medications to persons in need of financial assistance to ensure access to lifesaving therapies

Task Force on Pharmacy Technician Practice Responsibilities Recommends Amendments to Related *Model Act* Language

During the Task Force on Pharmacy Technician Practice Responsibilities meeting, members evaluated the current status of pharmacy technician practice responsibilities, including state laws and rules addressing pharmacy technician practice.

The task force meeting began by having invited guests representing the Accrediting Bureau of Health Education Schools (ABHES), Accreditation Council for Pharmacy Education (ACPE), American Society of Health-System Pharmacists (ASHP), National Healthcareer Association (NHA), and Pharmacy Technician Certification Board (PTCB) provide information on their organizations' focus regarding pharmacy technician scope of practice. Discussion ensued as to the various accredited specialty training programs and certifications that pharmacy technicians can earn to create a career ladder approach to obtaining site-specific knowledge and skills that ultimately allow them to expand their scope of practice responsibilities. Task force members recognized that, while boards of pharmacy might not necessarily require these advanced certification programs, it is analogous to a pharmacist earning additional professional credentials that are not required by a board of pharmacy.

The task force agreed that advanced training should be market-driven and depend primarily on employers to determine site-specific applicability. Members also concurred that, while uniformity across the country would be the ideal, boards of pharmacy should not necessarily require advanced training for technicians, mainly because states may have different interpretations of the term "advanced level certified pharmacy technician," especially within different practice settings. Task force members agreed that these individuals should be allowed to perform any duty that is delegated by a pharmacist, provided they are adequately trained, and it does not encompass any duties that require clinical decision making.

Ultimately, the task force decided that boards should refrain from being prescriptive in listing permitted duties and instead focus on a standard of care model that is based on an individual's training and competence as determined by the supervising pharmacist and not dictated by any type of corporate policy or rubric. Pharmacy technician training and experience should fit the assigned duties, and the supervising pharmacist should be responsible for not delegating duties beyond the pharmacy technician's capabilities.

In reviewing the "advanced level certified pharmacy technician" definition that had been recommended by the Task Force on Requirements for Pharmacy Technician Education and subsequently revised by the 2019-2020 Committee on Law Enforcement/ Legislation, the task force stressed that, regardless of designation, all pharmacy technicians require some level of supervision.

Task Force Charge

1. Evaluate the current environment of pharmacy technician practice responsibilities, including state laws and rules addressing pharmacy technician practice
2. Examine the language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing pharmacy technician practice and, if necessary, recommend amendments that allow technicians to practice in the best interest of patient care

NABP Creates New Committee to Review *Model Act*

NABP has created a new committee to help ensure that the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* reflects the most current regulatory environment. The *Model Act*, which provides the boards of pharmacy with model language that may be used when developing state laws or board rules, is updated annually based on member input from resolutions; task forces; Executive Committee recommendations; and newly enacted or amended federal laws, regulations, and guidance. Beginning in 2021, the *Model Act* Review Committee will conduct a thorough review of the document every five years to ensure that relevant and accurate updates are made to dates, footnotes, references to federal laws and regulations and standard setting organizations, and overall language. The eight-person committee, appointed by the NABP president, will consist of board of pharmacy executive directors and board members who possess a deep understanding of federal and state laws, regulations, and guidance, as well as standard setting organizations.

The first *Model Act* Review Committee will convene remotely during the third quarter of 2021. Committee members will be provided with a copy of the *Model Act* to review over a four-week period, and the results will be compiled and provided to the Committee on Law Enforcement/Legislation, which meets every January. As with all task forces and committees, NABP staff will compile the recommendations and provide the committee with a report. Once finalized, the report will be presented to the Executive Committee for its review and approval.

NABP President Caroline D. Juran, BSPharm, DPh (Hon), selected volunteers to serve on this committee in June. The current *Model Act* can be found in the Members section of the NABP website under Board Resources.

Task force members agreed that the language be kept broad in order for the individual boards to determine the level and type of supervision. They also agreed that supervision should be required for tasks such as stocking and/or restocking automated dispensing machines and that current language pertaining to those types of tasks should be maintained. Members noted that the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* (*Model Act*) should be used as a framework for the boards to refer to when promulgating rules.

However, the Committee on Law Enforcement/Legislation did not support creating a new pharmacy technician category due to the increased regulatory and administrative burden that may be placed on the boards and struck the definition.

After careful review and deliberation, the task force recommended that NABP retain the *Model Act* definitions and requirements currently in place for "Certified Pharmacy Technician" and "Certified Pharmacy Technician Candidate."

The Task Force on Pharmacy Technician Practice Responsibilities was established in response to Resolution 115-4-19, which was approved by the NABP membership during the Association's 115th Annual Meeting in May 2019. Task force members included:

- **Andrew Funk, PharmD, RPh (chair)**
- **Allison Vordenbaumen Benz, MS, RPh**
- **Robert Carpenter, RPh**
- **John Colaizzi, Jr, PharmD, RPh, CCP**
- **Laura Forbes, RPh**
- **Jillian Foster, MBA, PharmD, RPh, FACHE, FASHP**
- **Richard Geaney, RPh**
- **Debra B. Glass, RPh**
- **Lori Henke, PharmD, RPh**
- **Allison Hill, PharmD, RPh**
- **Sue Mears, RPh**
- **Joanne Trifone, RPh**
- **Cyndi Vipperman, CPhT**
- **Tejal J. Patel, MBA, PharmD, RPh, Executive Committee liaison**

Invited guests for the task force included:

- **Ryan Burke, PharmD, director of professional affairs, PTCB**
- **Jean Chappell, EdD, MT(ASCP)C, director of program review and development, ABHES**
- **Jan Engle, PharmD, PhD (Hon), FAPhA, FCCP, FNAP, executive director, ACPE**
- **Zachary Green, CPhT, associate director of partnership development, PTCB**
- **Jessica Langley, MS, executive director of education and provider markets, NHA**
- **Janet Silvester, MBA, PharmD, FASHP, vice president of accreditation services, ASHP**

The task force report was approved by the Executive Committee during its December 2020 virtual meeting and is available in the Reports section at *www.nabp.pharmacy*.

NABP Verifies Education of New Graduates Prior to Their Exam Administrations

New Requirement Aims to Increase Security, Offers Option to Streamline Board Processes

NABP has implemented a new transcript requirement for school and college of pharmacy graduates who are qualified to sit for the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®). Specifically, candidates graduating in 2020 or later are now required to submit transcripts to NABP for verification before they can purchase an exam.

This policy change has been implemented to increase examination security and further ensures that only qualified candidates may sit for licensing examinations.

Official transcripts must be sent to NABP by the school or college of pharmacy to meet the requirement. Transcripts must also include the dates the degree was awarded and conferred. NABP uses the confer date rather than the graduation date because the confer date signifies that all requirements have been met and the degree has been officially recognized.

Schools and colleges have several methods to provide transcripts to NABP, including via a bulk upload to NABP e-Profile Connect. Schools and colleges, as well as the boards of pharmacy, are able to access student transcripts in NABP e-Profile Connect. Students are able to check their Education Verified status in their e-Profiles.

The new transcript requirement is not expected to delay candidate examination scheduling. In fact, NABP's research on candidates taking exams in states with different transcript requirements indicates that candidates who apply within 30 days of their confer date will experience no difference in the number of days from the date their degree is conferred to the date they sit for their exam(s). Specifically, research shows that more than 70% of all students were able to test within 60 days of their confer date, and over 90% tested within 90 days of their confer date.

This new requirement offers the option to help boards of pharmacy streamline their eligibility processes, if desired. Instead of requiring that students also submit an official transcript to the board with their license application, boards may use NABP e-Profile Connect to access student transcripts.

Additional information on all NAPLEX and MPJE requirements is available in the *NAPLEX/MPJE Candidate Application Bulletin* and the Examinations section of the NABP website. Candidates, boards of pharmacy, and schools and colleges of pharmacy can contact NABP if they have further questions regarding the new transcript requirements. ●

Benefits of Policy Change for Boards of Pharmacy

- ☑ Increases examination security
- ☑ Ensures that only qualified candidates may sit for NAPLEX and MPJE
- ☑ Enables boards to access student transcripts via NABP e-Profile Connect, thus having the potential to streamline board of pharmacy exam eligibility processes

NABP Announces 2021-2022 ACE Appointments

NABP is pleased to announce the roster of individuals appointed to serve on the 2021-2022 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations. ACE oversees the development and administration of all the Association's examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically convenes twice per year. The committee consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers or individuals who have served within the last five years as a member or administrative officer of an active board of pharmacy. There are three ex officio members, one representing each of the examination or assessment programs. These members are currently members of the committees overseeing the program they represent. Members serve three-year terms and ex officio members serve one-year terms. The following members began their terms on June 1, 2021. Tejal J. Patel, MBA, PharmD, RPh, NABP Executive Committee member, is serving as the Executive Committee liaison.

Michael A. Burleson, RPh
Kentucky

Mark C. Decerbo, PharmD, RPh, BCNSP, BCPS
Nevada

Maria Marzella Mantione, PharmD, RPh, BCGP, FAPhA
New York

Edward G. McGinley, MBA, RPh, DPh
New Jersey

Anne Sodergren
California

Theresa M. Talbott, RPh
Pennsylvania

Kim Tanzer, PharmD, RPh
Texas

Kimberly A. "Kim" Burns, JD, RPh
Pennsylvania (ex officio member, Foreign Pharmacy Graduate Equivalency Examination®/Pharmacy Curriculum Outcomes Assessment®)

N. Katie Busroe, RPh, BCSCP
Kentucky (ex officio member, Multistate Pharmacy Jurisprudence Examination®)

Eric F. Schneider, PharmD
North Carolina (ex officio member, North American Pharmacist Licensure Examination®)

**Color denotes new member*

Help Ensure That Your State's MPJE Is Up to Date: Volunteer to Participate in the Remote MPJE State-Specific Review

The annual Multistate Pharmacy Jurisprudence Examination® (MPJE®) State-Specific Review and new item selection will take place August 9-September 10, 2021. State board participation is critical to ensure that the MPJE maintains the highest validity standards with the most up-to-date and defensible items. NABP requests that all MPJE-participating jurisdictions schedule resources and time to complete this important set of tasks.

Remote Review

Boards will participate remotely. The item pools will be available on a password-protected, secure website. NABP encourages your designated remote reviewers to schedule specific days and times to complete the review, just as if they were traveling to NABP Headquarters.

NABP will send complete details to the designated remote reviewers in August. All participants must sign conflict of interest and confidentiality agreements prior to participating. Contact CompAssess@nabp.pharmacy for a copy of the agreements.

During the MPJE State-Specific Review, the responsibility of each board is to:

- select new items to be pre-tested, which may become scored items in the future
- review their current operational item pool to confirm it is still valid.

New federal- and state-specific items to test the pharmacy jurisprudence knowledge of candidates seeking licensure were developed by board of pharmacy-designated item writers during the virtual MPJE Item Development Workshop held March 1-26, 2021.

The MPJE State-Specific Review provides each participating board the opportunity to ensure that items are appropriate for their state or jurisdiction. NABP is also available to work with boards throughout the year to identify any items that may be affected by statute or rule changes.

Please contact NABP any time there are regulation changes that may affect MPJE items.

Currently, 48 boards utilize the MPJE and are asked to review their item pools at least once per year in a State-Specific Review meeting to determine the appropriateness of items in the MPJE for candidates seeking licensure. ●

NABP Seeks Representative for ACPE Board of Directors

NABP is currently accepting letters of interest and curricula vitae (CVs) from individuals interested in serving as one of the Association's three representatives on the Accreditation Council for Pharmacy Education (ACPE) Board of Directors.

Interested board of pharmacy members, executive officers, or individuals who have served within the last five years as members or executive officers of an active board of pharmacy are encouraged to submit a current CV and a letter of interest to NABP Executive Director/Secretary Lemrey "Al" Carter at NABP Headquarters or ExecOffice@nabp.pharmacy by August 2, 2021. Appointees must be available to attend two to three ACPE Board meetings per year that require extensive preparatory reading, three to four school or college of pharmacy on-site visits, occasional virtual Board meetings, and an in-person orientation program to be held prior to and during the Board meetings in January and June 2022. The term will officially begin on July 1, 2022. Letters should be a short narrative, no longer than one page, highlighting relevant experiences and talents that qualify candidates for service, their views on educational and accreditation issues facing the ACPE Board of Directors, why they wish to serve, and what they would contribute as an appointee of NABP.

On June 30 of every even-numbered year, the term of one NABP representative expires. A subcommittee of the NABP Executive Committee will present a recommendation for the appointee to the full Executive Committee at its August 2021 meeting for final approval.

For more information, please contact NABP Executive Office at ExecOffice@nabp.pharmacy. ●

NABP Clearinghouse Records Over 1,000 Disciplinary Actions in First Quarter 2021

The Association's data results for the first quarter of 2021 showed that a total of 1,041 disciplinary records were submitted to the NABP Clearinghouse by state boards of pharmacy on 877 individual and business e-Profiles.

A full breakdown of the actions and bases for actions taken on individuals and the actions and bases for actions taken on businesses during the 2021 first quarter is in the tables below.

Of the 1,041 actions reported in the first quarter of 2021:

- 464 (45%) were on pharmacists;
- 286 (27%) were on pharmacy technicians;
- 209 (20%) were on pharmacies;
- 28 (3%) were on wholesalers, manufacturers, and distributors;
- 20 (1.9%) were on other individuals;
- 14 (1.3%) were on pharmacy interns;
- 11 (1.1%) were on other licensees;
- 5 (0.5%) were on controlled substance licenses; and
- 4 (0.4%) were on Food and Drug Administration registrants.

First Quarter 2021 Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Publicly Available Fine/ Monetary Penalty	240	24.6%	Suspension of License/ Certificate	65	6.7%
Other Licensure Actions Not Classified	124	12.7%	Summary or Emergency Action, Limitation, Suspension, or Restriction on License	48	4.9%
Revocation of License/ Certificate	121	12.4%	Denial of Initial License or Renewal License/Certificate	30	3.1%
Probation of License	108	11.1%			
License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	72	7.4%	Reduction, Modification, or Extension of Previous Licensure Action	21	2.2%
Voluntary Surrender of License/Certificate	67	6.9%	Limitation or Restriction on License	12	1.2%
Reprimand or Censure	66	6.8%	Miscellaneous	2	0.2%
			TOTAL	**976**	

First Quarter 2021 Bases for Action Code Categories INDIVIDUALS

	COUNT	%		COUNT	%
Noncompliance With Requirements	364	39.7%	Fraud, Deception, or Misrepresentation	68	7.4%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	266	29.0%	Confidentiality, Consent, or Disclosure Violations	6	0.7%
Other	95	10.3%	Unsafe Practice or Substandard Care	51	5.6%
Criminal Conviction or Adjudication	47	5.1%	Misconduct or Abuse	21	2.3%
			TOTAL	**918**	

First Quarter 2021 Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Revocation of License/ Certificate	11	3.7%	Monitoring, Closure, or Other Operational Business Modification	2	0.7%
Suspension of License/ Certificate	2	0.7%	Publicly Available Fine/ Monetary Penalty	197	66.8%
Reprimand or Censure	34	11.5%	Other Licensure Actions Not Classified	16	5.4%
Voluntary Surrender of License/Certificate	1	0.3%	License/Certificate Restored or Reinstated, Complete, Conditional, Partial, or Denied	10	3.4%
Probation of License	19	6.4%	Reduction, Modification, or Extension of Previous Licensure Action	2	0.7%
Denial of Initial License or Renewal License/Certificate	1	0.3%			
			TOTAL	**295**	

First Quarter 2021 Bases for Action Code Categories BUSINESSES

	COUNT	%		COUNT	%
Noncompliance With Requirements	236	75.4%	Fraud, Deception, or Misrepresentation	8	2.6%
Improper Prescribing, Dispensing, Administering Medication/Drug Violation	27	8.6%	Confidentiality, Consent, or Disclosure Violation	4	1.3%
Improper Supervision or Allowing Unlicensed Practice	22	7.0%	Substandard Care or Patient Neglect/Abuse	4	1.3%
Other	10	3.2%	Criminal Conviction or Adjudication	2	0.6%
			TOTAL	**313**	

NABP PMP InterConnect Celebrates 10th Anniversary

NABP PMP InterConnect® is celebrating its 10th anniversary this year. Developed in 2011 by the Association in partnership with Appriss Health, the system facilitates free interstate sharing of state prescription drug monitoring program (PDMP) data to help combat the opioid epidemic and subsequent overdose deaths nationwide.

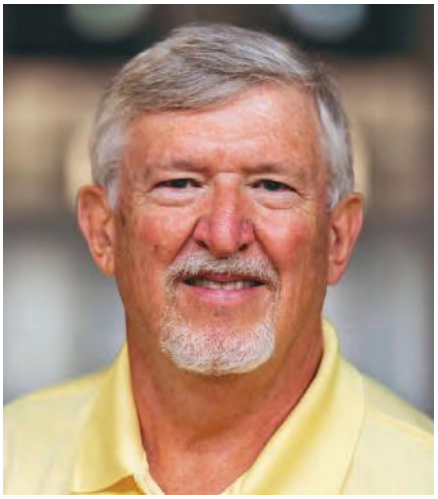
Before PMP InterConnect was established, data sharing between state prescription monitoring programs (PMPs) was virtually impossible. Physicians and pharmacists did not have an easy or reliable way to access full controlled substance patient histories prior to making prescribing or dispensing decisions.

"PMP InterConnect was a game-changing tool for states, physicians, pharmacists, and other authorized healthcare providers to address the opioid epidemic. The transparency into patients' full controlled-substance histories, including across state lines, enabled providers to better spot signs of substance use disorder," said Rob Cohen, president of Appriss Health. "Adoption by many state PDMPs was immediate and the impact on substance misuse was measurably profound. Appriss is proud of its decade of success partnering with NABP and states to combat the opioid crisis."

Provided at no cost to states, PMP InterConnect currently supports 52 of 54 PDMPs in the United States and its territories, and the technology processes more than 400 million interstate transactions each month. A newly modernized user interface and experience now support users accessing the PMP InterConnect web portal, reflecting continuous improvements to functionality based on customer feedback from the PMP InterConnect Steering Committee, which is comprised of PDMP administrators from the 52 participating PDMPs.

"PMP InterConnect is a shining example of a public-private partnership that has advanced the way PDMP data can be shared across state lines and clinically integrated into the workflow of prescribers and pharmacists across the country," said Lemrey "Al" Carter, PharmD, MS, RPh, executive director/secretary of NABP. "We are proud of what we have built with the state PDMPs and Appriss Health, but our work isn't done. In support of our mission to protect public health, NABP is committed to working with the state PDMPs to grow and enhance PMP InterConnect to ensure it remains a valuable and vital platform for our nation's network of PDMPs."

Appriss Health, a leading SaaS platform for behavioral health care coordination and a recognized leader in providing software and data analytics solutions to identify and mitigate substance use disorders, has managed PMP InterConnect since its launch and has continued to work with NABP to advance new PDMP solutions. In 2014, Appriss Health launched PMP Gateway, which integrates real-time PDMP data flowing across the nation via PMP InterConnect directly into physicians' and pharmacists' electronic workflows. Currently, PMP Gateway supports 43 out of 54 PDMPs and delivers PDMP information to more than one out of three US prescribers, adding 110 new facility integrations, on average, every day as of publication. Since 2019, the number of active PMP Gateway physicians and pharmacists has almost doubled to 970,000 users today. ●



West Virginia Board of Pharmacy

Number of Board Members
5 pharmacist members and 2 public members

Number of Compliance Officers/Inspectors
4

Rules & Regulations Established by
Board of Pharmacy and approved by the General Assembly

Number of Pharmacist Licensees
5,522

Number of Pharmacies
655 (includes home infusion and mail-order pharmacies)

Number of Wholesale Distributors
715

David G. Bowyer, RPh, FASHP

Member, West Virginia Board of Pharmacy

When were you appointed to the Board of Pharmacy?

I was appointed to the Board in July 2017. I am a pharmacist member.

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

First, you have to be well prepared. A lot of reading and preparation go into making a board meeting run smoothly. You have to sort through a lot of data in order to make an informed decision. You cannot just show up at a board meeting and expect to know everything. You have to do your homework. Second, you have to develop a good working relationship with the board staff and be able to understand how the policies that you develop as a board member and a board are going to impact the day-to-day operations of the board office.

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

Like other boards, the Board of Pharmacy is working on coronavirus disease 2019 (COVID-19) policies. The Board has adapted to changes in federal legislation as a result of COVID-19. For example, the Public Readiness and Emergency Preparedness Act allows pharmacists to vaccinate children as young as age three. Our state regulations allow pharmacists to immunize children ages 11 and up, so we had to ask for emergency rulemaking to authorize state law to follow the federal legislation. Last year, the West Virginia Legislature also passed laws that allow pharmacists to dispense tobacco cessation products and self-administered hormonal contraceptives pursuant to a standing order. Now, we are looking at the rules, so we can operationalize them for pharmacists. During the 2021 legislative session, we hoped to update our Collaborative Pharmacy Practice Act. The process that a pharmacist has to go through to get a collaborative practice agreement is very cumbersome. For example, it has to be reviewed by two boards (Pharmacy and Medicine or Osteopathic Medicine). We are trying to streamline that process and remove some of the barriers that pharmacists encounter.

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

Developing the rules to implement new laws regarding tobacco cessation and contraceptives has been challenging. There are very few states that have such rules in place, so it is all new territory for the Board. Our Board staff has done a really great job of researching what other states have done, working with NABP to get that information, and providing us with a good plan for implementing these rule changes.

What advice would you give to a new board member?

You have to understand that your primary responsibility is to the public. This has to drive every decision that you make. It is the board's responsibility to uphold the tenets of the profession of pharmacy. As a board member, you are the bottom line. On the other hand, you have to be responsive to the concerns of the pharmacist. For example, workload is a huge issue in the pharmacy profession right now. You want to make sure that any policy that you implement does not have unintended consequences in the pharmacy.

What are the benefits of participating in NABP activities?

I have attended Annual Meetings, Districts 1 & 2 meetings, and the 2020 Interactive Member Forum. I was elected to represent District 2 on the Committee on Resolutions last September, so I will be involved with that this year. I am also an alternate on the Committee on Constitution and Bylaws.

The benefits of attending NABP meetings are numerous. Hearing what is happening in other states is critical because problems that we have in West Virginia are not unique to West Virginia. Understanding the problems other states face and the steps they have taken to overcome them will help us – if, and when, those problems arise in our state. ●

Board Member Appointments

- **Jeffrey Huston, PharmD, RPh,** has been appointed a member of the State of Ohio Board of Pharmacy. Huston's appointment will expire June 30, 2024.
- **Jane Alcorn, PhD,** has been appointed a member of the Saskatchewan College of Pharmacy Professionals. Alcorn serves at the discretion of the governing Council.
- **Lyndsay Brakstad** has been appointed a pharmacy technician observer of the Saskatchewan College of Pharmacy Professionals. Brakstad serves at the discretion of the governing Council.
- **Bonnie Caven** has been appointed a public member of the Saskatchewan College of Pharmacy Professionals. Caven's appointment will expire June 30, 2023.
- **Michael Lummerding** has been appointed a public member of the Saskatchewan College of Pharmacy Professionals. Lummerding's appointment will expire June 30, 2022.
- **Michelle Miller** has been appointed a pharmacy technician observer of the Saskatchewan College of Pharmacy Professionals. Miller serves at the discretion of the governing Council.
- **Yvonne Shevchuk, PharmD,** has been appointed a member of the Saskatchewan College of Pharmacy Professionals. Shevchuk serves at the discretion of the governing Council. ●

NABP Accreditations and Verifications

NABP awarded a total of 94 accreditations and verifications from January 1 to March 31, 2021. The breakdown by program is as follows:

Drug Distributor Accreditation: 47	**DMEPOS Pharmacy Accreditation:** 9	**Digital Pharmacy Accreditation:** 7	**Compounding Pharmacy Accreditation:** 2
Home Infusion Therapy Pharmacy Accreditation: 1	**Specialty Pharmacy Accreditation:** 1	**.Pharmacy Verified Websites:** 27	

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

California Implements New Prescription Form Rules, CS Reporting Requirements

California state law is now requiring 15 features to appear on security prescription forms. The prescription forms must also be printed, produced, and licensed by the California Department of Justice's California Security Prescription Printers Program. Pharmacists will not be able to fill a controlled substance (CS) prescription that is not on a compliant form.

In addition, the dispensing of a CS must be reported to the Controlled Substance Utilization Review and Evaluation System (CURES) as soon as possible. The previous deadline to report CS to CURES was seven days after dispensing.

Both rule changes went into effect on January 1, 2021. More information, including the 15 features that must appear on the prescription forms, is available in the Board's March 2021 edition of *The Script,* which can be accessed at *www.pharmacy.ca.gov/publications/21_mar_script.pdf.*

Idaho Proposed Rule Changes to Remove Immunization Restrictions

The Idaho State Board of Pharmacy has proposed substantive changes to the Idaho Code in the Pharmacy Practice Act related to immunizations. Specifically, the proposed changes will update the practice of pharmacy definition to remove the age restriction on patients receiving immunizations from a pharmacist. It also removes restrictions on pharmacists providing compounded and biologic products for patients.

The changes seek to make permanent the restrictions and prohibitions waived during the coronavirus disease 2019 pandemic, to allow for continued safe access to pharmacist services. The Board notes that when many other providers' offices closed, pharmacies served as an important safe point of access for childhood immunizations and over-the-counter compounded drugs such as hand sanitizer.

The proposed rule change is anticipated to go into effect on July 1, 2021.

Iowa Adopts New Drug Utilization Rules

The Iowa Board of Pharmacy has recently adopted rule changes to clarify that the information needed for a pharmacist to conduct a complete drug utilization review must be collected, and that the pharmacist can delegate collection of the required information to a technician or intern. The rules also require that a prescription submitted electronically must include a phone number at which the prescriber can be contacted to resolve prescription-related issues. The CS rules were amended to clarify that a registrant's perpetual inventory log must always accurately reflect the actual on-hand inventory of those substances. The rule change went into effect on February 2, 2021. More information is available in the Board's March 2021 *Newsletter.*

Kansas Adopts New Electronic Prescribing Requirements

Effective July 1, 2021, Kansas will require every prescription order issued for a Schedule II-V CS that contains an opiate to be transmitted electronically. The Kansas State Board of Pharmacy was tasked with issuing waivers to prescribers who qualify for one or more of the exceptions outlined in Kansas Statutes Annotated (K.S.A.) 65-16, 128 and providing a verification method for pharmacists. The Board recently launched a web page dedicated to this topic.

- Prescribers can submit a request for a waiver at any time and can later apply for six-month extensions.
- Pharmacists may (but are not required to) verify a prescriber waiver using the list generated by the Board and posted on the website. The list contains the prescriber's name, license number, effective date, expiration date, and practice location for the waiver issued.

If a prescriber prescribes a CS by nonelectronic prescription, the prescriber must indicate the prescription is made pursuant to a Board waiver. The pharmacist/pharmacy is not required to verify the validity of any waiver, either with the prescriber or the Board, but may do so in accordance with K.S.A. 65-1637. More information is available in the Board's March 2021 *Newsletter.* ●

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.

NABP Urges Passage of the Mainstreaming Addiction Treatment Act by 117th Congress

NABP continues its call for the passage of the Mainstreaming Addiction Treatment Act to remove barriers that prevent those with opioid use disorder (OUD) from accessing vital, lifesaving addiction treatment. This bipartisan bill was introduced by Representatives Paul Tonko (D-NY), Michael Turner (R-OH), Antonio Delgado (D-NY), and Anthony Gonzalez (R-OH), and Senators Maggie Hassan (D-NH) and Lisa Murkowski (R-AK). The legislation ends outdated limits imposed through the so-called "X waiver" that have restricted health care providers from prescribing buprenorphine, a safe and proven treatment for OUD. The full news release can be found in the News section of the NABP website.

DEA Rolls Out New Initiative to Help Reduce Drug Misuse, Overdose Deaths

Drug Enforcement Administration (DEA) launched a new comprehensive law enforcement and drug prevention initiative aimed at reducing drug misuse and overdose deaths. The initiative, Operation Engage, builds on and replaces DEA's 360 Strategy, which strictly focused on reducing opioid abuse. Operation Engage will have the resources to target drugs that are presenting the greatest threats to the public health and safety in local communities. There are 11 field divisions that will target Operation Engage efforts; each will have a designated city or region and identify its most challenging drugs or trends within the community. More information on the new initiative can be found on DEA's website at *www.dea.gov/operation-engage.*

Propylhexedrine Abuse Can Cause Serious Harm, Warns FDA

Food and Drug Administration (FDA) has issued a warning on abuse and misuse of the over-the-counter (OTC) nasal decongestant propylhexedrine. OTC nasal decongestant propylhexedrine can cause serious harm, leading to heart and/or mental health problems. Other serious complications include high blood pressure, abnormal heartbeat, hospitalization, and death. FDA stated that propylhexedrine is safe and effective when it is used as directed. However, FDA is requesting all manufacturers of OTC propylhexedrine nasal decongestant inhalers to consider product design changes that support its safe use. The product could be modified with a physical barrier that would make tampering with the device and abuse more difficult. The full news release can be found by visiting *https://content.govdelivery.com/accounts/USFDA/bulletins/2c9781c.*

NABP Reaffirms Support for COVID-19 Vaccines

NABP proudly announces its continued confidence in the safety of the coronavirus disease 2019 (COVID-19) vaccines approved for emergency use authorization by FDA. "We can have greater control over the spread of this virus by getting vaccinated and encouraging patients to get vaccinated," said NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh. "Wearing masks, social distancing, and washing hands can be effective, but the vaccines have shown to be an important next step to gaining control of the virus." The full news release can be found in the News section of the NABP website.

Energy and Commerce Committee Refers to NABP's Concerns During Hearing on Big Tech Platforms

The House Committee on Energy and Commerce held a hearing on March 25, 2021, to work on policies ensuring that Big Tech platforms are transparent and accountable. NABP had the opportunity to submit written comments, which were cited by Republican Leader for Communications and Technology Subcommittee Bob Latta (R-OH) during the hearing. In its letter, NABP requested that the committee examine the growing issue of dangerous and illicit drugs sold via online platforms. The full letter can be found by visiting *nabp.pharmacy/wp-content/uploads/2021/03/NABP-Big-Tech-Platforms-House-Committee-Letter.pdf.*

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UPCOMING EVENTS

NABP/AACP District 5 Meeting
August 6, 2021 | Virtual Meeting

NABP/AACP Districts 6, 7, and 8 Meeting
August 29-31, 2021 | Carefree, AZ

NABP/AACP Districts 1 and 2 Meeting
September 7-10, 2021 | Annapolis, MD

NABP Interactive Executive Officer Forum
September 28-29, 2021 | Northbrook, IL

NABP/AACP District 3 Meeting
October 3-6, 2021 | Hilton Head Island, SC

NABP/AACP District 4 Meeting
October 20-22, 2021 | Columbus, OH

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