

# INNOVATIONS®



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## Fentanyl Supply Increase Brings '*Third Wave*' to Evolving Opioid Epidemic







# INNOVATIONS®

## table of contents

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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.

**4 Policy Perspectives**  
SUPPORT Act: One Year Later

**13 Association News**  
2019-2020 NABP Committee and Task Force Members Appointed by President Campbell

**17 NABP Launches Pre-MPJE;**  
Statistics Show Correlation Between Pass Rates and Pre-Exams

**20 Interview With a Board Member**  
Matthew D. Balla, RPh

**22 State Board News**  
Minnesota Updates Rules for Emergency Prescription Refills

**23 Professional Affairs Update**  
HHS and FDA Publish New Action Plan for Importation of Certain Prescription Drugs



### Feature News

Fentanyl Supply Increase Brings 'Third Wave' to Evolving Opioid Epidemic

### Pharmacy Practice Analysis Survey Coming Soon

NABP would like to remind all pharmacists that the Pharmacy Practice Analysis Survey will be available in October 2019. Pharmacists in all areas of practice are encouraged to participate in the Pharmacy Practice Analysis Survey. Analysis of the survey results will be used to validate the North American Pharmacist Licensure Examination® competency statements.

More information about the survey is available in the May 2019 issue of *Innovations*. ■

# Interview With a Board Inspector



**Yashwant Amin, PhD, RPh,  
Director of Drug Compliance,  
Illinois State Board of Pharmacy**

## **Yashwant Amin, PhD, RPh, Director of Drug Compliance, Illinois State Board of Pharmacy**

**How long have you been serving as an inspector for the Board? What was your role prior to working for the Board?**

I have been serving as the director of drug compliance for the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation — State Board of Pharmacy since 2003. Prior to working for the Department, I worked as a pharmacy manager for over 25 years. The State Board of Pharmacy is part of and is an advisory to the Department.

**In your opinion, what tools or skills are a must-have in a pharmacy inspector's toolkit?**

A pharmacy inspector needs to understand all applicable state and federal regulations, including the Pharmacy Practice Act, Controlled Substances Act, and the Wholesale Drug Distribution Licensing Act to properly enforce the regulations. The inspector would need to know United States Pharmacopeia standards to be able to inspect nonsterile and sterile compounding pharmacies. Inspection forms are the most important tool for an inspector/investigator to use.

**What are some common issues that you have witnessed and addressed as an inspector with the Board?**

Some common issues are a failure to counsel, improper registrant identification, poor food storage and sanitary conditions, and poor record keeping. Drug diversion is a major issue that is commonly addressed with the Board. To address issues of noncompliance, the Board has created self-inspection forms to assist and guide licensees toward a path of compliance with its regulations.

**In Illinois, do inspectors also conduct investigations for the Board of Pharmacy or other health regulatory boards?**

The pharmacy inspector conducts the pharmacy and wholesale drug distribution investigations. All information collected during an investigation is confidential. About five years ago, we investigated a licensed pharmacist who was the owner and pharmacist-in-charge of a pharmacy. He ordered about 100 bottles of promethazine with codeine, but the pharmacy's records indicated only 26 bottles. For about a year and a half, he dispensed over 700 medications to patients without receiving prescriptions and filled prescriptions without verified physician-patient relationships. He routinely dispensed promethazine with codeine to patients in 473-ml quantities, although this medication is more commonly prescribed by physicians in quantities of 240 ml or less. The Department prosecuted him, and his license was indefinitely suspended.

**What advice would you give to a new board inspector?**

An inspector must impartially conduct inspections and maintain confidentiality. ■

### **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

## SUPPORT Act: One Year Later

### *Tracking Progress and Barriers to Implementation*

**This article was written by  
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**“States, not the federal government, are best situated to make decisions on how to deploy resources to enhance their prevention efforts and serve their constituents during the height of the opioid epidemic.”**

In October 2017, President Donald J. Trump declared America’s opioid crisis to be a national emergency. On October 24, 2018, the president signed into law HR 6, the bipartisan Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

As with any wide-reaching and transformative law, many of HR 6’s policies will take years to see full implementation through guidance, reports, or regulations. However, a year into enactment, we have observed progress as agencies across government work to further the goals of the legislation. In this article we discuss the SUPPORT Act’s provisions that may be of interest to state boards of pharmacy, including those related to prescription drug monitoring programs (PDMPs), drug trafficking and counterfeit enforcement, authorities granted to the Drug Enforcement Administration (DEA), telemedicine, and prescribing policies.

#### **PDMPs**

##### *HR 6 Policy Highlights*

- \$500 million in Centers for Disease Control and Prevention (CDC) grants
- Substance Abuse and Mental Health Services Administration (SAMHSA) State Targeted Response grants
- Clarification of Medicaid programs’ ability to access and share PDMP data
- Federal support to states and localities to improve PDMPs, including clinical workflow and health internet technology integration

HR 6 authorized grants to states to establish, maintain, or improve their PDMPs. A February 2019 CDC Notice of Funding Opportunity, “Overdose Data to Action” (CDC-RFA-CE19-1904) for nearly \$1 billion, included “special conditions” that mandate state PDMPs to connect to the Department of Justice’s (DOJ’s) interstate data sharing hub called RxCheck – dismissing the integration completed by 47 states to share data across state lines. In response, NABP, in conjunction with several state partners, continues to advocate for states’ choice and flexibility in the use of these critical CDC funds. States, not the federal government, are best situated to make decisions on how to deploy resources to enhance their prevention efforts and serve their constituents during the height of the opioid epidemic. A report on progress from the secretary of the United States Department of Health and Human Services (HHS) is due to Congress on October 24, 2020.

Another funding stream supported by HR 6 is the State Targeted Response grant program administered by SAMHSA. The law reauthorizes this program, which aims to address the opioid crisis by increasing treatment access and reducing opioid-related deaths. In previous years, many states have used this funding to improve their PDMPs. In fiscal year 2019, Congress appropriated \$1.5 billion for the continuation of this program.

#### **Controlled Substance Importation, Diversion, and Misuse**

##### *HR 6 Policy Highlights*

- Combat illegal drug shipments from overseas by requiring shipments into the US postal system to provide advance electronic data (AED) before entering the US

- Provide resources and authority for Food and Drug Administration (FDA) to prevent illegal drug products from entering the US supply chain via mail
- Require DEA to provide drug manufacturers and distributors data to determine the quantity of opioids being delivered to pharmacies
- Require DEA to provide drug manufacturers and distributors with access to anonymized Automation of Reports and Consolidated Orders System (ARCOS) data to determine the total quantity of opioids being delivered to pharmacies
- Provide additional DOJ funding for DEA National Prescription Drug Take-Back Day

HR 6 took significant steps in granting federal agencies authority to intervene when illegal drugs enter the US supply chain and to monitor the potential diversion and abuse of controlled substances (CS). One provision of the law, language from the Synthetics Trafficking and Overdose Prevention (STOP) Act, requires that foreign shipments coming into the US postal system provide AED before entering the country. On December 31, 2018, US Customs and Border Protection notified all air and ocean carriers that an AED would be required for all shipments into the US from China. While this is great progress, some stakeholders and members of Congress have expressed concerns about the number of packages entering the country and failing to comply with the new AED requirements in the law. In fact, in a July 2019 testimony before the House Committee on Energy and Commerce, Chief Postal Inspector Gary Barksdale stated that AEDs are only received for

85% of shipments from China versus the 100% required by the STOP Act.

In addition to these directives given to customs authorities, other key provisions in the law provide FDA with stronger recall and destruction authority to intercept illegal drugs from entering the US through international mail facilities.

The law also provides authority and funding for DEA to promote drug disposal programs, consider diversion risks and public health impacts when setting opioid quotas, and centralize data to improve reporting of suspicious orders to the agency. In its first related regulatory action following enactment of the law, DEA announced in February 2019 progress in providing drug manufacturers and distributors with anonymized data through ARCOS to help identify, report, and stop suspicious orders of opioids by pharmacies.

## Prescribing

### *HR 6 Policy Highlights*

- Require e-prescribing and electronic prior authorization for CS in Medicare
- Allow plans to suspend payments pending investigations of credible allegations of fraud by pharmacies
- Require the federal government to develop guidance and training on when pharmacists may decline to fill a prescription due to suspicion of fraud or diversion
- Encourage the use of telemedicine for prescribing medication-assisted treatment (MAT)

Perhaps the topic of most immediate interest to NABP member boards is how the law treats the prescribing

of CS. HR 6 included wide-ranging policies impacting e-prescribing, electronic prior authorization, and how pharmacists and drug plans react to suspicion and allegations of fraud. For example, we anticipate federal guidance on when pharmacists may decline to fill a prescription for a CS due to suspicion of fraud or diversion. The law directs the government to disseminate this information within one year from the date of enactment.

The law mandates the use of e-prescribing for all Medicare Part D CS by January 1, 2021. The Centers for Medicare & Medicaid Services (CMS) has stated rulemaking on this issue should be expected in 2020. The agency has not released additional details to date, but the Office of the National Coordinator for Health Information Technology at HHS has detailed several potential barriers to implementation for providers, including cost, education, and multifactor authentication.

On a related topic, the law requires that the secretary of HHS adopt standards for e-prescribing in Part D to ensure secure electronic prior authorization request and response transmissions. The new transaction standard was issued in a proposed rule on June 19, 2019, and adoption by prescribers and plan sponsors is required no later than January 1, 2021.

Another CMS provision we have been closely following is reimbursement of telemedicine services for substance use disorder treatment, including prescribing MAT. For services provided after July 1, 2019, the law removes onerous originating site and geographic restrictions from Medicare's statute for the provision of telehealth services for the treatment of substance use

continued on page 7



## Provisions and Deadlines for SUPPORT Act

### Past Due – January 1, 2019

**Health and Human Services (HHS) resources on pain management** – Requires the secretary to compile and provide educational resources on topics covering opioid use, pain management, and alternative pain management. Sec 6021

### Past Due – April 24, 2019

**HHS-US Department of Homeland Security (DHS)-US Postal Service (USPS) report to Congress** – Requires the secretary of HHS, in consultation with DHS and USPS, to submit report to Congress on the implementation of progress toward sharing and interoperability of information. Sec 3014(c)

### Past Due – July 24, 2019

**HHS-DHS report to Congress** – Requires the secretary of HHS in consultation with DHS to submit a report to Congress on restricting the entrance of illicit drugs into the United States. Sec 3022(a)(2)

### October 24, 2019

**Department of Justice (DOJ) e-prescription update** – Requires US attorney general to update requirements for the biometric component of multifactor authentication related to electronic prescriptions for controlled substances (CS). Sec 2003

**Food and Drug Administration (FDA) report to Congress** – Requires FDA commissioner to submit report to Congress on how it plans to use prescribing guidelines to protect public health. Sec 3002(c)

**Government Accountability Office (GAO) report to Congress** – Requires GAO to submit report to Congress on disposal technologies and packaging. Sec 3032(d)

**HHS resources on declining prescriptions** – Requires secretary of HHS to develop and disseminate materials for pharmacists, providers,

and patients on circumstances where a pharmacist may decline to fill prescription. Sec 3212

**DOJ-HHS telemedicine regulations** – Requires attorney general, in consultation with secretary of HHS, to disseminate final regulations related to special registration for telemedicine. Sec 3232

**DOJ report to Congress** – Requires attorney general to submit report to Congress on utilization of Automation of Reports and Consolidated Orders System. Sec 3274

**DOJ database and GAO report to Congress** – Requires attorney general to establish database for collecting reports on drug diversion; requires GAO, in consultation with Drug Enforcement Administration administrator, to submit report to Congress on reporting of suspicious orders. Sec 3292(b)

### October 24, 2020

**GAO report to Congress** – Requires GAO to submit report to Congress on access to and diversion of CS administered by implantation or injection. Sec 3204(b)

**HHS reporting system** – Requires secretary to establish a secure system for data sharing and

reporting of waste, fraud, and abuse related to Medicare Part D. Sec 6063

**HHS report to Congress** – Requires secretary to submit report to Congress on availability of supplemental benefits for the treatment and prevention of substance use disorders under Medicare Advantage (MA) plans. Sec 6084

### January 1, 2021

**Medicare electronic prescribing** – Requires Part D prescriptions for CS to be transmitted electronically. Sec 2003

**Medicare electronic prior authorization** – Part D e-prescribing system to allow for prior authorization requirements. Sec 6062

**Medicare pain treatment information** – Beginning in plan year 2021, requires that Part D plans provide enrollees with information related to the treatment of pain. Sec 6102

**MA information** – Requires MA plans to provide enrollees with information related to the safe disposal of prescription drugs. Sec 6103

## Second Quarter 2019 Clearinghouse Totals Announced

During the second quarter of 2019, a total of 1,516 disciplinary records were submitted by the state boards of pharmacy. The majority of disciplinary records submitted were for pharmacists, pharmacies, and pharmacy technicians.

Of the 1,516 disciplinary records, 1,824 actions were reported to the NABP Clearinghouse. Of the 1,824 actions, the three most reported actions in the second quarter were publicly available fine/monetary

penalty (676 or 37% of all actions); other actions not classified (223 or 12.2% of all actions); and reprimand or censure (164 or 9% of all actions).

Of the 1,756 bases for actions cited in second quarter 2019, violation of federal or state statutes, regulations and rules, or health and safety requirements (467 bases or 26.6%); other bases not classified (197 bases or 11.2%); and failure to comply with continuing education or competency requirements (132 bases or 7.5%)

were the top reasons why disciplinary actions were taken during the quarter.

As stated in the NABP Constitution and Bylaws, participation in the Clearinghouse is required as part of a board of pharmacy's membership to the Association. Timely reporting to the Clearinghouse is essential to maintaining the integrity of the licensure transfer program. Boards may access the Clearinghouse using NABP e-Profile Connect. ■

### Policy Perspectives

continued from page 5

disorder or a co-occurring mental health disorder. We are also tracking the expected publication of CMS guidance to states on federal reimbursement under Medicaid for using telehealth to deliver services and treatment for substance use disorders. The law directs CMS to deliver this guidance within one year of enactment.

### Looking Ahead

As we near the one-year anniversary of the enactment of HR 6, we anticipate the release of new regulations, guidance documents, and reports across the federal government. Many of these actions will undoubtedly impact the practice of pharmacy across the nation, and we have detailed some of the topics we continue to track in the table on page 6.

Even while HR 6 continues to be implemented, many across the federal government believe more must be done. For example, Senator Jeanne Shaheen (D-NH) has introduced legislation, Senate Bill 2102, to provide further funding for programs and activities originally authorized in HR 6. We also anticipate debate on Senator Edward Markey's (D-MA) Safer Prescribing of Controlled Substances Act and/or Senator Elizabeth Warren's (D-MA) Comprehensive Addiction Resources Emergency Act. As the voice of NABP in Washington, DC, we will continue to track administrative and Congressional activity on these topics.

*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.* ■

## FPGEE/PCOA Review Committee Convenes in August



Members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®)/Pharmacy Curriculum Outcomes Assessment® (PCOA®) Review Committee met in August 2019 at NABP Headquarters to review and develop new test questions for the FPGEE and PCOA programs. Pictured are (left to right) Carolyn Friel, PhD, RPh, Massachusetts College of Pharmacy and Health Sciences; Jennifer Mathews, MA, MS, PhD, Albany College of Pharmacy and Health Sciences; Bruce Waldrop, PhD, Samford University McWhorter School of Pharmacy; and Sreejayan Nair, PhD, University of Wyoming School of Pharmacy. ■

# Fentanyl Supply Increase Brings ‘Third Wave’ to Evolving Opioid Epidemic



As efforts to combat the opioid crisis multiply, the problem itself continues to evolve – from the abuse of prescription drugs to higher heroin use rates, to the increasing prevalence of illegal synthetic opioids such as fentanyl. Some indicators are positive: heroin and opioid use overall dropped in 2018, the number of prescriptions written for opioids decreased by as much as a third between 2013 and 2018, and deaths from prescription opioids have edged down. Nonetheless,

opioid-related death rates overall continued to rise through 2017, the most recent date for finalized data, coinciding with an increased availability of illicitly manufactured fentanyl and fentanyl-related substances. These substances are playing such a large role in the opioid crisis that fentanyl-related deaths have been referred to as “the third wave” of the opioid epidemic.

“These substances are playing such a large role in the opioid crisis that fentanyl-related deaths have been referred to as ‘the third wave’ of the opioid epidemic.”

As fentanyl prevalence and overdose deaths have continued to rise and as the White House and Congress have prioritized the opioid issue, responses to the crisis have likewise evolved, with increasing attention paid to such measures as boosting naloxone availability to reduce overdose deaths and improving access to medication-assisted treatment (MAT) and other addiction treatments. In addition, state and federal governments continue to work to reduce the supply of prescription opioids and prevent their misuse. Measures designed to inform prescribing, such as prescription monitoring programs (PMPs) and professional education, continue in importance, along with limits on the length and quantity of opioid prescriptions, while strategists also point to the need to develop non-addictive approaches to pain relief.

### Crisis Trends

Not all the news from the opioid crisis is bleak. In 2017, deaths from prescription opioids held roughly stable, and preliminary data released by the Centers for Disease Control and Prevention (CDC) in mid-July 2019 indicated about a 5% drop in total drug overdose deaths from the previous year – the first decline since 1990. Although the total number of deaths remains dauntingly high – overall, more than 68,000 people are estimated to have died from drug overdoses in 2018 – authorities were cautiously optimistic. “The latest provisional data on overdose deaths show that America’s united efforts to curb opioid use disorder and addiction are working. Lives are



being saved, and we're beginning to win the fight against this crisis," said United States Department of Health and Human Services (HHS) Secretary Alex Azar in a statement. But then he continued: "While the declining trend of overdose deaths is an encouraging sign, by no means have we declared victory against the epidemic . . . This crisis developed over two decades and it will not be solved overnight."

Data from the latest National Survey on Drug Use and Health (NSDUH) examining substance abuse and mental health in the US in 2018, released in August 2019, confirmed some of these encouraging signs, while highlighting the work that remains to be done. The number of people who reported illicitly using opioids in the past year had dropped from about 11.4 million in 2017 to about 10.3 million in 2018 for ages 12 or older, and those who reported misusing prescription pain relievers in general in the past year fell from about 11.1 million in 2017 to about 9.9 million in 2018 for ages 12 or older. Even heroin use had dropped, from an estimated 886,000 users in 2017 to about 808,000 in 2018. When prescription pain reliever misuse was broken down into subcategories, prescription fentanyl was one of the only pain relievers that appeared to increase slightly in misuse from 2017 to 2018, from 245,000 to 269,000. Meanwhile, the Substance Abuse and Mental Health Services Administration, which administers the NSDUH, noted that the survey did not address clandestinely produced fentanyl or fentanyl-related substances, and also may not have included fentanyl that had been mixed with heroin or sold as heroin.

## The Spread of Fentanyl

Despite the encouraging reduction in prescription opioid misuse and related overdoses, abuse levels and overdoses nevertheless remain high, and other aspects of the opioid crisis continue trending the wrong way, according to the latest available data. (Finalized, detailed data on 2018 overdose deaths

was not yet available at press time.) In 2017, deaths from all opioids climbed to more than 47,000, an increase of about 12% over the previous year, almost entirely due to the continued increase of overdose deaths involving fentanyl and fentanyl-like synthetic opioids. According to a 2019 HHS report, the number of fentanyl-related overdose deaths began increasing dramatically in about 2013, roughly doubling each year through 2016 (the last year analyzed by the study), and more recent data shows the number of deaths increased by 45% from 2016 to 2017. Even the preliminary 2018 data, with its overall reduced overdose death rates, showed an increase in fentanyl-related deaths.

Illicitly produced fentanyl and fentanyl-related substances – substances that are in the fentanyl chemical family but with minor variations in their chemical structure – have become widely available across the US. Numerous factors contribute to fentanyl's prominent role in overdose deaths, including its potency (at least 50 to 100 times more potent than morphine), its potential lethality at very low concentrations, and its increasing presence mixed in with other drugs, with wide variations in the amount present, and often unbeknownst to the user. Its lethality is such that it has endangered law enforcement and first responders who have accidentally been exposed to it during investigations. High-purity fentanyl (sometimes over 90% pure) is generally shipped into the US from China via parcel packages; largely adulterated fentanyl (with an average purity of less than 10%) is smuggled in larger quantities across the southwest border of the US from Mexico. In the past, fentanyl has often been mixed with or sold as heroin; more recently it is also increasingly being used in counterfeit pills purporting to be prescription opioids. "It is highly likely many distributors do not know what exactly they are selling when it comes to differentiating between heroin, fentanyl, and fentanyl-laced

heroin, as well as differentiating between diverted pills and fentanyl-containing counterfeit pills," the Drug Enforcement Administration (DEA) noted in its 2018 National Drug Threat Assessment. "This probably means many distributors are not intentionally deceiving customers; instead, suppliers do not always inform distributors specifically what substances or combinations of substances they are selling."

The increasing use of pill presses for the clandestine production of realistic-appearing counterfeit medications has also facilitated the spread of fentanyl use and associated overdoses. The realistic appearance of these counterfeit drugs means that users cannot differentiate between a prescription opioid such as oxycodone and a counterfeit pill laced with a potentially lethal amount of fentanyl – and uneven mixing can result in wide variations of potency even in a single batch. Fentanyl has been identified even in popular non-opioid counterfeit medications such as alprazolam (Xanax®), raising the probability of overdose in users who never knew they had been exposed to fentanyl. The rising number of clandestine pill press operations and the related ease of high-volume, low-profile domestic drug counterfeiting has raised concerns for these trends going forward. In March 2019, NABP teamed up with the National Association of Drug Diversion Investigators and the Partnership for Safe Medicines to publish "Illegal Pill Presses: An Overlooked Threat to American Patients," which examines this rising threat.

## Federal Efforts

Federal and state governments alike have remained active in their efforts to help combat the opioid overdose epidemic. Members of Congress introduced numerous bills in 2019 addressing the opioid addiction issue on many different angles. The focus of each legislative bill ranged widely, but included such topics as:

continued on page 10

## Evolving Opioid Epidemic

continued from page 9

- Extending the State Opioid Response Grants program;
- Adding addiction-warning labels to opioid prescriptions;
- Levying punitive fines on pharmaceutical manufacturers involved in extensive opioid sales;
- Setting limitations to certain opioid prescriptions;
- Establishing strategies to limit illicit opioid importation;
- Funding safe medication disposal programs; and
- Evaluating the country's opioid treatment infrastructure.

A few bills took aim at the fentanyl supply issue, such as imposing sanctions on foreign fentanyl-trafficking entities, or inspecting all incoming shipments from countries deemed high-risk. While most of the proposed bills are unlikely to become law, they represent Congressional thinking on best ways to continue to address the opioid addiction situation at the federal level. At press time, the Expanding Findings for Federal Opioid Research and Treatment Act, or EFFORT Act, HR 3153, which directs

the director of the National Science Foundation to support research on opioid addiction, has moved on for consideration in the Senate, after passing the House in July.

Other efforts involving various federal agencies stem from or were augmented by actions taken in 2018, including passage of the comprehensive Substance Use-Disorder Prevention that Promotes Communities Act (SUPPORT Act), signed into law last October. (For a more complete discussion of this legislation and other measures taken in 2018, see “Continued Opioid Overdose Epidemic Prompts New Legislative Action,” in the November/December 2018 issue of *Innovations*.) Further, earlier this year, DEA announced the launch of an enhanced tool to assist pharmaceutical manufacturers and distributors to more easily identify potential drug diversion. The enhancement to the agency's Automation of Reports and Consolidated Orders System, made in response to a provision in the SUPPORT Act, will allow registered drug manufacturers and distributors to know the number of distributors and the amount of a drug each distributor sold to a given customer in the last six months for which data is available. DEA expects that access to this data will assist manufacturers and distributors to fulfill the agency's requirement that they know their customers and develop a system to identify and report suspicious orders, and in making informed decisions about whether a particular customer is purchasing excessive quantities of controlled substances (CS).

In 2019, DEA also continued the agency's long-standing effort to remove CS and other unused drugs from the citizenry's personal medicine cabinets with its 17<sup>th</sup> National Prescription Drug Take-Back Day, which collected 468.72 tons of medications. Since the program's inception, the Take-Back Day event has collected 5,908.2 tons of medications for proper disposal. NABP has long advocated for the safe disposal of CS as an important

measure in reducing potential opioid misuse and offers a locator tool for permanent drug disposal sites. The next DEA Take-Back Day is scheduled for October 26, 2019. In DEA's most recent National Drug Threat Assessment (released in late 2018), the agency noted that 53% of people reporting misuse of prescribed pain relievers – used by someone other than for whom they were intended or used in a manner other than prescribed – said they obtained the drugs from a friend or relative.

HHS, which is also deeply involved in opioid crisis response, has identified five major crisis-related priorities for its agencies:

- Improving access to treatment and recovery services;
- Encouraging the use of overdose-reversing drugs, such as naloxone;
- Promoting better public health data collection;
- Supporting research on pain and addiction; and
- Promoting better pain management practices.

HHS is a conduit for administering hundreds of millions of dollars in crisis-related grants to numerous state and local organizations through its various agencies. CDC, for example, received \$475 million in fiscal year 2019, for opioid overdose prevention and surveillance activities, with a majority of the funds supporting state-based efforts. CDC has divided its efforts into four main categories, with the goal of preventing opioid misuse and overdose, as well as other opioid-related impacts to the public health:

- Funding data collection and analysis;
- Facilitating safer and more effective opioid prescribing;
- Supporting state, local, and tribal programs; and
- Educating consumers about the dangers of opioid misuse.

The National Institutes of Health is channeling a portion of its research

“State PMPs have been highlighted as an important factor in the reduction of the prescription opioid supply, one of the many factors likely influencing the decline in related deaths.”

funding through its Helping to End Addiction Long-term Initiative, announced in 2018; the initiative has identified 26 research priorities under the broad umbrella categories of improving treatment for opioid misuse and addiction, and enhancing new pain management. The Centers for Medicare & Medicaid Services (CMS) is involved in the provision of health care for those individuals struggling with an opioid use disorder (OUD). According to the Kaiser Family Foundation, almost 40% of the nearly 2 million non-elderly adults with an OUD in 2017 were covered by Medicaid, and Medicaid covered more than 50% of those adults with an OUD who reported receiving treatment during the previous year. CMS' efforts related to opioid misuse in 2019 include efforts to reduce treatment barriers for OUD, including increasing access to MAT, improving provider availability in low-access communities, and raising availability of non-opioid pain treatments. CMS also aims to limit inappropriate opioid prescribing through such methods as prescription drug databases, incentivizing practitioners to prescribe appropriately, and sharing best practices among Medicaid agencies.

## State Efforts

Most of the federal efforts by necessity closely involve the states, and the states also initiate many of their own efforts to impact the opioid problem. Acknowledging the impact of the issue on its members, the National Conference of State Legislatures established an Opioid Policy Fellows program; the group's meetings have such goals as learning about the issues from researchers, policy experts, and other legislators, and exchanging ideas and practical suggestions about combating opioid misuse. Since 2015, state lawmakers have introduced well over 1,000 bills intended to combat various aspects of prescription drug misuse. A popular recent approach has been legislatively limiting the length and sometimes the dosage of opioid prescriptions, usually targeting

initial prescriptions written for acute pain. Massachusetts passed the first law enacting opioid prescribing limits in 2016; by early 2019, at least 36 states had passed legislation involving opioid prescribing limits. This year, more states are considering bills addressing opioid limits, including Illinois, Minnesota, Missouri, New York, North Dakota, Rhode Island, Texas, and Vermont; a bill in Maine, meanwhile, sought to expand opioid limits for chronic pain patients over 63 years of age.

State PMPs have been highlighted as an important factor in the reduction of the prescription opioid supply, one of the many factors likely influencing the decline in related deaths. The White House's 2019 National Drug Control Strategy highlighted the importance of expanding their use further, emphasizing in particular the advantages of improving data sharing between states and reducing workflow integration barriers. (NABP PMP InterConnect®, with 51 participating PMPs, has played a key role in this ongoing process, allowing information to flow across state lines while adhering to state law, and assisting with integrating PMP access into providers' workflows.) Awareness of the addiction issue, and provider education, has also been an important element in reducing prescription opioid supplies. The American Medical Association reports that the number of opioid prescriptions decreased by about 33% – from 251.8 million to 168.8 million – between 2013 and 2018, including a drop of 12.4% between 2017 and 2018 alone.

A number of states are also working to increase treatment and recovery options, including facilitating access to MAT. In California, for example, the state's Department of Health Care Services is using federal grant money to implement the California MAT Expansion Project, a compilation of nearly 30 projects intended to "increase access to MAT, reduce unmet treatment need, and reduce opioid overdose related deaths through the provision

of prevention, treatment, and recovery activities," with a focus on populations with hitherto limited MAT access.

Access to the overdose-reversing drug naloxone has also been credited with positively impacting opioid death rates, and naloxone's visibility is only likely to increase with the opioid crisis' turn toward fentanyl. All 50 states and the District of Columbia have passed laws designed to improve access to naloxone, and efforts continue to increase naloxone distribution even more. One 2019 study examined state-level changes in fatal and non-fatal overdoses from 2005 to 2016, to assess which of three types of naloxone access laws had the greatest effect: those providing direct authority to pharmacists to prescribe naloxone (for example, to dispense the drug to anyone who requested it), those providing indirect authority to prescribe (such as to patients enrolled in certain treatment programs or who met other criteria), and others. The study found that opioid-related deaths decreased an average of 27% the first year after direct authority naloxone access laws were passed, with steeper declines in following years; the other approaches appeared to have little correlation with a decrease in opioid death rates. The study also found that the states with direct access laws saw an increase in the number of patients treated at emergency rooms for non-fatal overdoses even as death rates dropped. The trend is currently toward increasing access to naloxone; and states are starting to require health care practitioners to prescribe (or offer to prescribe) naloxone to patients taking prescription opioids.

As stakeholders discover which efforts impact the opioid abuse problem and how both the crisis itself and responses to it continue to evolve, NABP will continue to lend its expertise where appropriate and monitor the overall situation. ■





**Interactive Executive  
Officer Forum**  
October 1-2, 2019

**Interactive Compliance Officer  
and Legal Counsel Forum**  
December 4-5, 2019

**Interactive Member  
Forum**  
January 28-29, 2020

The forums provide attendees a unique opportunity to discuss issues facing their boards with fellow pharmacy regulation experts. Highlights of the forums 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**

Executive officers received registration information for the Executive Officer Forum in July, including a request to identify staff they wish to attend the Compliance Officer and Legal Counsel Forum. Information about the Interactive Member Forum will be sent to executive officers soon.

One compliance officer and one legal counsel per board may attend the Interactive Compliance Officer and Legal Counsel Forum at no charge. 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.”

## 2019-2020 NABP Committee and Task Force Members Appointed by President Campbell

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

NABP President Jack W. “Jay” Campbell IV, JD, RPh, made the following appointments for task forces and standing committees for 2019-2020.

### 2019-2020 Task Forces

Three task forces were established in response to Resolution No. 115-4-19, passed at the NABP 115<sup>th</sup> Annual Meeting. The resolution states that the purpose of these task forces is to evaluate the current environment and make recommendations to NABP to ensure a more active role in establishing requirements for the education, practice responsibilities, and competence assessment of pharmacy technicians.

The **Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment** met on September 11-12, 2019, at NABP Headquarters. It was charged with the following objectives:

1. Evaluate the current environment for the regulation of pharmacy technicians.
2. Make recommendations for the task force subgroups to focus on ensuring that boards of pharmacy take a more active role in establishing requirements for the education, practice responsibilities, and competence assessment of pharmacy technicians.

Chairperson of this task force was Lemrey “Al” Carter, MS, PharmD, RPh, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy.

Individuals appointed to serve as members included:

- Gary W. Dewhirst, RPh, DPh, Colorado
- Cindy Fain, PD, Arkansas State Board of Pharmacy
- John R. Genovese, RPh, New Hampshire Board of Pharmacy
- Jacqueline L. Hall, MBA, RPh, Louisiana Board of Pharmacy
- Jason Hansel, PharmD, RPh, Iowa Board of Pharmacy
- Timothy R. Koch, PD, CHC, Arkansas
- Gary J. Merchant, MBA, RPh, New Hampshire Board of Pharmacy
- Kristen Snair, CPhT, Arizona State Board of Pharmacy
- Donna S. Wall, PharmD, RPh, Indiana Board of Pharmacy
- Anita Young, EdD, RPh, Massachusetts

The Executive Committee liaison was Bradley S. Hamilton, RPh.

The **Task Force on Requirements for Pharmacy Technician Education** will meet on October 21-22, 2019, at NABP Headquarters.

The task force is charged with the following objectives:

1. Evaluate the recommendations of the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence

Assessment related to pharmacy technician education.

2. Evaluate the current environment for pharmacy technician education requirements.
3. Make recommendations to ensure that boards of pharmacy take a more active role in establishing requirements for the education of pharmacy technicians.

Chairperson of this task force is Diane Halvorson, RPhTech, CPhT, North Dakota State Board of Pharmacy.

Individuals appointed to serve as members include:

- Kerstin Arnold, JD, Texas State Board of Pharmacy
- Sabrina L. Beck, PharmD, RP, Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit
- James Bracewell, Georgia
- Jonathan Brunswig, PharmD, RPh, Kansas State Board of Pharmacy
- Debbie Chisolm, RPh, Connecticut Commission of Pharmacy
- Megan E. Marchal, PharmD, RPh, State of Ohio Board of Pharmacy
- Patricia L. Richards-Spruill, RPh, Virginia Board of Pharmacy
- Karen M. Ryle, MS, RPh, Massachusetts
- Kim Tanzer, PharmD, RPh, Massachusetts Board of Registration in Pharmacy
- Deborah Veale, RPh, California State Board of Pharmacy

The Executive Committee liaison is Lenora S. Newsome, PD.

continued on page 14

## Committee, Task Force Appointments

continued from page 13

The **Task Force on Pharmacy Technician Competence Assessment** will meet on October 22-23, 2019, at NABP Headquarters.

The task force is charged with the following objectives:

1. Evaluate the recommendations of the Overview Task Force on Requirements for Pharmacy Technician Education, Practice Responsibilities, and Competence Assessment related to pharmacy technician competence assessment.
2. Evaluate the current environment for pharmacy technician competence assessment.
3. Make recommendations to ensure that boards of pharmacy take a more active role in establishing requirements for the competence assessment of pharmacy technicians.

Chairperson of this task force is Kimberly A. Grinston, JD, executive director, Missouri Board of Pharmacy.

Individuals appointed to serve as members include:

- Joseph Leyba, PharmD, RPh, Arizona State Board of Pharmacy
- Bradley A. Miller, PhTR, Texas State Board of Pharmacy
- Cynthia "Cindy" Warriner, RPh, CDE, Virginia Board of Pharmacy
- Fred M. Weaver, RPh, State of Ohio Board of Pharmacy
- Stuart T. Williams, JD, Minnesota Board of Pharmacy

The Executive Committee liaison is Shane R. Wendel, PharmD, RPh.

## 2019-2020 Standing Committees

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

The **Committee on Law Enforcement/Legislation** will meet on January 14-15, 2020, at NABP Headquarters. The committee is charged with the following tasks:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Reginald B. "Reggie" Dilliard, DPh, executive director, Tennessee Board of Pharmacy, will serve as the committee chairperson. Committee members include:

- Darren R. Covington, JD, Indiana Board of Pharmacy
- Robert Graves, North Carolina Board of Pharmacy
- Sebastian Hamilton, MBA, PharmD, RPh, Massachusetts Board of Registration in Pharmacy
- Tony King, RPh, Montana Board of Pharmacy
- Deborah C. Mack, PD, RPh, CHC, CCEP, Arkansas State Board of Pharmacy
- Jeenu Philip, RPh, Florida Board of Pharmacy
- Shauna White, MS, PharmD, RPh, District of Columbia Board of Pharmacy
- J. David Wuest, RPh, Nevada State Board of Pharmacy
- Jenny Downing Yoakum, RPh, Texas State Board of Pharmacy
- Gayle D. Ziegler, RPh, North Dakota State Board of Pharmacy

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

The **Committee on Constitution and Bylaws** will meet on April 6, 2020. The charge of this committee, as defined by the NABP Constitution and Bylaws, is to review proposed amendments, suggest changes where appropriate, and issue a recommendation for each proposed amendment.

Laura Forbes, RPh, Virgin Islands Board of Pharmacy, will be the committee chairperson. Committee members include:

- Lindsey Laliberte, RPh, New Hampshire Board of Pharmacy



- Tamara McCants, PharmD, RPh, District of Columbia Board of Pharmacy
- William “Bill” Mixon, MS, RPh, FIACP, FACA, North Carolina Board of Pharmacy
- Lorri Walmsley, RPh, Arizona State Board of Pharmacy

Mark Mikhael, PharmD, RPh, of the Florida Board of Pharmacy, and Daniel Guerrero, MS, of the Texas State Board of Pharmacy, will serve as alternates. The Executive Committee liaison is Tejal J. Patel, MBA, PharmD, RPh.

## Work Group

On September 5, 2019, NABP convened the meeting of the **Work Group on the Development of an Interstate Endorsement Credential**, which was created to address an initiative by NABP President Jack W. “Jay” Campbell IV, JD, RPh.

The work group was charged with the following objectives:

1. Develop an interstate endorsement credential for non-dispensing or cognitive pharmacy practices and expand the current Electronic Licensure Transfer Program® service by creating:
  - a. an interstate endorsement credential that expedites the licensure process by offering credible alternatives to certain, existing requirements; and
  - b. a mechanism to integrate mutual recognition among the states through the enhancement of the state-based and uniform processes currently in place.

Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy, served as the work group chairperson. Work group members included:

- Traci Collier, PharmD, RPh, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy

- Mark J. Hardy, PharmD, RPh, North Dakota State Board of Pharmacy
- Virginia “Giny” Herold, MS, California
- Sam Lanctin, BScPharm, MBA, New Brunswick College of Pharmacists
- Richard A. Palombo, RPh, New Jersey
- Laura Rang, RPh, Colorado State Board of Pharmacy
- Steven W. Schierholt, Esq., State of Ohio Board of Pharmacy
- Ellen Vick, PharmD, JD, RPh, North Carolina Board of Pharmacy
- Dennis F. Wiesner, RPh, Texas State Board of Pharmacy
- Cathy J. Winters, RPh, Wisconsin Pharmacy Examining Board

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

## Volunteer to Serve on Advisory Committee on Examinations

Be part of the Advisory Committee on Examinations (ACE) – a long-standing committee that safeguards the integrity and validity of NABP examinations. Each ACE appointment is for a three-year term, beginning June 1, 2020. ACE convenes two to three times a year to do the following:

- Oversee the development and administration of NABP examination and certification programs
- Evaluate long-range planning strategies
- Consider policy matters
- Recommend actions to the NABP Executive Committee

### Interested?

To be considered for ACE, an individual must hold an active, unrestricted pharmacist license in a state or territory of the United States and meet at least one of the following requirements:

- Be a member or administrative officer of an active member board of pharmacy,

- Have served within the last five years as a member or administrative officer of an active member board of pharmacy,
- Be a practicing pharmacist, or
- Serve as pharmacy school faculty.

Open positions on ACE are determined by the current composition of the committee and in accordance with NABP policy. Interested individuals are asked to submit a written statement of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Drive, Mount Prospect, IL 60056, or via email to [ExecOffice@nabp.pharmacy](mailto:ExecOffice@nabp.pharmacy) no later than December 31, 2019. Please contact the NABP Competency Assessment department at [CompAssess@nabp.pharmacy](mailto:CompAssess@nabp.pharmacy) with any questions regarding ACE. ■

## NABP Partners With PTCB on Technician Profile Data Exchange

NABP has partnered with the Pharmacy Technician Certification Board (PTCB) on a data exchange between the NABP e-Profile system and PTCB's database of technician profiles. The organizations have already used the exchange technology to successfully share data on continuing education (CE) activities and other technician data, such as certification data. In addition, NABP is piloting an expansion of this service, which would share disciplinary data with PTCB for use in monitoring any violations of its certification requirements by technicians.

### How Does it Work?

In early 2019, PTCB certified technicians were to enter their e-Profile ID in their PTCB profile. Once their e-Profile ID is entered, the new application programming interface (API) automatically queries NABP's system. If it is verified that a technician's PTCB profile is correctly matched to their NABP e-Profile, the ID is considered validated in PTCB's system.

The API is also used when PTCB is reviewing a technician's request to renew PTCB certification. In this situation, the API allows PTCB's system to query NABP e-Profile Connect for the individual's continuing pharmacy education (CPE) activities. The exchange technology is enabling PTCB to greatly streamline its recertification process for technicians. Technicians can process their renewal entirely online, and the system is able to quickly determine if a technician has met his or her CE requirements using e-Profile data. Previously, PTCB certificants were required to enter all CPE activity they had earned into their PTCB account. The new API eliminates this manual step because it reads any Accreditation Council for Pharmacy Education (ACPE)-accredited CPE earned and recorded in the technicians' e-Profile via the CPE Monitor® program.

Similarly, new certification data for certified pharmacy technicians flows

from PTCB accounts to NABP's e-Profile system, where (when matched) it automatically updates CPhTs' e-Profile accounts. This ongoing profile synchronization will allow the NABP e-Profile system to include current and accurate PTCB certification information.

To facilitate the data exchange, PTCB is requiring all CPhTs seeking recertification to have a validated NABP e-Profile ID in their PTCB account by October 2019. Many PTCB CPhTs have already benefited from the exchange service by experiencing a more streamlined review process for their renewal.

In addition, NABP is sharing any disciplinary actions on technicians from the NABP Clearinghouse, a national database of disciplinary information, with PTCB. This information allows PTCB to enhance its compliance process, and more quickly initiate complaints and take action against PTCB-certified technicians whose actions, as documented in the NABP Clearinghouse, violate the PTCB code of conduct.

### Data Exchange Benefits

The data exchange service is a benefit to member boards of pharmacy by making more comprehensive and up-to-date data on PTCB-certified technicians available through e-Profile Connect. Twenty-one states currently require certification for technicians, and 12 states recognize PTCB certification as fulfilling a requirement for registration or licensure. Further, the technology supports PTCB's efforts to ensure that certified technicians are staying current with CE requirements, and are therefore more likely to practice competently, which contributes to public health protection.

The API technology used for the PTCB data exchange may also be used by board of pharmacy systems, if the board's database requires the NABP e-Profile, so that profiles may be matched against NABP data.

Further, each successful data exchange process that NABP builds for the e-Profile system sets the stage for additional projects to support the member boards. ■

## PTCB Certification Eligibility Requirements

To achieve Pharmacy Technician Certification Board (PTCB) certification in 2019, candidates must meet the following eligibility requirements:

- Have a high school diploma or equivalent educational diploma (eg, a General Educational Development or foreign diploma). Candidates who are within 60 days of acquiring their high school diploma or equivalent will be eligible to apply for the Pharmacy Technician Certification Exam (PTCE). PTCB certification will not be granted until proof of high school completion (or equivalent) is provided to PTCB;
- Provide full disclosure of all criminal and state board of pharmacy registration or licensure actions;
- Be in compliance with all applicable PTCB certification policies; and
- Have a passing score on the PTCE.

Beginning in January 2020, PTCB will require technicians to complete a PTCB-recognized education/training program or have equivalent work experience to be eligible to apply.

For more information, visit the PTCB website at [www.ptcb.org](http://www.ptcb.org).

## NABP Launches Pre-MPJE; Statistics Show Correlation Between Pass Rates and Pre-Exams

NABP is excited to announce the launch of the Pre-MPJE™, a practice examination that helps individuals prepare for the Multistate Pharmacy Jurisprudence Examination® (MPJE®). Developed in response to feedback from pharmacists who have taken the MPJE, which combines federal- and state-specific questions to test the pharmacy jurisprudence knowledge of prospective pharmacists, the Pre-MPJE features valid questions that have appeared on and have been withdrawn from past MPJE exams. The exam also covers topics specific to each jurisdiction that uses the MPJE as well as subjects common to all jurisdictions.

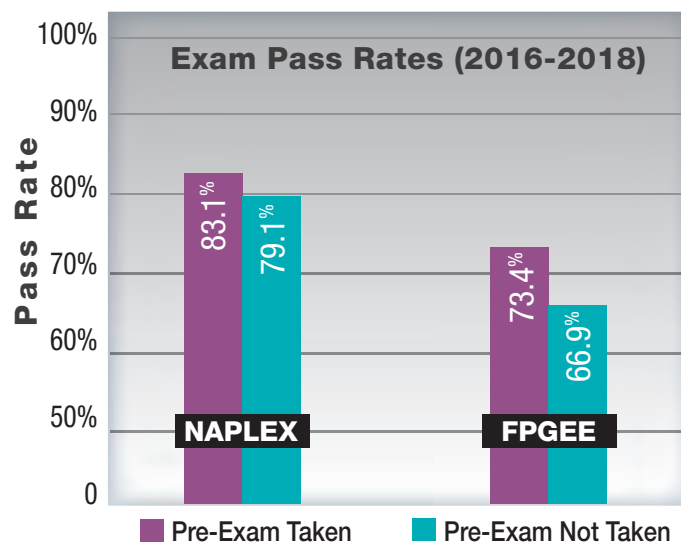
The Pre-MPJE was piloted by the MPJE Review Committee and a school of pharmacy with more than one campus. It follows the model of two other NABP pre-exams: the Pre-NAPLEX®, which prepares pharmacy students for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Pre-FPGEE®, a practice exam for foreign pharmacists preparing to take the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®).

As with the Pre-NAPLEX, schools and colleges of pharmacy will be able to purchase Pre-MPJE vouchers, which will be jurisdiction-specific, to give to students. Candidates will be able to take the exam once a year per jurisdiction.

### Practice Exams Correlate With Better Scores

NABP statistics show a correlation between passing scores and the pre-examinations. According to NABP statistics from 2016-2018, 61% of candidates took the Pre-NAPLEX before taking the NAPLEX for the first time. During that time, the NAPLEX pass rates for candidates who took and who did not take the Pre-NAPLEX were as follows:

- 83.1%, or 33,853 individuals (pre-exam taken)
- 79.1%, or 20,556 individuals (pre-exam not taken)



NABP statistics show a correlation between passing NAPLEX and FPGEE scores and pre-examinations.

Also from 2016-2018, 36% of candidates took the Pre-FPGEE before taking the FPGEE for the first time. During that time, the FPGEE pass rates for candidates who took and who did not take the Pre-FPGEE were as follows:

- 73.4%, or 1,513 individuals (pre-exam taken)
- 66.9%, or 2,661 individuals (pre-exam not taken)

The table on this page illustrates these differences.

The Pre-MPJE is now available for \$65 per exam. For more information about the Pre-MPJE, visit [www.nabp.pharmacy](http://www.nabp.pharmacy). ■

### Candidate Comments on NABP Pre-Exams

NABP developed the Pre-MPJE™ examination in response to feedback from test takers throughout the United States who have taken other pre-examinations.

- *Please consider providing a Pre-MPJE exam like NABP offers for Pre-NAPLEX. I found it very helpful* — Arizona
- *Pre-MPJE practice tests would be nice to have in order to prepare* — Florida
- *Practice exams through NABP for MPJE would be very beneficial. I wish there was one similar to the NAPLEX practice to help prepare me for the MPJE* — North Carolina



## NABP, CriticalPoint Offer Board Staff USP <797> Webinars *July 2019 CISCi Recipients Announced*

NABP and CriticalPoint, LLC, are pleased to announce a new class of inspectors who earned the CriticalPoint Certification in Sterile Compounding for Inspectors (CISCi) training as part of the Sterile Compounding Inspector Training program held on July 9-12, 2019. Individuals from several state boards of pharmacy, federal and state health departments, and other agencies participated in the certification program. Congratulations to the following CISCi recipients:

- Dmitry Kunin, Colorado State Board of Pharmacy
- Justin Ortique, District of Columbia Department of Health
- Kimberly Kaptain, Georgia Drugs and Narcotics Agency
- Alicia Harris, Louisiana Board of Pharmacy
- Becky Parker, Louisiana Board of Pharmacy
- James Ramsey, Mississippi Board of Pharmacy
- Leo Basch, Nevada State Board of Pharmacy
- Bobby Padilla, New Mexico Board of Pharmacy
- Brent Slaughter, North Carolina Board of Pharmacy
- Jason Smith, North Carolina Board of Pharmacy
- Kathryn Baldwin, Oregon State Board of Pharmacy
- Joseph Ball, Oregon State Board of Pharmacy
- Steven Zahn, Pennsylvania State Board of Pharmacy
- Derek Johnston, Tennessee Board of Pharmacy

- Derek Everett, Vermont Office of Professional Regulation
- Patrick Johnson, Wyoming State Board of Pharmacy

### Live and Online CPE Webinars

In addition to CISCi training, NABP, in conjunction with CriticalPoint, is hosting a series of six continuing pharmacy education (CPE) webinars that will provide a comprehensive update on the changes to United States Pharmacopeia Chapter <797>, which take effect December 1, 2019. The training is by invitation only for board of pharmacy inspectors/compliance officers as well as board staff and members who are tasked with inspection oversight and related enforcement of the standards. The Pew Charitable Trusts has provided grant funding to cover the cost of this webinar series.

During the webinar series, which began in September 2019, CriticalPoint

subject matter experts identify changes to sterile compounding requirements as well as address information on the behaviors, standard operating procedures, documentation, and training by which licensees may demonstrate compliance.

The webinar series will continue twice per month through November. Each live webinar begins at 2 PM EDT, is 60 minutes long, and includes time for a question-and-answer period. The webinars are also recorded and available online for those unable to attend the live versions. Those who attend the live webinar or complete the recorded webinar online will be eligible to receive one hour (0.1 CEU) of CPE credit. For more information about the webinar series, including learning objectives, dates, and registration, visit the CriticalPoint website at [www.criticalpoint.info/nabp-sponsored-webinars-presented-by-criticalpoint](http://www.criticalpoint.info/nabp-sponsored-webinars-presented-by-criticalpoint). ■

### CISCi Requirements

To earn NABP/CriticalPoint Certification in Sterile Compounding for Inspectors (CISCi) participants must complete the following components of the Sterile Compounding Inspector Training (SCIT) program:

- Preliminary eLearning training modules (must be completed before taking the live training);
- Three and one-half days of live, on-site training at the state-of-the-art CriticalPoint Center for Training and Research facility; and
- A post-test.

The on-site training is Accreditation Council for Pharmacy Education-approved for 27.5 hours of continuing pharmacy education. Participants must complete all portions of the training and become certified to receive funding.

NABP continues to fund the cost of tuition for one person per state, per year, to attend the training. CISCi training was launched by NABP and CriticalPoint in 2016 to assist state boards of pharmacy in credentialing individuals to promote public health and safety for compounded medicines.

## NABP Calls for Nominations for 2020 Awards; Recipients Will Be Announced at the 116<sup>th</sup> Annual Meeting in Baltimore

NABP is accepting nominations for its 2020 awards, which recognize individuals or boards of pharmacy that represent the Association's mission to protect the public health. The awards will be presented during the 116<sup>th</sup> Annual Meeting, to be held May 14-16, 2020, at the Renaissance Baltimore Harborplace Hotel in Baltimore, MD. Nominations are being accepted for the following awards:

### Lester E. Hosto DSA

Originally known as the Distinguished Service Award (DSA), the Lester E. Hosto DSA is the highest honor bestowed by the Association. NABP renamed the award to serve as a memorial to the 1990-1991 NABP President Lester E. Hosto, whose motivating presence in the practice of pharmacy was recognized by practitioners of his state, Arkansas, as well as by pharmacy leaders across the nation and former United States President Bill Clinton.

The Lester E. Hosto DSA recognizes those individuals whose efforts to protect the public health greatly furthered the goals and objectives of NABP. Any individual who meets these criteria may be nominated for the DSA, regardless of his or her member affiliation with NABP.

### Honorary President

To be considered for the position of honorary president, nominees must meet the following criteria:

- service on at least one NABP committee or task force;
- participation in NABP/American Association of Colleges of Pharmacy District Meetings and NABP Annual Meetings;
- exemplary services for, or on behalf of, NABP;
- strong commitment to NABP, the mission of the Association to protect the public health, and the practice of pharmacy; and
- affiliation (either current or past) as a board member or as an administrative officer of an active or associate member board.

Individuals submitting nominations for honorary president must be from an active or associate member board.

### Fred T. Mahaffey Award

This award is named after the late NABP Executive Director Emeritus Fred T. Mahaffey, who held the executive director position from 1962 to 1987. His leadership and contributions to NABP, state boards of pharmacy, and the protection of the public health were significant and established NABP as one of the leading pharmacy organizations. The award recognizes boards of pharmacy that have made substantial contributions to the regulation of the practice of pharmacy over the past year.

Boards considered for this award must have contributed to protecting the

public health and welfare through the enforcement of state and federal laws and regulations and to the advancement of NABP goals and objectives as specified in the Association's Constitution and Bylaws.

### John F. Atkinson Service Award

Recipients of the John F. Atkinson Service Award are individuals who have provided NABP with exemplary service in protecting the public health and have shown significant involvement with the Association. The award also recognizes exceptional accomplishments related to pharmacy law and compliance. This award is named in honor of the late John F. Atkinson, who served as NABP outside legal counsel for more than 40 years.

### Submitting Nominations

To submit a nomination for any of the aforementioned awards, individuals are asked to complete a nomination form, which may be accessed by visiting the Meetings section of the NABP website. Instructions for submission are provided online. Nominations must be received no later than December 31, 2019. The NABP Executive Committee will review the nominations and select the honorary president and award recipients.

For more information, please contact the NABP Executive Office via email at [ExecOffice@nabp.pharmacy](mailto:ExecOffice@nabp.pharmacy). ■

## Henry Cade Memorial Award

In addition to the Lester E. Hosto Distinguished Service Award, NABP Honorary President, Fred T. Mahaffey Award, and John F. Atkinson Service Award, NABP will present the 2020 Henry Cade Memorial Award during the Annual Meeting. **Nominations are not accepted for this award.** The NABP Executive Committee selects recipients for this award who have supported the goals and objectives of the Association and the state boards of pharmacy to protect the public health and advanced the need to maintain the safety

and integrity of the distribution and dispensing of medications.

The Henry Cade Memorial Award is named in honor of the late Henry Cade, who served as NABP president from 1987 to 1988. Tireless in his efforts on behalf of NABP and the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy, Cade was also a longtime pharmacy practitioner. ■

# Interview With a Board Member



**Matthew D. Balla, RPh,  
Member,  
Indiana Board of Pharmacy**

## **Matthew D. Balla, RPh, Member, Indiana 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 originally appointed by Governor Eric Holcomb to serve out the remaining term of a Board member who moved from Indiana. This past year, I was reappointed for a full term and voted president-elect by the other Board members. I have been a pharmacist for 29 years, serving most of that time as a hospital pharmacist with Ascension Indiana.

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

I think the key to being a successful board member is to be engaged. There is typically a steep learning curve when familiarizing yourself with the way a board operates. As pharmacists, we need to know the state pharmacy laws, however, sitting on a board requires a much deeper understanding of the law. This is where it can get tricky. As a board member, we need to ensure we do not express opinions about the rules and regulations. I think another thing board members need to be successful is to find a board member to learn from. Asking procedural questions and following his or her lead can be very helpful. The board's legal counsel is another great source of information. As in our professional lives, being authentic and intentional goes a long way. It is OK to say, "I don't know the answer, but I will find out." This mindset builds trust.

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

Two of the biggest challenges that I suspect all boards are facing are the pace of change in health care and the pace of legislation. These two processes are about as far apart as they can be. Health care is changing rapidly, and organizations are trying to advance patient care, while reducing the cost of care to the patient. This often requires creative and innovative solutions that are not addressed in current rules and regulations. Couple this challenge with the seemingly slow process of new laws or changes to existing laws, and it becomes quite a hurdle to overcome. I think it would be wise for legislators to consult with board members prior to introducing legislation. What looks good on paper, and even in intent, may not be practical or even possible to put into practice.

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

As I mentioned before, be engaged, be humble, and ask a lot of questions. Participate in the process as much as you can. Each board member has a unique set of experiences that may seem obvious and really do bring value to the conversation. This is a time-consuming role that does take some time away from your full-time job; however, it is a true honor to serve the people of your state with reverence and active participation. Having this awareness is important. ■

### **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



## Around the Association

### Executive Officer Change

- **Matthew Martineau, PharmD, RPh**, has been named executive director of the Wyoming State Board of Pharmacy. Martineau joined the Board in September 2017 as an inspector/compliance officer. Prior to joining the Board staff, he worked at Albertsons/Safeway. Martineau is a graduate of the University of Wyoming School of Pharmacy.

### Board Member Appointments

- **Ashlee Parker Bow, PharmD, RPh**, has been appointed a member of the District of Columbia Board of Pharmacy. Bow's appointment will expire April 2, 2022.
- **Justin Messenger, PharmD, RPh**, has been appointed a member of the Idaho State Board of Pharmacy. Messenger's appointment will expire June 30, 2024.
- **Terica L. Gatewood, PharmD, RPh**, has been appointed a member of the Kansas State Board of Pharmacy. Gatewood's appointment will expire April 30, 2023.

- **Tiffany D. Strohmeyer, PharmD, RPh**, has been appointed a member of the Kansas State Board of Pharmacy. Strohmeyer's appointment will expire April 30, 2023.
- **Richard Lopez, MD**, has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Lopez's appointment will expire December 1, 2021.
- **Amy Paradis, PharmD, RPh**, has been appointed a member of the Minnesota Board of Pharmacy. Paradis' appointment will expire January 2, 2023.
- **Michelle Murray, RPh**, has been appointed a member of the Oregon State Board of Pharmacy. Murray's appointment will expire June 30, 2023.
- **Paul Capuano, RPh**, has been appointed a member of the Rhode Island Board of Pharmacy. Capuano's appointment will expire June 1, 2021.
- **Anita Jacobson, PharmD, RPh**, has been appointed a member of the Rhode Island Board of Pharmacy. Jacobson's appointment will expire June 19, 2022.

- **Brian Musiak, PharmD, MBA, RPh**, has been appointed a member of the Rhode Island Board of Pharmacy. Musiak's appointment will expire February 1, 2022.
- **Patrick Gallaher, MBA, MPH, RPh**, has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Gallaher's appointment will expire January 1, 2024.
- **Craig Ritchie, JD, RPh**, has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Ritchie's appointment will expire January 19, 2023.

### Board Member Reappointments

- **Samantha Schirmer, MS**, has been reappointed a public member of the Minnesota Board of Pharmacy. Schirmer's appointment will expire January 2, 2023.
- **Justin Wilson, DPh**, has been reappointed a member of the Oklahoma State Board of Pharmacy. Wilson's appointment will expire June 30, 2023. ■

## New NABP Accreditations

The following entities were recently granted NABP accreditation through the select programs noted below. Full listings of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) facilities and Verified-Accredited Wholesale Distributors® (VAWD®) facilities can be found in the Programs section at [www.nabp.pharmacy](http://www.nabp.pharmacy). ■

### Accredited DMEPOS Facilities

**Bridgeport Community Pharmacy, LLC**  
Bridgeport, CT

**Kenby Pharmacy**  
Brooklyn, NY

**Med-Fast Compounding Pharmacy**  
Aliquippa, PA

**Pewex Pharmacy**  
Ridgewood, NY

**West Atlantic Pharmacy Inc**  
Delray Beach, FL

### Accredited VAWD Facilities

**Encore Scientific LLC**  
Broken Arrow, OK

**Lincare Pharmacy Services, Inc**  
Pinellas Park, FL

**McKesson Medical-Surgical Inc**  
Rock Hill, SC

**McKesson Medical-Surgical, Inc**  
Suwanee, GA

**Sharps Compliance, Inc of Texas, dba Sharps Compliance, Inc**  
Carthage, TX

## Minnesota Updates Rules for Emergency Prescription Refills

In Minnesota, pharmacists will be allowed to refill emergency prescriptions, even if no refills remain, provided that certain conditions are met. A list of special conditions are provided in the Board's July 2019 *Newsletter*.

The Board notes that if those conditions are met, the amount of the drug dispensed by the pharmacist to the patient must not exceed either a 30-day supply or the quantity originally prescribed, whichever is less. If the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold must not exceed the standard unit of dispensing. Also, a pharmacist cannot dispense or sell the same drug to the same patient, as allowed under this new provision, more than once in any 12-month period.

The pharmacist must also notify the practitioner who issued the prescription drug order no later than 72 hours after the drug is sold or dispensed. The pharmacist must request and receive authorization before any additional refills may be dispensed. If the practitioner declines to provide authorization for additional refills, the pharmacist must inform the patient of that fact. In addition, insurers and pharmacy benefits managers are required to pay for these emergency refills, even though no refills were remaining.

## New Hampshire Creates a License for a Licensed Advanced Pharmacy Technician

In October 2018, the New Hampshire Board of Pharmacy endorsed the creation of a license for a licensed pharmacist assistant, which was changed to licensed advanced pharmacy technician during the legislative process. New Hampshire Governor Chris Sununu signed House Bill 463 on June 5, 2019, and it became law on July 1, 2019.

The law requires the Board to write rules regarding the requirements for licensure, renewing the license, and the duties allowed to be performed by new licensees.

The law allows the Board to assign any duty or function allowed by federal and state law, including verifying products, processing refills, verifying repackaged drugs, completing final checks, and any other task not specifically required to be performed by a pharmacist.

A licensed advanced pharmacy technician may perform duties that either a certified or registered pharmacy technician can do. The only functions the law specifically prohibits are interpreting or evaluating a prescription or drug order, verifying or validating a compounded drug or medication, and counseling or advising an individual on the clinical use of a medication.

The Board notes that a key factor in establishing this new category of licensure is that the licensee will be accountable to the Board and not to the pharmacist on duty for the duties he or she performs allowed by the Board. This is comparable to a licensed practical nurse who works under the supervision of a registered nurse. The licensee will be required to have liability insurance. More details on the creation of this license category is provided in the Board's July 2019 *Newsletter*.

## New Jersey Holds Its First Narcan Distribution Day

Overdose deaths in New Jersey rose to over 3,000 in 2018. To address this ongoing public health emergency, the New Jersey Department of Human Services (DHS), New Jersey Cares, and the New Jersey Division of Consumer Affairs requested and received the New Jersey State Board of Pharmacy's approval of a pilot program. The purpose of the pilot program is to distribute opioid antidotes to anonymous recipients at no cost at pharmacies that have obtained naloxone standing orders from the New Jersey commissioner of health or a New Jersey-licensed physician. The first Narcan® distribution day occurred on June 18, 2019, and the approved pilot program allows for additional distribution days over the next 12 months, as DHS advised. The opioid antidotes will be made available through state and/or federal funding and be administered by DHS.

Participating pharmacies will be required to have a valid standing order and must agree to specific conditions set forth in the pilot program, such as separating the opioid antidotes provided for the program from regular pharmacy drug stock, having a process for the anonymous distribution of opioid antidotes, record keeping, and counseling obligations. More information is available in a State of New Jersey Department of Human Services news release. ■

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

## HHS and FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The United States Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions “to reflect further consideration of the relevant issues.”

The action plan can be accessed on the HHS website at [www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf](http://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf).

## Partnering With Pharmacists May Reduce Primary Care Provider Burnout, Research Suggests

Due to high rates of burnout among primary care providers, a new study published in *The Journal of the American Board of Family Medicine* suggests that partnering with pharmacists could help reduce the occurrence of this condition, which affects more than half the number of physicians, according to a research brief on the University of Minnesota website.

According to the Agency for Healthcare Research and Quality, burnout is defined as a long-term stress reaction marked by exhaustion, depersonalization, and a lack of sense of personal accomplishment. According to the

research brief, this can lead to increased depression and higher rates of suicide; poor patient outcomes; and increases in medical errors.

The research found that when pharmacists are “embedded in a clinical team,” primary care providers experienced improvement in multiple work-life aspects, including:

- decreased workload;
- satisfaction that patients are receiving better care;
- reassurance;
- decreased mental exhaustion;
- enhanced professional learning;
- increased provider access; and
- achievement of quality measures.

“As a medical community, we are very concerned about burnout,” said Kylee Funk, PharmD, BCPS, lead author of the study and assistant professor at the University of Minnesota College of Pharmacy. “Our findings are promising for healthcare leaders who are seeking solutions to decrease burnout and improve joy in work. It is exciting to identify that working with a pharmacist may offer very important benefits for clinicians.”

To respond to ongoing concerns related to practitioner burnout, NABP and its member boards of pharmacy have previously reviewed and discussed the topic. On July 29, 2019, NABP joined several other pharmacy organizations in agreeing to a set of 50 recommendations to address critical issues related to pharmacist well-being. A complete list of the conference recommendations can be found at <https://apha.us/ConsensusConfRecs>. In addition, at the NABP 115<sup>th</sup> Annual Meeting in Minneapolis, MN, members voted to approve Resolution 115-3-19, Workload Study Request, authorizing the Association to encourage the Institute for Safe Medication Practices, the American Association of Colleges of Pharmacy, and other stakeholders to undertake efforts to obtain objective data analysis to determine the impact of workload, working conditions, and related topics on substantiated patient safety outcomes.

The research brief and a link to the full study is available at <https://twin-cities.umn.edu/news-events/research-brief-partnering-pharmacist-may-decrease-burnout-among-primary-care-providers>. ■

Health care providers and patients are encouraged to report adverse events or quality problems to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).





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## UPCOMING EVENTS

### **NABP Interactive Executive Officer Forum**

October 1-2, 2019  
NABP Headquarters

### **NABP/AACP Districts 6, 7, and 8 Meeting**

October 6-9, 2019  
Boise, ID

### **NABP/AACP District 4 Meeting**

October 16-18, 2019  
Indianapolis, IN

### **National Prescription Drug Take-Back Day**

October 26, 2019

### **NABP Interactive Compliance Officer and Legal Counsel Forum**

December 4-5, 2019  
Rosemont, IL

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