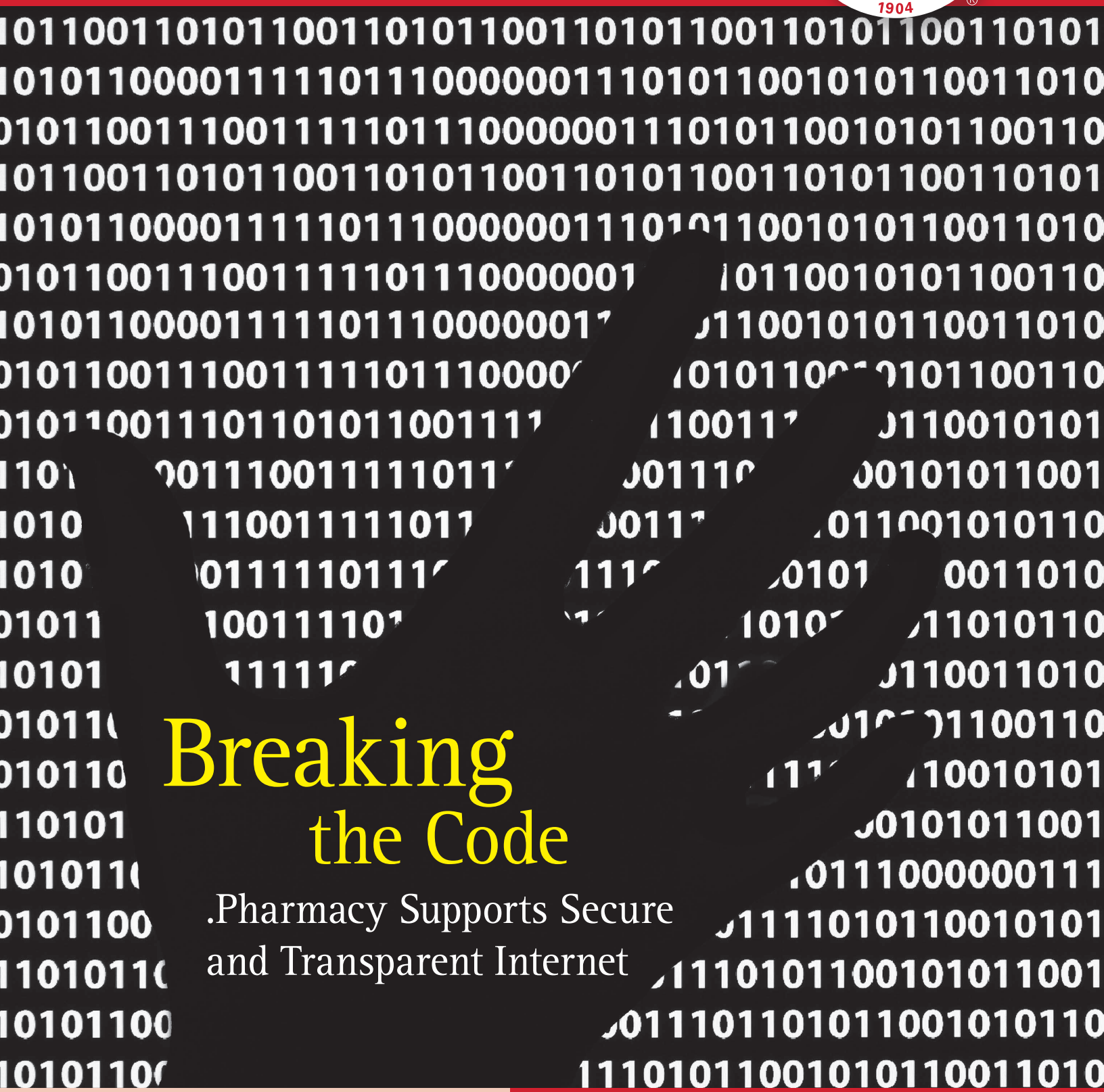
NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

# INNOVATIONS®



# Breaking the Code

## .Pharmacy Supports Secure and Transparent Internet

NOVEMBER/DECEMBER 2018 | VOLUME 47 | NUMBER 10

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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.


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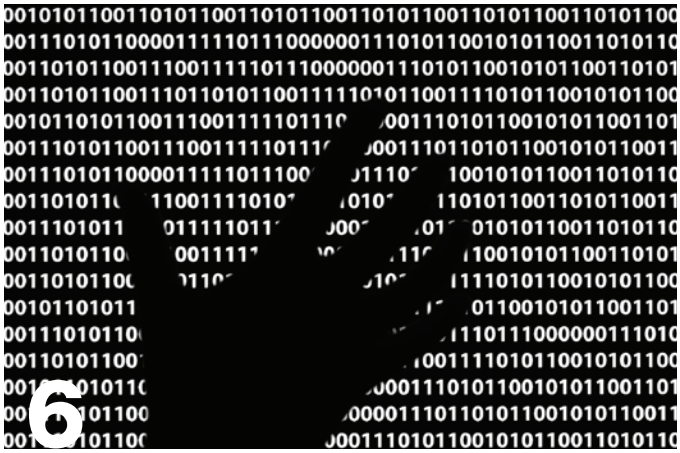



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**Feature News**
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# Interview With a Board Executive Director

Michael D. Bullek, BSP, RPh, Administrator/Chief of Compliance, New Hampshire Board of Pharmacy

## Michael D. Bullek, BSP, RPh

### Administrator/Chief of Compliance, New Hampshire Board of Pharmacy

**How long have you served as administrator/chief of compliance of the New Hampshire Board of Pharmacy? What was your role prior to working with the Board?**

I have held the position of administrator/chief of compliance for one and a half years. Previously, I was a commissioner on the Board for seven years and also worked in the retail setting.

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

Our Board is responsible for all licensing concerning pharmaceuticals, both in-state companies and companies that ship into New Hampshire, the Prescription Drug Monitoring Program (PDMP) and all compliance and inspections involved, and inspecting all providers' offices for medication-related issues. Last April, the Board had a legislative audit performed involving the PDMP and our compliance unit, verifying our processes to current statutes and rules. We have developed new guidelines, as well as a strategic plan, to move forward on recommendations stated in the audit.

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

The Board reviewed and updated all our inspection policies and procedures and started the process of developing software to access our databases to streamline the process. We also looked at how the PDMP was operating and made changes to programs to meet the audit requirements for outcomes management information we send to our providers.

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

The Board has moved to a paperless system, with all pharmacy demographics, licensing, inspection, and investigations performed through the state computer system.

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

New Hampshire is unique in how it has integrated the PDMP into normal Board operations as well as into inspections of providers' offices to state and federal drug laws. These programs would not be successful without reaching out to various boards and investigators from other states, as well as to NABP, for guidance. ■

### New Hampshire Board of Pharmacy

**Number of Board Members:** 6 pharmacist members and 1 public member
**Number of Compliance Officers/Inspectors:** 3
**Rules and Regulations Established by:** Board of Pharmacy
**Number of Pharmacist Licensees:** 2,572
**Number of Pharmacies:** 310 (in-state)
**Number of Wholesale Distributors:** 1,305 (including manufacturers)

# Flotsam and Jetsam, Redux

**Attorney Dale J. Atkinson, JD,** outside counsel for NABP, is a partner in the law firm of Atkinson & Atkinson.

> **“Ample case law supports administrative actions based upon actions (or inactions) of professionals without a need for proof of harm, but this case also addresses the protocols of decision making.”**

As readers will recall, a previous NABP newsletter article addressed the case of a correctional facility physician subjected to administrative proceedings based upon a fact pattern involving pills that were spilled and ultimately reused. Due to a procedural issue related to notice of the alleged violation(s), the administrative sanctions rendered by the Delaware Board of Medical Licensure and Discipline was remanded by the court back to the Medical Board. (See “Flotsam and Jetsam,” *Innovations,* January 2018, addressing *Spraga v. Delaware Board of Medical Licensure and Discipline*, 2017 Del Super LEXIS 384 (Superior Ct DE 2017).) In this companion case, the court addressed an appeal by two nurses (Respondents) who were subjected to discipline by the Delaware Board of Nursing (Nursing Board).

As a reminder of the facts, an inmate (Patient) was housed in a correctional facility in Delaware. The Patient was diagnosed with hepatitis C and prescribed Sovaldi®. Each Sovaldi pill costs $1,000 and is sold only in lots of 28. The infectious disease physician prescribed the administration of one tablet per day for 84 days. While not a narcotic, the pills’ count and distribution are tightly controlled based on their expense.

On March 17, 2015, a nurse (not subject to this proceeding) spilled 12 Sovaldi tablets onto the floor. As trained, the pills were “wasted” by placing them in the “sharps” container, a box intended for biohazard materials. In an attempt to maintain the course of treatment, the relevant pharmacist was contacted to request a refill. The pharmacist contacted the supervisor regarding the request, and what transpired thereafter was the subject of debate. The supervisor asked the physician to retrieve the pills from the sharps container. Next, the physician directed the nurse supervisor to retrieve the pills.

The nurse supervisor and the Director of Nursing (collectively Respondents) located the sharps container and emptied its contents. Among the “flotsam and jetsam” emptied from the container were diabetic syringes with safeties engaged, and an equal number of diabetic test strips and lancets. Additional unidentifiable materials were also mixed into the contents. The pills were examined and cleaned by the Respondents and placed back in their original bottle. They were reused in the course of the drug regimen and no adverse effects were experienced by the Patient.

Thereafter, the Nursing Board filed charges against the Respondents. The matter was heard by a Hearing Officer whereby expert testimony opined that the administration of the pills after their “adventure” was acceptable and that any harm to the Patient was “nil or incalculably small” and that each expert would have ingested the pills under these circumstances. After the hearing, the Hearing Officer found that the Respondents engaged in unprofessional conduct as prescribed by Delaware regulations. Specifically, the Hearing Officer determined that the Respondents were “obligated

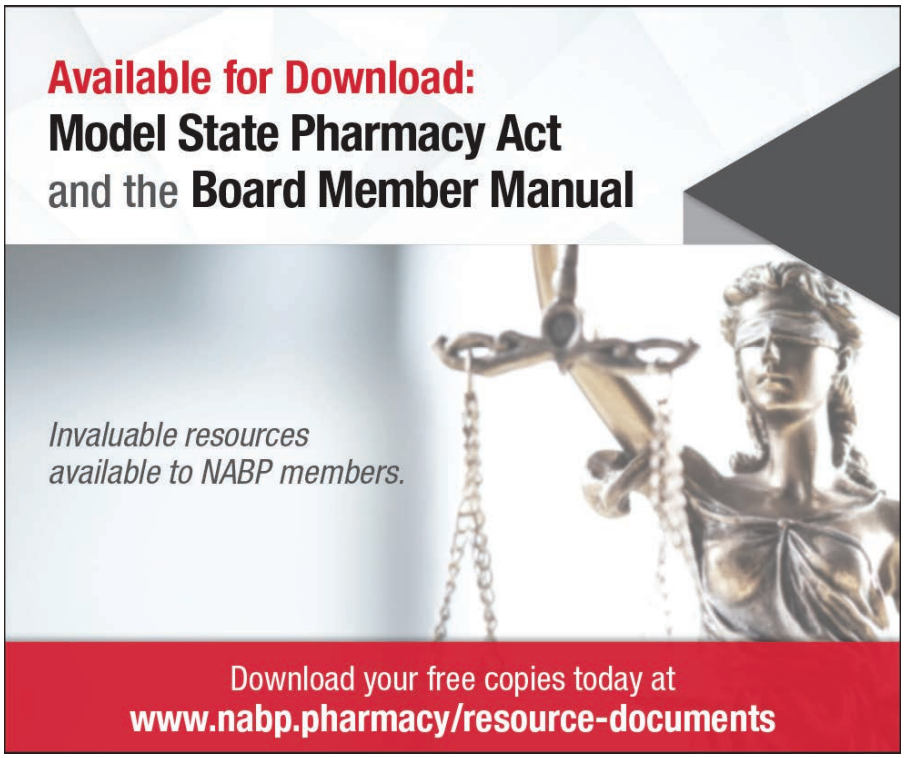
to exercise independent judgment and object or refuse" to return the pills. Further, the Hearing Officer found that the Respondents acted unethically by failing to conform to professional standards. The Nursing Board upheld the Hearing Officer's findings and recommended sanctions of a 90-day probation period and certain specific continuing education. The Nursing Board order was deemed to be public and reportable to the relevant databases. The Respondents appealed.

On appeal, the court reviewed the Spraga case and found it to be instructive. In part, one of the issues argued in both Spraga and the current case was whether the opinions of the physician and the pharmacists to clean and reuse the pills was a "directive" or whether the nurses could have used their independent professional judgment in the decision-making process. Ultimately, the court found that there was no evidence to support that the nurses engaged in harmful conduct.

To support this finding, the court noted that the only witnesses who testified as to the "risk of harm" opined that such risk was negligible. In fact, there was no evidence of harm and, as noted by the court, each of the three regulations cited by the Nursing Board as alleged to having been violated require evidence of harm. Each regulation uses language regarding the potentiality of adverse effects on the public or preventing harm by safeguarding the patient. The court noted that where there is no evidence of harm, requiring a nurse to exercise independent judgment to prevent harm is an "unnecessary redundancy."

Although the Delaware Superior Court found that the Nursing Board's ruling was not supported by substantial evidence, on October 2, 2018, the Delaware Supreme Court reversed the ruling of the lower court. In so doing, the Delaware Supreme Court affirmed the original findings of the Board of Nursing, citing that both nurses should be disciplined. Importantly, the Supreme Court found that the Board's decision was sound, rejecting the nurses' plea that a "clash of professional judgment" substantiates a failure to follow the standards of practice. Thus, the Board sanctions were reinstated. This case presents interesting facts related to directives and mandates when it comes to protocols and decision making. Ample case law supports administrative actions based upon actions (or inactions) of professionals without a need for proof of harm, but this case also addresses the protocols of decision making.

*Francis v. Delaware Board of Nursing*, 2018 Del Super LEXIS 34 (Superior Court, DE 2018)

# Breaking the Code: .Pharmacy Supports Secure and Transparent Internet

Illicit online markets, both on the surface web and on the dark web, provide criminal networks the opportunity to peddle various illicit commodities, including counterfeit pharmaceutical drug products. NABP has joined the Coalition for a Secure and Transparent Internet (CSTI), along with other organizations, to advocate for a transparent internet that promotes safe e-commerce and prevents criminal safe havens online. CSTI advocates before United States and European Union (EU) policymakers, the Internet Corporation for Assigned Names and Numbers (ICANN), registrars, registries, and other stakeholders about the importance of open access to WHOIS data.

> **"NABP has joined the Coalition for a Secure and Transparent Internet (CSTI), along with other organizations, to advocate for a transparent internet that promotes safe e-commerce and prevents criminal safe havens online."**

With WHOIS data now being largely withheld from public access, rendering website operators virtually anonymous, consumer safety initiatives like the .Pharmacy Verified Websites Program become all the more critical. When consumers see .pharmacy at the end of a web address, they can be sure the registrant has been screened and that the site is safe, legitimate, and verified.

## What Is 'WHOIS Data'?

On May 25, 2018, EU's General Data Protection Regulation went into effect and reshaped data privacy regulation across every sector — from health care to banking and beyond. Around the same time, on May 17, 2018, ICANN issued an interim guidance on the regulation, which has led domain name registrars and registries worldwide to restrict access to major elements of the WHOIS record. In fact, the largest internet domain registrar in the world, GoDaddy, began restricting access to some WHOIS data in March 2018.

WHOIS data provides information (ie, name, address, phone number, and email address) on domain name registrants for generic top-level domain spaces like ".com" and certain country-code domain spaces. This data on domain names provides transparency, showing who owns what on the internet.

WHOIS records are used by law enforcement, cybersecurity investigators, copyright and trademark holders, consumers and their advocates, academics, and others to determine who is operating a website, sending an email, or even attacking them online. Blocking public access to full WHOIS directories renders the removal of illegal or malicious content and communications much more difficult and inefficient.

## Challenges to Combating Criminal Activity Online

CSTI encourages federal lawmakers to make WHOIS registration data publicly available to help protect consumers from online criminal activity and to enable

action against cybersecurity risks, intellectual property violations, and consumer fraud and abuse online.

As many agencies and organizations have relied on WHOIS data to help determine who is operating a criminal website, sending malicious emails, or initiating cyberattacks, government and enforcement agencies in the US and EU have echoed similar sentiments and concerns about keeping the internet safe, secure, and sustainable for all internet users.

"Data-protection policies, both in the United States and internationally, should not disrupt existing tools, such as the widely used WHOIS database of domain ownership data," indicate US federal government agencies – the Departments of Commerce and Homeland Security – in its joint May 22, 2018 *Report to the President on Enhancing the Resilience of the Internet and Communications Ecosystem Against Botnets and Other Automated, Distributed Threats*.

Similarly, the European Union Agency for Law Enforcement Cooperation, known as Europol, indicates the challenges of ICANN's May 2018 mandate for investigators in the fight against cybercrime. "This is significantly hampering the ability of investigators across the world to identify and investigate online crime," states Europol's 2018 report *Internet Organised Crime Threat Assessment (IOCTA)*, which provides a comprehensive overview of the current trends of crimes conducted and/or facilitated online as well as anticipated future threats.

Europol's 2018 *IOCTA* report states that, as of May 25, 2018, law enforcement agencies need to initiate a formal legal process and get a specific authorization from a prosecutor or a judge to obtain information on registrants of domain names from registries, registrars, and lower-level providers. As a result, the report notes, this comes "with a substantial administrative burden as well as long delays which may be much longer than the period for which the data in question is being retained. By the time formal procedures are concluded, the data may therefore no longer exist."

## Raising Awareness About Opioids Illegally Obtained Online

NABP has been evaluating rogue internet drug outlets for many years now and serves as a robust resource of information related to this topic. As reported in the Association's September 2018 *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators,* NABP has reviewed 11,943 internet drug outlets selling prescription medications to US patients. Of these, 11,324 (94.8%) were found to be operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards.

NABP's research on internet drug outlets supports the assertion that controlled substances, including those commonly counterfeited with fentanyl, are readily available from rogue internet drug outlets, as detailed in the February 2018 *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators*.

This past year, NABP has been raising awareness of counterfeit drugs made with fentanyl and policies that are being developed to help protect law enforcement from fentanyl exposure. The Fentanyl Council – a joint project of NABP, National Association of Drug Diversion Investigators (NADDI), and The Partnership for Safe Medicines – is working to develop federal and state solutions to the problem of illicitly manufactured fentanyl contaminating illicit and counterfeit medications. Specifically, the Fentanyl Council is developing a guide to help local law enforcement agencies develop policies to protect their officers from fentanyl exposure and a white paper

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## Definitions

- **Internet Corporation for Assigned Names and Numbers (ICANN):** a nonprofit public benefit corporation that develops policy on unique identifiers and coordinates the internet's domain naming system. In other words, ICANN is the multi-stakeholder administrative body overseeing the coordination of domain names on the internet.[1]
- **Domain name:** Your domain name is connected to the specific IP address of your website. Put another way, a domain name serves as the online address of your website. Domain names consist of two or more textual segments separated by dots (such as "*nabp.pharmacy*") and identify a specific IP address on the internet that belongs to an entity such as a company, organization, institution, or individual.[2]
- **Registrant:** the individual or entity that registers a domain name.
- **Registrar:** an intermediary that sells and helps manage domain names. GoDaddy is the world's largest domain name registrar.
- **Registry operator:** an organization that manages a domain name. They create domain name extensions, set the rules for that domain name, and work with registrars to sell domain names to the public. NABP is the registry operator for the .pharmacy domain.[3]

[1] *https://www.techopedia.com/definition/2425/internet-corporation-for-assigned-names-and-numbers-icann*

[2] *https://www.icann.org/icann-acronyms-and-terms/en/G0168*

[3] *https://www.godaddy.com/help/what-is-the-difference-between-a-registry-registrar-and-registrant-8039*

# Continued Opioid Overdose Epidemic Prompts New Legislative Action

As industry leaders, including boards of pharmacy, and government at every level continue efforts to address the ongoing opioid epidemic, millions of Americans are still misusing prescription opioids. This abuse contributes to an estimated 40% of all opioid overdose deaths in the United States, according to the Centers for Disease Control and Prevention (CDC). In 2016 alone, prescription opioids – including methadone, oxycodone, and hydrocodone – were involved in an estimated 46 overdose deaths per day.

While state and local efforts to combat the problem appear to have reduced the number of opioids being prescribed, and overall abuse of prescription medications appears to be relatively stable, the number of overall opioid overdose deaths (including those related to prescription painkillers as well as heroin) is continuing to climb at a dramatic rate. In response, the country's lawmakers are weighing more comprehensive action at the national level to address the crisis.

> **"Bipartisan legislation containing dozens of bills that could have a direct effect on how opioids are prescribed and dispensed nationwide have been passed by both chambers of the US Congress."**

## Both Houses of Congress Have Passed Opioid-Related Legislative Packages

Bipartisan legislation containing dozens of bills that could have a direct effect on how opioids are prescribed and dispensed nationwide have been passed by both chambers of the US Congress.

On September 17, 2018, the Senate passed the Opioid Crisis Response Act of 2018 (OCRA), a bipartisan package of 70 bills related to the epidemic. The measure passed with a vote of 99-1. In June 2018, the House of Representatives passed HR 6, a similar package containing 58 bills with a vote of 396-14.

Highlights of the Senate legislation include reauthorization for $500 million per year in opioid grant extensions for the next three years, and provisions for doctors to understand how to treat young addicts. OCRA also reauthorizes the White House's ability to oversee narcotic-related issues among federal agencies and directs funding to federal agencies to establish or expand programs dealing with prevention, treatment, and recovery.

OCRA would also require Food and Drug Administration to order specialized safety packaging for opioids, such as sealing them in plastic blister packs and limiting doses from three to seven days. Notably, two dozen states have already limited the number of pills that can be prescribed at one time. The bill may also include

incentives for the development of non-addictive painkillers.

The OCRA legislative package includes the Synthetics Trafficking and Overdose Prevention Act, a bill intended to reduce illegal shipments of fentanyl from entering the country. Currently, the US Postal Service is the only domestic transportation carrier that does not collect electronic information on overseas cargo entering the US, which makes it harder for Customs and Border Protection agents to screen packages for illegally imported prescription drugs.

On October 24, 2018, President Donald J. Trump signed HR 6, the SUPPORT for Patients and Communities Act into law. The comprehensive bill was passed by the House and Senate by votes of 393-8 and 98-1, respectively. The bill includes Medicaid, Medicare, and public health reforms to combat the opioid crisis by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to combat illicit synthetic drugs like fentanyl.

In addition, Congress has directed $7.4 billion for 32 key programs related to the opioid crisis in the March 2018 omnibus spending bill. Specifically, the funding will be used for programs in CARA; treatment, prevention, recovery, and criminal justice programs; and research and policy activities. Additional appropriations are expected to be made for the new fiscal year, which began October 1, 2018. On August 30, 2018, the Senate approved an additional $3.7 billion to specifically address the epidemic.

## President's Opioid Commission

In late 2017, President Trump declared the opioid crisis a "nationwide public health emergency." As part of that declaration, President Trump created the Commission on Combating Drug Addiction and the Opioid Crisis. In a March 2018 report, the Commission provided a series of 56 recommendations to curtail the crisis and reduce overdose deaths. Those recommendations include funding for opioid-related federal grants to the states, a national media campaign managed in collaboration with private and nonprofit organizations, creating model statutes and regulations to ensure informed patient consent prior to prescribing opioids for chronic pain, and enhanced penalties for people found to be illegally trafficking fentanyl and fentanyl-analogues.

The full report and recommendations from the summit are available on the White House's website at *whitehouse.gov/opioids*.

## Legislative and Regulatory Changes Continue at the State Level

The states continue to implement new laws, policies, and regulations to combat the opioid crisis. On July 1, 2018, three states enacted new laws intended to further reduce opioid prescribing and to limit opportunities for abuse of these drugs. In Michigan, patients suffering from short-term pain are prohibited from receiving more than a seven-day supply of opioid medications; refills for the medications cannot be written until the seven-day period has elapsed. A similar new law in Florida, which also went into effect on the same day, further restricts opioid prescriptions to three days. Florida added additional requirements for physicians and pharmacists to consult Florida's state prescription drug monitoring program (PDMP) for a patient's prescription history before writing or filling a prescription for an opioid or any other controlled substance for all patients over age 16.

The third law, which applies to health care providers in Tennessee, requires pharmacists to provide only partial fills of opioids, limited to half the number of days the prescription is written for. In addition, the law limits the number of days opioids may be prescribed for certain types of use. For example, prescriptions related to surgery are now limited to a 20-day supply, while general prescriptions are limited to a 10-day supply.

Other trends in state regulatory changes related to the epidemic include laws to increase access to the overdose-reversal drug naloxone, increased use of PDMPs, and additional education for providers.

In addition to these regulatory changes, some states and local government have also started taking legal action in response to the crisis. As of June 2018, more than 600 state, county, and city governments have filed opioid-related lawsuits, according to *ConsumerSafety.org*. The lawsuits are primarily aimed at large pharmaceutical corporations and health care provider practices. These lawsuits also include those that target "influential doctors" who either prescribed high amounts of opioids in the states or published or participated in studies funded by pharmaceutical companies.

## NABP Continues to Monitor Crisis, Supports Appropriate Action in NCPO Statement

The NABP February 2018 *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators* highlighted the connection between fraudulent online drug sellers and the opioid epidemic. Pointedly, NABP recently evaluated 100 websites illegally selling medication to patients in the US and found that 54% of them were selling controlled substances, and 40% were selling one or more of the drugs frequently counterfeited with fentanyl, a commonly abused synthetic opioid.

In January 2018, the National Conference of Pharmaceutical

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## Opioid Abuse Update

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Organizations (NCPO), which includes NABP and 10 other organizations representing over 300,000 pharmacy practitioners, scientists, and companies engaged in diverse aspects of health care delivery, released a statement supporting the action components of the President's Commission on Combating Drug Addiction and the Opioid Crisis. The statement also noted the commitment of the NCPO organizations to advancing individual and collaborative efforts, and a goal to make meaningful progress in reducing inappropriate treatment of pain, addiction, and the loss of life associated with opioid use disorder, while still ensuring patients with legitimate need for pain management have timely access to appropriate treatment regimens.

### Opioid Prescribing Down, Overdose Deaths Rise

Between 2013 and 2017, the number of prescriptions being written for opioids decreased 22%, according to the American Medical Association. In addition, the number of people misusing prescription drugs in the last year has remained relatively stable. According to the 2017 National Survey on Drug Use and Health, approximately 2.2% of the population age 12 or older (6 million people) reported abusing psychotherapeutics, including prescription pain relievers, stimulants, tranquilizers, and sedatives, within the previous month. This number is a slight decrease from the 2.4% reported in the 2016 version of the survey.

Despite the decrease in opioid prescriptions, opioid-related overdose deaths continue to rise. Over 70,000 Americans died from opioid-related overdoses in 2017, according to CDC. In 2016, the number was just over 64,000, and nearly 53,000 in 2015. In addition, the National Institute of Health reports that from July 2016 through September 2017 there was a 30% increase in opioid overdoses in 52 areas in 45 states. Overall, 2017 was the worst year for drug overdose deaths in the history of the country, and at least two-thirds of the deaths were linked to opioids, including prescription opioids and heroin.

### Link Between Prescription Opioid Abuse and Heroin Use

As previously reported in *Innovations*, it is widely believed that prescription opioid use is a major risk factor for heroin use. In fact, a study published by the Substance Abuse and Mental Health Services Administration in August 2013 found that heroin initiation incidents were 19 times higher among those who reported prior nonmedical pain reliever use than among those who did not. This seems to represent a historical shift between the 20th and 21st centuries. A July 2014 study published in *JAMA Psychology* found that among people receiving treatment for opioid dependence, since the 2000s, most began abusing opioids with a prescription drug. Between the 1960s and 1990s, most opioid abusers first began their abuse with heroin.

Through the AWAR$_X$E® Prescription Drug Safety Program, NABP continues its efforts to educate both health care providers and the public on how to safely purchase, use, and dispose of both prescription and over-the-counter medications. For more information on AWAR$_X$E, visit *www.nabp.pharmacy/initiatives/awarxe*. ■

## Breaking the Code

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about the regulation of the pill presses which make the production of fentanyl-laced counterfeits possible.

On November 14, 2018, NABP joined leading global researchers at the research symposium, *Spotlight on Illegal Online Drug Sales*, hosted by the Alliance for Safe Online Pharmacies and the ASOP Global Foundation in Washington, DC. This symposium included presentations on topics related to the illegal advertisement and sale of prescription drugs and illicit narcotics online. In addition, the symposium provided an opportunity to share new research on patient safety and medication quality, search engine algorithm science, law enforcement best practices, and online consumer behavior.

As part of its initiatives to raise awareness and educate the public, NABP participated on a panel at the NADDI annual meeting in Norfolk, VA, in October 2018, and discussed the fentanyl crisis to ensure that the needs of victims, law enforcement, and health care professionals are heard in public discussions.

NABP also remains abreast of ICANN's activities and related procedures and policy development for new top-level domains. As part of this effort, the Association also attended ICANN63 in Barcelona, Spain, in October 2018.

The .Pharmacy Program continues to serve as a trusted domain for legitimate internet pharmacies and pharmacy-related organizations worldwide. In order to protect and serve the collective interests of patients as consumers, NABP's .Pharmacy Program continues to promote its mission, which is to assist its member boards of pharmacy to protect the public health. ■

## Suspicious Orders Work Group Convened in August 2018

The Suspicious Orders Work Group convened in August 2018 at NABP Headquarters to review existing state and federal laws and regulations regarding suspicious orders of controlled substances placed by pharmacies to wholesale distributors. Work group members pictured are (left to right) Darren R. Covington, JD, Indiana Board of Pharmacy; Lisa V. Hunt, RPh, MBA-HM, Wyoming State Board of Pharmacy; Reginald B. "Reggie" Dilliard, DPh, NABP Executive Committee liaison; Kim Gaedeke, Michigan Department of Licensing and Regulatory Affairs; Steven W. Schierholt, Esq, State of Ohio Board of Pharmacy, chairperson; Traci Collier, RPh, South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy; Virginia "Giny" Herold, MS, California State Board of Pharmacy; and Jessica A. Baer, JD, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy.

## Task Force on Mutual-Recognition Licensure Explores Interstate Registration System in September 2018

The Task Force on Mutual-Recognition Licensure met in September 2018 at NABP Headquarters to explore developing an interstate registration system to provide for pharmacists' participation in interstate dispensing models, while maintaining boards of pharmacy jurisdiction to initiate possible administrative proceedings to protect the public health. Task force members pictured are (left to right) Carl "Trip" Hoffman III, PharmD, RPh, Utah Board of Pharmacy; Laura Rang, RPh, Colorado State Board of Pharmacy; Mark J. Hardy, PharmD, RPh, North Dakota State Board of Pharmacy, chairperson; Deborah C. Mack, PD, RPh, CHC, CCEP, Arkansas State Board of Pharmacy; Tony King, PharmD, RPh, Montana Board of Pharmacy; Tejal Patel, PharmD, MBA, RPh, Delaware State Board of Pharmacy; Mark Klang, MS, PhD, RPh, BCNSP, New York State Board of Pharmacy; Pamela L. Marshall, RPh, Missouri Board of Pharmacy; Joanne Trifone, RPh, Massachusetts Board of Registration in Pharmacy; Caroline D. Juran, RPh, DPh, NABP Executive Committee liaison; and James Bracewell, BBA, Georgia.

# Department of Justice Priority Area: Enforcement Against Illegal Online Opioid Sales

**Libby Baney, JD,**
Faegre Baker Daniels Consulting

> **With the addition of the Joint Criminal Opioid Darknet Enforcement team to the DOJ's longstanding work of the Organized Crime Drug Enforcement Task Force program, indictments for illegal online sales of drugs are increasing.**

In recent months the United States Department of Justice (DOJ) and several state US attorneys have taken action against illegal online pharmacy websites, including those advertising and selling controlled substances (CS) and illicit narcotics. With the addition of the Joint Criminal Opioid Darknet Enforcement team to the DOJ's longstanding work of the Organized Crime Drug Enforcement Task Force program, indictments for illegal online sales of drugs are increasing.

## High-Profile Enforcement Action

Former Attorney General Jeff Sessions recently announced the indictment of two Chinese nationals for their role in distributing counterfeit and potentially dangerous drugs, including fentanyl and an estimated 250 others, to consumers in 25 countries and 37 states. According to the indictment, the defendants manufactured and distributed hundreds of different synthetic opioid analogues and other dangerous products through numerous websites, catering to patients and caregivers in more than 35 different languages. Co-conspirators within the US were responsible for repackaging and redistributing the drugs once they entered the country, feigning legitimacy and hiding the products' origin. Furthermore, the indictment also alleges the defendant agreed to produce adulterated cancer and anti-anxiety medications that would include dangerous synthetic drugs and non-drug substances. There are two acetyl fentanyl-related deaths associated with drug products sold by these illegitimate actors.

## Other Recent Actions

While startling, this case is not unique. Over the last several months, federal prosecutors have targeted several individuals advertising and selling adulterated or counterfeit health care products and prescription drugs peddled by actors that place profits ahead of public health and patient safety.

- In July 2018, the US attorneys for the Southern District of New York arrested two individuals for conspiracy to distribute CS and other synthetic and illicit narcotics over the internet. According to the indictment, the defendants conspired to distribute significant amounts of oxycodone, hydrocodone, and fentanyl analogues through a supposed online pharmacy.
- In Springfield, MO, federal prosecutors accepted a guilty plea from an individual for marketing misbranded dietary supplements found to contain sildenafil, an active pharmaceutical ingredient in some erectile dysfunction medications. He faces up to 23 years in federal prison without the opportunity for parole.
- In Euclid, OH, a 28-year-old individual pled guilty to the purchase and distribution of fentanyl and several analogues from China using cryptocurrencies.
- Three Canadian citizens were arraigned in July for the wholesale distribution of misbranded prescription drugs that lacked Food and Drug Administration approval due to the fact that they were made and labeled for use outside of the US. Many of the drug products were purchased from suppliers in Turkey and elsewhere and drop-shipped through the United Kingdom.

## Implications

As evidenced by the handful of cases under direction by federal prosecutors, it is clear that the threat of illegal online drug sellers still

persists on the surface web. This issue is only amplified further by the recently released statistics from the Centers for Disease Control and Prevention that estimated a 9.5% increase in the total number of drug overdose deaths in 2017 from the previous year, topping 72,000.

For more information about new efforts by the US government and boards of pharmacy to address the ongoing opioid epidemic, see "Continued Opioid Overdose Epidemic Prompts New Legislative Action" on page 8 of this newsletter.

As evidenced by previous NABP *Internet Drug Outlet Identification* reports, the number of websites selling CS or other drugs known to be adulterated with dangerous products is on the rise. This triumvirate of factors relating illegal online sellers and patient harms, especially overdose deaths due to synthetic narcotics, underscores the value of resources such as NABP's .Pharmacy Verified Websites Program to ensure that consumers remain safe and well educated when purchasing prescription medications online.

*Please note, the opinions and views expressed by Faegre Baker Daniels Consulting do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated.* ■

# NABP Report Shows How Social Media Sites Can Lead Consumers to Illegal Online Pharmacies

NABP recently published the September 2018 *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators*. The report shows how social media sites can lead consumers to dangerous rogue pharmacy sites through simple keyword searches.

The report findings are the result of an Association study in which staff conducted keyword searches on multiple social media platforms and easily found posts leading to rogue pharmacy websites selling commonly counterfeited and/or abused prescription medications. On the social media platform Pinterest, for example, NABP found 66 posts promoting the sale of medications, and 38% of these posts provided links to websites selling prescription medicines illegally. Characteristics of these illegal sites include selling medicine that was not approved by the United States Food and Drug Administration, not requiring a prescription, and selling controlled substances.

Keyword searches performed on Instagram, Facebook, Twitter, Reddit, and eBay garnered similar results.

Keywords and terms used to perform the searches included "Viagra," "Ciprofloxacin" (brand name Cipro®), and "Xanax for sale online." This review of social media sites was a subset of NABP's ongoing study of online drug sellers, which has found that 95% of websites selling prescription drugs online are doing so illegally.

NABP has been working with social media companies and other stakeholders to protect consumers from fake pharmacies. One example is Twitter's and Snapchat's requirement that advertisers of pharmacies and pharmacy products must be verified by NABP. In addition, NABP shared the results of the study with representatives from Pinterest, who said they are aware of the problem and are taking steps to further reduce the number of illicit Pins that slip through their filters.

The full report is available on the Program and Committee Reports page in the Publications and Reports section of *www.nabp.pharmacy*. ■

# Executive Officers Discuss Current Regulatory Challenges During NABP Interactive Forum

Thirty-five board of pharmacy executive officers gathered for the annual NABP Interactive Executive Officer Forum, held October 2-3, 2018, at NABP Headquarters. Themed "Left or Right? Making Medication Safe Again," the event offered attendees an opportunity to discuss challenges faced by the state boards, as well as reinforced the partnership between the boards of pharmacy and NABP and their shared mission to protect the public health. The meeting format featured two days of sessions to provide executive officers an opportunity to discuss specific topics as well as issues of special interest provided by invitees via a pre-meeting survey.

(Above) The session "Is the Special Counsel After You?" focused on the impact opioid lawsuits have on state boards of pharmacy and the implications of sending information via text messages. Pictured are (left to right) Steven W. Schierholt, Esq, executive director, State of Ohio Board of Pharmacy; Jessica A. Baer, JD, director, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy; session moderator Richard B. Mazzoni, RPh, member, NABP Executive Committee; Alexandra Blasi, JD, MBA, executive secretary, Kansas State Board of Pharmacy; and John Clay Kirtley, PharmD, RPh, executive director, Arkansas State Board of Pharmacy.

(Above) During the session "Big League Data Exchange: It's Going to Be Huge!," panelists discussed sharing data via Twitter and a new feature NABP is developing for e-Profile Connect. Pictured are (left to right) Nicole L. Chopski, PharmD, BCGP, ANP, member, NABP Executive Committee, who moderated the preceding Shared Discussion Topics session; Beverley Zwicker, BSc Pharm, registrar, Nova Scotia College of Pharmacists; session moderator Timothy D. Fensky, RPh, DPh, FACA, member, NABP Executive Committee; and Danna Droz, JD, RPh, PMP senior manager, NABP.

(Above) The session "Competency, Standards of Care, and ICE (Independent Confirmation of Eligibility)" focused on competency, standards of care, and independent confirmation of eligibility and how they relate to tariffs. Pictured are (left to right) Alex J. Adams, PharmD, MPH, executive director, Idaho State Board of Pharmacy; Lawana Lyons, licensure programs senior manager, NABP; session moderator Gary W. Dewhirst, RPh, DPh, member, NABP Executive Committee; and Maureen Garrity, PharmD, competency assessment director, NABP.

(Above) The session "Follow the Freedom Road – Republicans, Democrats, and Socialists – Oh My!" provided updates from the meetings of the NABP Suspicious Orders Work Group and the Task Force on Mutual-Recognition Licensure. Panelists also discussed perspectives on developing regulations based on standards of care in anticipation of the upcoming Task Force to Develop Regulations Based on Standards of Care. Pictured are (left to right) Darren R. Covington, JD, director, Indiana Board of Pharmacy; Virginia "Giny" Herold, MS, executive officer, California State Board of Pharmacy; session moderator Lenora S. Newsome, PD, member, NABP Executive Committee; Andrew Funk, PharmD, RPh, executive director, Iowa Board of Pharmacy; and Mark J. Hardy, PharmD, RPh, executive director, North Dakota State Board of Pharmacy.

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## Interactive Forum

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(Above) During the session "The Big Blue-Red Wave," panelists focused on the impact of federal policy on regulation of pharmacy in the states. Pictured are (left to right) session moderator Philip P. Burgess, MBA, DPh, RPh, member, NABP Executive Committee; Deena Speights-Napata, MA, executive director, Maryland Board of Pharmacy; Shauna White, MS, PharmD, RPh, executive director, District of Columbia Board of Pharmacy; and Bradley S. Hamilton, RPh, member, NABP Executive Committee, who moderated the Shared Discussion Topics session that followed.

(Above) The New Executive Officer Orientation Program was held the morning of Tuesday, October 2, 2018, prior to the events of the Interactive Executive Officer Forum. The orientation enabled newly appointed executive officers to get acquainted with NABP membership and governance. Pictured are (left to right) Larry A. Hadley, RPh, executive director, Kentucky Board of Pharmacy; Jack W. "Jay" Campbell IV, JD, RPh, member, NABP Executive Committee; Lisa V. Hunt, RPh, MBA-HM, executive director, Wyoming State Board of Pharmacy; Donna C. Yeatman, RPh, executive secretary, Alabama State Board of Pharmacy; Michael L. Goff, executive director, West Virginia Board of Pharmacy; and Jesse Cushman, office administrator, Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit.

# Sixteen Member Boards Deemed Blueprint States

*Participation Continues to Rise, Strengthening Uniform Inspection Processes*

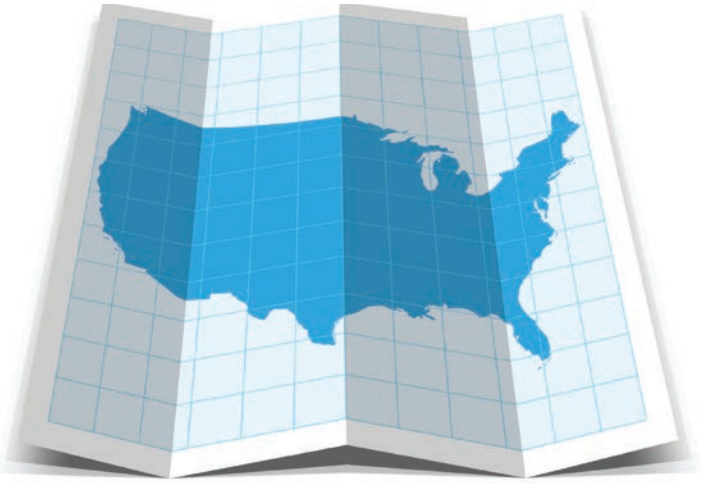
The Rhode Island Board of Pharmacy is the latest state to join the Multistate Pharmacy Inspection Blueprint Program, bringing the total number of "Blueprint states" to 16. The other states that have signed the Multistate Pharmacy Inspection Blueprint Program Participation Agreement include Arizona, Arkansas, Kentucky, Louisiana, Michigan, Mississippi, New Jersey, North Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, West Virginia, and Wyoming.

Member boards deemed Blueprint states share a common goal of ensuring that the sterile compounding pharmacies shipping products out-of-state are routinely and consistently inspected by trained inspectors. The participating states also aim to ensure that the inspection reports shared on these facilities reflect the robust, uniform approach of the Blueprint Program.

## Inspection Criteria and Qualified Training

Blueprint states utilize inspection forms and processes that cover the minimum requirements agreed upon by most member boards. These requirements focus on general areas of pharmacy and national compounding standards, primarily United States Pharmacopeia Chapter <797> and referenced chapters. To become a Blueprint state, boards may use either the Universal Inspection Form provided by NABP or their own state inspection form that has been cross-walked by NABP and deemed equivalent to the Universal Inspection Form.

Boards of pharmacy that join the Blueprint Program must ensure that the inspectors and compliance officers who conduct these inspections receive qualified training in inspecting sterile compounding facilities. Qualified training includes either the NABP and CriticalPoint



Sterile Compounding Inspector Training, where inspectors earn the CriticalPoint Certification in Sterile Compounding Inspections, in-state inspection training with NABP, or other training approved by NABP.

## Uniformity Across States

In keeping with its mission to protect public health, NABP continues to offer participating state boards an accessible database of consistent, current inspection information to help them make informed licensure decisions for nonresident compounding pharmacies. For more detail about how to become a Blueprint state or to learn more about sterile compounding training opportunities, contact the NABP Member Relations and Government Affairs department at GovernmentAffairs@nabp.pharmacy. ■

## Inspection Mapping Survey to Facilitate Nonresident State Decision Making

In summer 2018, NABP surveyed its member states and jurisdictions about their processes for conducting resident state inspections of pharmacies that engage in sterile compounding and ship those preparations to other states. There are a number of states that are unable to become a Blueprint state at this time for various reasons, such as lack of inspection resources or laws inconsistent with United States Pharmacopeia standards. However, because these states may actually be conducting inspections at or near Blueprint standards, the Association is developing a resource table (to be made available in late 2018). This resource will provide insight on a resident state's inspection program practices and capacities to assist nonresident states in evaluating whether to accept resident state inspection reports when making licensing or renewal decisions.

Balancing the needs of state boards in tandem with protecting the public health, NABP is working closely with board members, inspectors and compliance staff, and board executive officers to create tools and services that will enable state boards to exchange knowledge and build robust inspection programs within their state. ■

# CriticalPoint Grants Certifications to Sterile Compounding Inspectors in United States and Canada

NABP and CriticalPoint, LLC, are pleased to announce a new class of inspectors who earned the Certification in Sterile Compounding for Inspectors as part of the Sterile Compounding Inspector Training program. Individuals from several state boards of pharmacy, federal and state health departments, and other agencies attended informative classroom sessions and practicums that took place in cleanroom settings on July 16-19, 2018, completed the entire Sterile Compounding eLearning Series prior to attending the live on-site training, and successfully passed the post-test.

The Association partnered with CriticalPoint to launch this certificate program in 2016, in an effort to assist state boards of pharmacy in credentialing individuals to promote public health and safety for compounded medicines.

Congratulations to the following inspectors:

- Kerri O'Kane, Alberta College of Pharmacy
- Christopher Weimer, Connecticut Drug Control Division
- Zoe Glaras, Connecticut Drug Control Division
- William Moore, Georgia Drugs and Narcotics Agency
- Amy Hickerson, Idaho State Board of Pharmacy
- Shelley Rosebrook, Kansas State Board of Pharmacy
- John Romines, Kentucky Board of Pharmacy
- Huey Savoie, Louisiana Board of Pharmacy
- Jered Pasay, Maryland Board of Pharmacy
- Julienne Tran, Commonwealth of Massachusetts
- Tim Litsey, Minnesota Board of Pharmacy
- Aaron Patterson, Minnesota Board of Pharmacy
- Jill Phillips, Minnesota Board of Pharmacy
- Bennie Dean, Missouri Board of Pharmacy
- Yenh Long, Nevada State Board of Pharmacy
- Alejandro Amparan, New Mexico Board of Pharmacy
- Jooyung Han, New Mexico Board of Pharmacy
- Keevie Ridener, Oklahoma State Board of Pharmacy
- Scott Campbell, Rhode Island Department of Health
- Brittany Sharkey, Saskatchewan College of Pharmacy Professionals
- Robert Moura, Texas State Board of Pharmacy ■

### 2019 Sterile Compounding Training Dates

- July 9-12, 2019
- October 29-November 1, 2019

To register or learn more, visit *www.criticalpoint.info/sterile-compounding-inspector-training.*

# AWAR$_X$E's Prescription Drug Disposal Locator Tool Now Includes More Than 6,000 US Locations

The AWAR$_X$E® Prescription Drug Safety Program's Drug Disposal Locator Tool currently has more than 6,000 disposal locations and is continuously adding new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medication. In early 2018, NABP partnered with CVS and Walgreens to update the tool to include address and contact information for hundreds of pharmacies, law enforcement agencies, and other types of facilities where they had recently installed prescription drug disposal boxes. Independent pharmacies, retail pharmacies, and law enforcement agencies with disposal boxes are all included in AWAR$_X$E's nationwide database. Additionally, some locations include information on the types of medication they accept, such as controlled substances. The searchable database of disposal locations for prescription drugs can be found on the NABP website at *www.nabp.pharmacy/drug-disposal*.

Pharmacies or law enforcement agencies that offer permanent disposal sites may submit their locations for inclusion in the locator tool by downloading and emailing the form per the instructions on the site. Information about setting up permanent disposal boxes for pharmacies, long-term care facilities, and law enforcement agencies can be found under Pharmacist Resources in the AWAR$_X$E Prescription Drug Safety section on the NABP website. ■

# Security Awareness Training Provides Best Practices to Counter Cyber Threats

This past year, NABP accomplished two major feats with the relaunch of its e-Profile system, which now houses all program applications on one interconnected platform, and the launch of the NABP e-Profile Mobile App. Building on its data security initiatives, NABP continues to take proactive measures to protect its information systems.

In September 2018, NABP invited an industry expert to provide all staff with security awareness training. Staff were presented with common threats to data security via emails, fringe websites, and shared networks. Among the topics discussed were tools for identifying tactics used by bad actors as well as strategies for responding to these scenarios. The security awareness training also reinforced to staff the Association's policies and procedures related to protecting data.

## What Is Data Security?

From an information security perspective, security refers to protecting the characteristics of data – confidentiality, integrity, and availability (also known as CIA Triad). In other words, this means protecting who can see the data and change the data and ensuring that the data is available to authorized people.

Social engineering, malicious software (or malware), phishing, ransomware, and baiting are just some of the modern-day cyber threats facing organizations, governments, corporations, financial institutions, and other agencies alike. The objective of social engineering methods is to con people into disclosing confidential information or providing access to networks. In contrast to the technical vulnerabilities of computer programs, social engineering tactics take advantage of people through trust, fear, politeness, and helpfulness to exploit weaknesses.

One example of a social engineering tactic is phishing, which is the practice of sending emails that appear to be from a reputable source, such as a family member, friend, a well-known financial institution, or government agency. Phishing emails either make a promise or threaten people and require urgent action. Bad actors send phishing emails to gain access to a computer by installing programs, such as ransomware, that can lock a person out of his or her computer.


Other social engineering tactics include sending emails that contain malware (eg, viruses and spyware) hidden in attachments, internet downloads, and links to compromised websites. Baiting is another social engineering method, which entails a bad actor leaving a USB flash drive with malware on it and hoping a person finds it and inserts the flash drive into his or her computer.

## Enhancing Awareness

The purpose of the training was to inform staff of the best practices in securing and protecting information and integrating these practices into their day-to-day activities. In addition, the training session addressed the process for reporting suspected security incidents.

The industry expert shared some strategies to counter cyberattacks and imparted the following insights: delete suspicious emails without opening them; verify the identity of the person requesting sensitive data; encrypt confidential information; look for "https" at the beginning of web addresses; never share passwords; do not forward spam emails; and more. Staff were also advised on following established policies and procedures for using NABP computer equipment as well as maintaining physical security, including properly archiving or disposing of sensitive documents and locking computers when leaving workstations. NABP remains steadfast in enhancing and monitoring its resources, including ensuring the security and reliability of critical data, to assist the state boards of pharmacy in protecting public health.

A small percentage of security safeguards are technical and mostly rely on individuals to adhere to good security practices.

Further, the September 2018 security awareness training is one of the many ways the Association is continually exercising industry best practices for protecting its infrastructure. More details about NABP's prior data security initiatives – such as penetration testing, enhanced programming tools, and customer service processes – can be found in the November-December 2017, February 2018, and June-July 2018 issues of *Innovations*. As the Association stays abreast of industry trends for protecting data, any additional efforts will be relayed in future articles. ■

# Pharmacist-Administered Immunizations Now Allowed in All States; Limitations Vary Among Jurisdictions

Vaccines are known to be one of the greatest advancements to public health in the history of medicine. Edward Jenner's smallpox vaccine eventually led to the near-eradication of the once dreaded disease, and over the last century, diseases like tuberculosis, polio, and the measles have become extremely rare in most of the world. But, in addition to helping control and even eliminate diseases, the World Health Organization has described comprehensive vaccination programs as "a cornerstone of good public health" that can reduce inequities and poverty.

In the last 20 years, the ability for pharmacists to offer immunizations to consumers has undergone significant change in the United States. In 1995, only nine states allowed pharmacists to issue immunizations. Today, pharmacists in all 50 states, the District of Columbia, and Puerto Rico have authorization to provide certain vaccines to adults, if conditions are met.

> "In the last 20 years, the ability for pharmacists to offer immunizations to consumers has undergone significant change in the United States."

This regulatory shift began as part of a national effort to increase access to childhood and adolescent vaccines. However, as states began enacting new regulations, they often limited the availability of these services to adults only. As regulators have grown more comfortable with the concept of pharmacist-administered vaccines, that has changed. At least 27 states now allow pharmacists to administer vaccinations to patients of any age. Similarly, initial regulations often limited pharmacists to administering influenza vaccines only, but most states have now expanded that authorization, allowing pharmacists to offer routine vaccines for pneumonia, polio, shingles, Tdap (tetanus, diphtheria, and pertussis), and varicella (chicken pox). Many pharmacies also offer travel immunizations for meningitis, typhoid, yellow fever, and other diseases.

Reflecting this change in practice, all pharmacists who administer vaccines are trained to meet the Centers for Disease Control and Prevention (CDC) national immunization standards and recommendations by completing a nationally-recognized training program provided by the American Pharmacists Association.

## Low Vaccination Rate Cause for Concern

Despite pharmacists' expanding authority making immunizations more accessible, some public health officials have become concerned that US vaccination rates are too low. For example, measles vaccinations have fallen below what is known as the "herd immunity threshold," which is the

percentage of a population that must be immunized to protect a community from a vaccine-preventable disease. This is especially important for children who are too young to be vaccinated, and patients with weakened immune systems. CDC is one agency that has expressed concern over the statistics, which include the following:

- Since 2010, flu-related hospitalizations have ranged from 140,000 to 710,000 and flu-related deaths have ranged from 12,000 to 56,000.
- About 900,000 people get pneumococcal pneumonia every year, leading to as many as 400,000 hospitalizations and 19,000 deaths.
- 700,000 to 1.4 million people suffer from chronic hepatitis B, with complications such as liver cancer.
- Human papillomavirus (HPV) causes over 27,000 cancers in women and men each year. About 4,000 women die each year from cervical cancer.

## Why Pharmacist-Administered Vaccines May Help

Public health officials and many health care providers believe that improved vaccination rates may help reduce the adverse effects of vaccine-preventable illnesses on a community. For example, CDC's Healthy People 2020 initiative includes the goal to "increase immunization rates and reduce preventable infectious diseases."

Advocates for pharmacist-administered vaccines argue that pharmacists are better positioned to manage inventory of pharmaceutical products, including vaccines, when compared to other health care providers. In fact, some physicians already refer their patients to pharmacies for certain vaccinations. According to a 2012 survey of doctors, "only 31% of family physicians and 20% of general internists reported stocking all 11 adult vaccines that were recommended for routine use in 2012." The low number of physicians carrying these immunizations is most commonly attributed to financial concerns.

One study, published by Pacific Research Institute (PRI), *Promoting Access and Lowering Costs in Health Care: The Case for Empowering Pharmacists to Increase Adult Vaccination Rates* argues that regulation to improve pharmacists' ability to administer vaccines would increase vaccination rates, improve convenience for patients, and improve access to health care in rural areas. Another study published February 16, 2018, in the journal *Innovations in Pharmacy* found that the opportunity to receive a vaccine quickly without an appointment was an important factor for parents and their peers without children in choosing to use a pharmacy. Other factors included cost, counseling, and increased access to educational materials.

A variety of evidence supports the argument that pharmacist-administered vaccines can help increase vaccination rates. For example, consumers sometimes delay getting flu shots or other vaccines because it takes too much time to schedule an appointment and get access to a doctor. Pharmacies are often able to administer vaccinations without requiring an appointment or schedule patients for immunization appointments more quickly than physicians' offices. Because pharmacists are trained in immunization techniques and well-versed in how to administer shots, "more patients are receiving their vaccinations from pharmacists than other health care providers," NABP told *Consumer Reports* in 2017.

A recent pilot study in Washington also found that vaccination rates improved when pharmacists were given access to the necessary data and had the authority to act on the information. The authors of the study, published in *Population Health Management* in February 2018, examined the impact from eight community pharmacies in Washington that were granted access to patients' vaccination histories. Pharmacists were able to identify patients who were due for vaccinations. As a result, the eight community pharmacies increased the number of vaccines administered by 41.4% over the six-month pilot program.

## State Regulatory Differences

While all states now allow pharmacists to administer at least some immunizations under certain circumstances, the actual regulations vary greatly; however, in a 2017 article published in *Pharmacy Times*, Sharon Xavioer, PharmD, and Jeff Goad, PharmD, MPH, both with the Chapman University School of Pharmacy, classify these policies into three models, which are listed below:

- States that require a prescription from a physician. Requires that patients obtain prescriptions from physicians before vaccines can be administered at a pharmacy.
- States that require a vaccination protocol. The protocol determines which vaccines, under which conditions, and which procedures to follow for pharmacists administering vaccines. In some states, the protocols must be agreed to by a physician or, in some cases, a state public health department.
- States that empower pharmacists to independently vaccinate without a prescriber's order or protocol. In these cases, the state grants pharmacists the authority to directly screen, assess, and administer vaccines autonomously without a protocol or a prescription from a physician.

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## Vaccinations Update

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As of July 2016, 17 states allowed pharmacists to independently administer certain vaccines without a prescriber's order or protocol. These policies enable pharmacies to provide patients with vaccination services most efficiently. If applied to all adult vaccines recommended by CDC, "this policy will create the largest positive incentive to encourage greater adult vaccination rates," according to PRI. However, many of these states impose limits on the vaccines that pharmacists can independently administer. For example, several states authorize pharmacists only to administer the annual flu vaccine, while others restrict pharmacy-administered immunizations to flu, pneumococcal, and zoster. In addition, some states continue to impose age restrictions on who can receive access to this care.

Vaccination regulations in 33 states (states that require a prescription or vaccination protocol) have additional restrictions. In five of these states, pharmacists must first obtain a prescriber-issued protocol before they can administer a vaccine.

> **"Providing immunizations is a vital aspect of protecting the public health and a service that many pharmacists are trained to provide."**

State regulations regarding the HPV vaccine are an example of variance between states. Of 50 states and the District of Columbia, 40 jurisdictions had laws expressly granting pharmacists the authority to administer HPV vaccines to patients, according to a study published in *Public Health Reports* in December 2017. However, only 22 states authorized pharmacists to vaccinate preadolescents at the CDC-recommended age, and only five states allowed pharmacists prescriptive authority. Thirty-two states allowed prescriptive authority pursuant to general third-party authorization, and an additional three states allowed prescribing authority for patient-specific third-party authorization.

### Recent State Actions on Pharmacist-Provided Vaccines

Several states have taken recent regulatory action regarding pharmacist authorization to provide immunizations since 2017. In 2017, Idaho became the first state to allow certified pharmacy technicians to administer a vaccine if he or she has completed an Accreditation Council for Pharmacy Education (ACPE)-accredited course on appropriate immunization administration techniques and holds a current certification in basic life support from the American Heart Association or a comparable provider. A pharmacist must be available on site when the technician administers the immunization, but direct supervision by the pharmacist is not required.

In April 2017, Senate Bill 51 was signed into law in Indiana, allowing pharmacists to administer immunizations against measles, mumps, rubella, varicella, hepatitis A and B, and haemophilus influenzae type B under protocols set by the state health commissioner. Pharmacists were already authorized to administer immunizations for influenza, herpes zoster, pneumonia, tetanus, HPV, PPSV-23, and meningitis.

In Kansas, immunization authority for pharmacists was also expanded. With the rollout of the new regulations, pharmacists or interns who have completed a Board-approved ACPE-accredited course may administer influenza vaccines to patients over the age of six and may administer any other vaccine to patients over age 12.

On January 25, 2018, New York Governor Andrew Cuomo signed an executive order allowing children (ages two to 18) to receive flu shots at pharmacies in response to a particularly deadly flu season that resulted in a 9% increase in lab confirmed flu cases and deaths of at least four pediatric patients. In February, the governor announced a 30-day budget amendment that would provide permanent authorization for pharmacists to provide flu vaccines to patients age two and up.

Providing immunizations is a vital aspect of protecting the public health and a service that many pharmacists are trained to provide. By increasing vaccination rates, pharmacists help to reduce the spread of preventable diseases like HPV and hepatitis. Consumers who are interested in receiving vaccinations from their pharmacists should be encouraged to check with their health care provider about what immunizations are recommended for their circumstances. For additional information on this topic, including a map of which states follow certain policy models, access the PRI study at *www.pacificresearch.org/health-care*. ■

# 2017-2018 ACE Members Convene in August 2018

Members of the 2017-2018 Advisory Committee on Examinations (ACE) convened at NABP Headquarters in August 2018 to oversee the development and administration of the Association's examination and certification programs. Pictured are (left to right) Lenora S. Newsome, PD, NABP Executive Committee liaison; Bruce Waldrop, PhD, RPh, Samford University McWhorter School of Pharmacy (ex officio member, Foreign Pharmacy Graduate Equivalency Examination®/Pharmacy Curriculum Outcomes Assessment® program); Mark T. Conradi, JD, RPh, Clanton, AL (ex officio member, Multistate Pharmacy Jurisprudence Examination® program); Anita Young, EdD, RPh, Northeastern University Bouvé College of Health Sciences; Theresa M. Talbott, CVS Health; David Chikao Young, PharmD, RPh, Salt Lake City, UT; Michael A. Burleson, BSPharm, RPh, former executive director, Kentucky Board of Pharmacy; Debra Glass, BPharm, RPh, Tallahassee, FL; Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences; and Neal F. Walker, RPh, Hill City, MN.

# 2019 *Survey of Pharmacy Law* Available Soon

The 2019 edition of the *Survey of Pharmacy Law*, which will become available this December, is a valuable resource for anyone looking for an overview of the laws and regulations that govern pharmacy practice in all 50 states and three jurisdictions: District of Columbia, Guam, and Puerto Rico.

The *Survey*, which is published in a downloadable pdf format, consists of four chapters: a state-by-state overview of organization law, licensing law, drug law, and census data. The 2019 *Survey* includes state responses to the following four new questions:

**Section 16. Pharmacy Licensure Requirements:**

1. Does your state have a separate license category for specialty pharmacy?

**Section 20. Drug Control Regulations:**

2. Does your state have medical marijuana laws?
3. Does your state have cannabidiol laws?

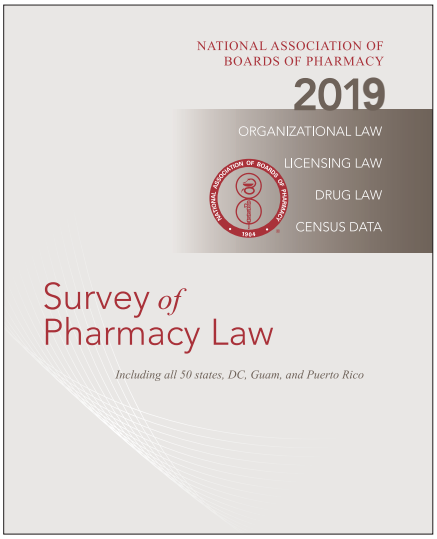
**Section 22. Prescription Requirements:**

4. Is a prescription order valid if based on an online questionnaire?

Updates for the 2019 *Survey* were graciously provided by the state boards of pharmacy.

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

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

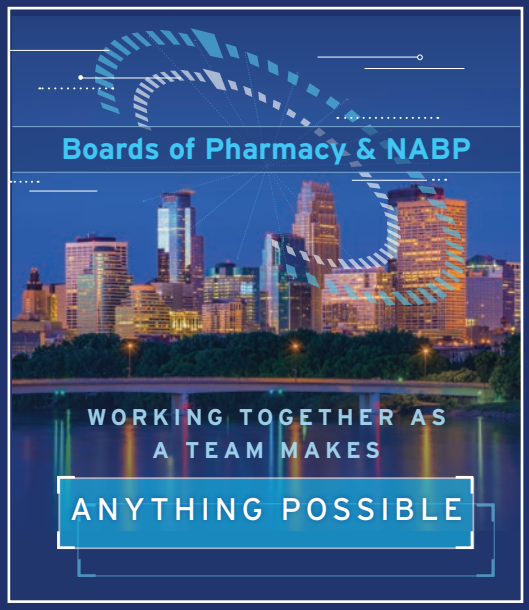



For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via email at help@nabp.pharmacy.

# Proposed Amendments to the NABP Constitution and Bylaws Due by April 1

To be considered during the 115th Annual Meeting, proposed amendments to the NABP Constitution and Bylaws:

- must be submitted between Friday, February 15, 2019, and Monday, April 1, 2019.
  - Proposed amendments will be accepted no earlier than 90 days and no later than 45 days before the First Business Session of the Annual Meeting.
- may be proposed by any active member board of pharmacy, the NABP Executive Committee, or the Committee on Constitution and Bylaws.
- must be submitted in writing to NABP Executive Director/Secretary Carmen A. Catizone
  - ExecOffice@nabp.pharmacy
  - NABP Headquarters
    1600 Feehanville Dr
    Mount Prospect, IL 60056 ■




## *Save the Date!*

**115th NABP Annual Meeting**

May 16-18 • 2019 • Minneapolis, MN

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

# Around the Association

## Executive Officer Changes

- **Traci Collier, PharmD, RPh,** has been named administrator/chief drug inspector, South Carolina Department of Labor, Licensing and Regulation – Board of Pharmacy, replacing Lee Ann Bundrick. Collier has served as the Board's assistant administrator since 2016. Prior to joining the Board staff, she spent 17 years with Kaiser Permanente working in various practice settings, including ambulatory care, pharmacy management, and pharmacy systems optimization.
- **Thomas "Tom" Ryan, MPA, JD,** has been named executive director of the Wisconsin Pharmacy Examining Board, replacing Dan Williams. Ryan has been the lead administrator for several boards during his 15 years of experience with the Wisconsin Department of Safety and Professional Services. He has served the Medical Examining Board, the Dentistry Examining Board (2003-2011), the Pharmacy Examining Board (2003-2011), and several other boards and councils. In addition, Ryan has been involved with several national regulatory federations in various capacities. He is currently a member of the Board of Directors of the Federation of State Medical Boards and the Federation of State Massage Therapy Boards (FSMTB). Recently, he served as chair of the FSMTB's Task Force on Human Trafficking and as chair of the Federation of State Boards of Physical Therapy Nominating Committee. He has prior experience with the Wisconsin Office of the Commissioner of Insurance and as a practicing attorney for Legal Action of Wisconsin.

## Board Member Appointments

- **Lewis McCleskey, RPh,** has been appointed a member of the New Mexico Board of Pharmacy. McCleskey's appointment will expire July 1, 2023.
- **Larry "Glenn" Bolyard, Jr, RPh,** has been appointed a member of the Virginia Board of Pharmacy. Bolyard's appointment will expire June 30, 2022.
- **James "Jim" Jenkins, Jr,** has been appointed a public member of the Virginia Board of Pharmacy. Jenkins' appointment will expire June 30, 2019.
- **Cheryl Nelson, RPh,** has been appointed a member of the Virginia Board of Pharmacy. Nelson's appointment will expire June 30, 2022.
- **Kristopher "Kris" Ratliff, DPh, RPh,** has been appointed a member of the Virginia Board of Pharmacy. Ratliff's appointment will expire June 30, 2022.
- **Patricia "Pat" Richards-Spruill, RPh,** has been appointed a member of the Virginia Board of Pharmacy. Richards-Spruill's appointment will expire June 30, 2022.

## Board Member Reappointments

- **Melvin L. Boone, Sr,** has been reappointed a public member of the Virginia Board of Pharmacy. Boone's appointment will expire June 30, 2022. ■

## Newly Accredited VIPPS Facilities

The following internet pharmacies were accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) program:

**Echo Drugs, Inc, dba Echo Care Specialty Pharmacy**
*www.echodrugs.net*

**ES Drugs, Inc, dba Matlock Specialty Pharmacy**
*www.matlockspecialtypharmacy.com*

**Indiana University Health, Inc**
*www.iuhealth.org/patients/pharmacies*

**Infinity Compounding Solutions, LLC, dba Infinity Care Solutions**
*www.icsrx.com*

**Trillium Health, Inc**
*www.mylocalrx.org*

A full listing of the accredited VIPPS pharmacy sites representing more than 16,900 pharmacies is available on the NABP website at *www.nabp.pharmacy.*

## Ohio Board Opens Medical Marijuana Helpline

The State of Ohio Board of Pharmacy announced the opening of the Ohio Medical Marijuana Control Program toll-free helpline in June 2018. The toll-free helpline responds to inquiries from patients, caregivers, and health professionals regarding adverse reactions to medical marijuana and provides information about available services and additional assistance as needed.

The Ohio Board has received questions about cannabidiol (CBD) oil (derived from hemp or marijuana). House Bill 523, which legalized medical marijuana and created the state's Medical Marijuana Control Program, includes CBD oil in the definition of marijuana, regardless of whether it is an extract or wholly synthesized. Additionally, the Board notes that all marijuana products will need to be dispensed in a licensed Medical Marijuana Control Program dispensary, and those products will have to comply with the rules and regulations of the program. All products must have a known source, as well as known quantities of active ingredients. Testing laboratories licensed by the Ohio Department of Commerce will conduct testing procedures.

The Medical Marijuana Control Program became operational in September 2018. For additional updates, visit the program's website at *www.medicalmarijuana.ohio.gov.*

## New Oklahoma Legislation Allows Pharmacists to Fill Non-CDS Prescriptions From Out-of-State Mid-Level Practitioners

As of November 1, 2018, Oklahoma pharmacies are able to fill non-controlled dangerous substance (CDS) prescriptions from out-of-state optometrists, physician assistants, advanced practice registered nurses-certified nurse practitioners, advanced practice registered nurses-certified nurse midwives, and advanced practice registered nurses-clinical nurse specialists. Additional information about Oklahoma's legislative updates is available in the August 2018 *Oklahoma State Board of Pharmacy Newsletter* found on the Board's contact page in the Boards of Pharmacy section of the NABP website.

## Minnesota's PMP Controlled Substance Alerts Continue to Decline

Since the Minnesota prescription monitoring program (PMP) began sending prescribers and pharmacies notifications in 2015 – known as "Controlled Substance Insight Alerts (CSIAs)" – to alert them when a patient's prescription history indicated a potential high-risk behavior, the number of notices distributed has declined each year. A total of 1,661 CSIAs were sent to prescribers in 2015, and in 2017, this number decreased to 322 prescriber notices. This decline may be due to several factors, including an increase in prescriber registration and use of the PMP database, and a rise in the awareness of controlled substance prescription misuse. PMP staff are considering the implementation of enhanced notices aimed at minimizing overdose risk and increasing patient safety. State and federal guidelines will be used in defining the additional patient safety notices currently under consideration. More information regarding CSIAs can be found under Frequently Asked Questions on the Minnesota PMP's website at *http://pmp.pharmacy.state.mn.us*.

## South Carolina Law Limits Initial Opioid Prescriptions

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy implemented a new law (S.918) that establishes limitations on initial opioid prescriptions for acute pain management or postoperative pain management and designates exceptions to those limitations. Section 1 was amended to require the following:

- Initial opioid prescriptions for acute pain management or postoperative pain management must not exceed a seven-day supply, except when clinically indicated for cancer pain, chronic pain, hospice care, palliative care, major trauma, major surgery, treatment of sickle cell disease, treatment of neonatal abstinence syndrome, or medication-assisted treatment for substance use disorder.
- Any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new opioid prescription.
- The amendment does not apply to opioid prescriptions issued by a practitioner who orders an opioid prescription to be wholly administered in a hospital, nursing home, hospice facility, or residential care facility.

The South Carolina Board specifies other requirements that were amended under the new legislation, which was passed by the South Carolina General Assembly on May 9, 2018, and signed into law by the governor on May 15, 2018. Additional details about S.918 can be found in the Board's *August 2018 Newsletter* available on the NABP website in the Boards of Pharmacy section. ■

Newsletters of state boards 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.

## First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first Food and Drug Administration (FDA)-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

## Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *againstopioidabuse.org*.

## Final *Opioid Analgesic REMS* Includes New Safety Measures

On September 18, 2018, FDA approved the final *Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)*. Now, the new *Opioid Analgesic REMS:*

- Applies to immediate-release opioid analgesics intended for outpatient use, as well as the extended-release and long-acting opioid analgesics, which have been subject to a REMS since 2012.
- Includes several measures to help better communicate the serious risks about the use of opioid pain medications to patients and health care professionals.
- Requires that training be made available to all health care providers who are involved in the management of patients with pain, including nurses and pharmacists.
- Requires that the education cover broader information about appropriate pain management, including alternatives to opioids for the treatment of pain.

FDA is also approving new product labeling containing information about the health care provider education available through the new REMS, notes the agency's news release, which can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620935.htm*.

Further, FDA also approved the new *FDA Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (FDA Blueprint)*, which includes updated educational content. The continuing education (CE) training under the modified REMS is expected to be available to health care providers by March 2019.

According to FDA, drug companies with approved opioid analgesics will provide unrestricted grants to accredited CE providers for the development of education courses for health care providers based on the September 2018 *FDA Blueprint*. FDA maintains a website listing the medications with approved REMS that are currently active and their associated materials on the REMS@FDA website at *www accessdata.fda.gov/scripts/cder/rems/index.cfm*. To download a pdf of the FDA Blueprint and to obtain background resources on the Opioid Analgesic REMS, visit *www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm*.

## Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, FDA issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). The following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcement of manufacturers' requirement to include product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm621095.htm.* ■

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## UPCOMING EVENTS

**Committee on Law Enforcement/ Legislation**
January 23-24, 2019
NABP Headquarters

**Committee on Constitution and Bylaws**
April 8, 2019
Teleconference

**FPGEE Administration**
April 10, 2019

**NABP 115th Annual Meeting**
May 16-18, 2019
Minneapolis, MN

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