

INNOVATIONS®



Reassess, Rebrand

Positioning NABP for a Future of Continued Member Value



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*NABP Executive
Committee elections
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Association's Annual
Meeting.*

Innovations

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Interview With a Board Executive Director



**Larry A. Hadley, RPh,
Executive Director,
Kentucky Board of Pharmacy**

Larry A. Hadley, RPh, Executive Director, Kentucky Board of Pharmacy

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

I have served as executive director of the Kentucky Board of Pharmacy since January 1, 2018. Prior to being appointed executive director, I served as a member of the Board for eight years, from January 1, 2009, through December 31, 2016. My career prior to appointment as executive director was primarily in community retail as a store pharmacist, pharmacist-in-charge, and district and regional manager for one regional and one national chain. Additionally, I owned an independent pharmacy in partnership with a classmate from the University of Kentucky College of Pharmacy. We sold the store in March 2017.

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

All boards of pharmacy are dealing with many significant issues in the current regulatory environment. The Commonwealth of Kentucky passed legislation that requires the promulgating agency to review every regulation every seven years. The process began last year and, being the first year, we had 31 regulations to review. Our options are to amend, keep as is, repeal, allow to expire, or incorporate with another regulation. The Board has 18 months to address these regulations.

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

The Board created a regulation review committee consisting of the Board president, Board staff members, and members of various stakeholder groups across the state to accomplish the task. The first committee meeting was to triage the 31 regulations, deciding which of the available options to adopt for each regulation. Subsequent meetings have dealt primarily with wordsmithing for those regulations that are to be amended. We have six regulations remaining that require updated language. The others are proceeding through the regulatory process.

What other key issues has the Board been focusing on?

We are also focusing on issues that include United States Pharmacopeia Chapters <795>, <797>, and <800>; opioid use disorder; telepharmacy; board-authorized protocols; safe medication disposal; cannabidiol oil; medication errors; unused permits; pharmacy services in long-term care facilities; pharmacists practicing in non-permitted areas; and requests for approval for unique practice ideas.

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

Our experience has been to create topic-specific committees with Board members, Board staff, stakeholders, and other interested parties. These committees should meet at least once a month for at least two hours each time to ensure they can accomplish the work they need to do to meet the charge from the Board in a reasonable period of time. ■

Kentucky Board of Pharmacy

Number of Board Members: 5 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors: 5

Rules and Regulations Established by: Board of pharmacy

Number of Pharmacist Licensees: 9,889

Number of Pharmacies: 2,071

Number of Wholesale Distributors: 1,406

The Rise of Security Threats and Online Pharmacies – The Perfect Cybersecurity Storm



Doriann Cain, JD,
Faegre Baker Daniels LLP

“As cybercriminals develop new mechanisms to breach systems, it is paramount that pharmacies – especially those with a strong online presence – develop a clear, specific, and current incident response plan.”

The health care landscape continues to evolve with the rise of e-commerce, growing digital health offerings, and the globalization of pharma production, leading to a growing need for online pharmacies. At the same time, we are entering a period where we are seeing a continuous rise in cyberattacks in the health care arena through technology connected to the internet. While providers and consumers are reliant on these technologies to facilitate clinical support and data aggregation, they are often not secured appropriately, leading to attackers shutting down entire systems, siphoning off patient data, and hijacking online portals to mine cryptocurrency.

To understand why there is such an enormous target on pharmacies and, specifically, online pharmacies, it is important to understand the value of health care data. The information in patient files can include names, Social Security numbers, financial information, and dates of birth, to name a few. This information is highly valuable on the dark web because it is possible for individuals to steal identities, procure fraudulent prescriptions, and secure financial gain. Simply put, hackers see the greatest payout when targeting health care technology.

Additionally, health care data sets are growing rapidly, both in size and intricacy, increasing the incentive to extort them; the pharmacy community is experiencing internet-based consulting, remote workers, and patients accessing their records online, meaning the attack surface is expanding exponentially.

Along with these risks comes great cost. According to the Ponemon

Institute, the average cost of a breach in the health care sector is \$408 per record compared to the financial and service industries, where the average cost is \$206 and \$181 per record, respectively. These numbers take into account civil money penalties, interruption of critical business functions, reduction in credit worthiness, reputation, and loss of future business, demonstrating the importance of protecting health information.

In this article, we discuss considerations for ensuring the safety of patient information in today's technologically focused era.

Data Mapping

Understanding how a pharmacy transmits, maintains, creates, and receives data is the foundation of any security program. If an organization does not understand where its data lives, it is impossible to protect it. With the increase of networks and vendors being utilized in the pharmacy community, it is important to understand the life cycle of medical information to ensure there are no unknown exposure points.

Incident Response Plan

Being prepared to respond to a cyberattack is one of the most important steps pharmacies can take. As cybercriminals develop new mechanisms to breach systems, it is paramount that pharmacies – especially those with a strong online presence – develop a clear, specific, and current incident response plan. A well-implemented incident response plan can decrease damage, improve recovery time, and alleviate losses after a security incident.

When drafting an incident response plan, it is important to identify key team members and stakeholders who have decision-making authority in the event of a cyberattack. Pharmacies should also define security incident types. In this day and age, there are a multitude of different types of attacks, but these incidents may not rise to the level of a reportable breach. Accordingly, it is important that an incident response plan addresses these different situations.

The plan should also discuss how the organization will contain the incident, the process for preservation to ensure all artifacts and details of the incident are gathered for further analysis, how the organization will return its systems back to normal, and how it will conduct post-incident analyses.

Security Risk Assessment

It is not unusual for pharmacy systems to interface through the Cloud, and most pharmacies today have a system that interconnects with an e-prescribing network. Pharmacy regulators may want to consider encouraging pharmacies to conduct annual vulnerability assessments on all systems, so that the organization can identify security gaps that need to be mitigated. Additionally, the security assessment will alert pharmacies to those critical security controls that should be in place to monitor the activities of all pharmacy systems and networks.

Vendor Assessment

In addition to recognizing the cybersecurity risks within their systems, pharmacies should also take an active approach in evaluating their vendors. Pharmacies should establish



a vendor diligence program that includes procedures to identify and assess vendor risk, policies outlining the minimum cybersecurity practices that they require from vendors, and due diligence questionnaires to evaluate vendors' cybersecurity practices, including a review of any security risk assessments completed by vendors.

Employee Training

It is not enough for pharmacies to employ robust firewalls, disaster recovery plans, workstation security measures, and other defenses, as the human factor continues to be one of the weakest links.

To minimize human error, pharmacy regulators may also want to consider actively engaging organizations, alerting them of the need to continuously remind all staff about risky behavior. This includes anything

from downloading unauthorized software and creating weak passwords to clicking on malicious links. Pharmacies should also educate employees on these threats to reduce internal risks. Training should be done on at least an annual basis and should be tailored to fit individual job descriptions.

As pharmacy regulators and other relevant stakeholders continue to shepherd the increased use of technology into pharmacy practice, it is critical to develop and implement cybersecurity into the culture of every pharmacy.

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

NABP Surveyors/Inspectors Participate in Annual Training



(Left) NABP surveyors met for their annual workshop on July 29-31, 2019, at NABP Headquarters. The surveyor workshop included compliance updates for accreditation and inspection programs; an overview of the changes to United States Pharmacopeia Chapters <795>, <797>, and <800>; training and updates on the Health Insurance Portability and Accountability Act; a forum with questions and answers; and more. Surveyors/inspectors who inspect sterile compounding facilities also completed gown and garb training, during which they learned how to dress appropriately for sterile compounding. ■

Board Staff Network, Learn About NABP Programs and Services at Annual Program Review and Training



(Above) Twenty board of pharmacy staff representing 16 boards of pharmacy attended the NABP Annual Program Review and Training session on June 18-19, 2019, at NABP Headquarters. The two-day interactive session provided information about NABP's examinations, licensure transfer, accreditation programs, and more. Information about the 2020 training, which will take place in summer 2020, will be provided in future issues of *Innovations*. ■



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.

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.

**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

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.”

Reassess, Rebrand

Positioning NABP for a Future of Continued Member Value



In August 2019, NABP changed its logo as part of an Association-wide rebranding. The new NABP logo was released on NABP’s websites, social media platforms, electronic newsletters, and documents. Redesigns of various documents will be released throughout the year to meet new branding guidelines, which include updates to the typeface, colors, and imagery. The Association is excited to announce this brand update and the reasons behind it.

“The sleek and modern design retains elements of the original logo, connecting us to our past and exemplifying how the Association will continue to adapt and change as we support the boards of pharmacy and their missions, now and in the future.”

A great deal of thought went into considering whether the brand should be updated. After many weeks of research and strategizing, the Association moved forward in designing a new look for NABP.

The Association’s mission to support the boards of pharmacy in protecting the public health has remained unchanged, but the breadth of program and service offerings has grown exponentially since the previous NABP logo was developed and adopted for use by the Association. In less than two decades, the Association has developed 15 new programs and services to provide innovative solutions to the evolving challenges encountered by our member boards, pharmacists, pharmacies, and consumers in an ever-changing pharmacy landscape. The new NABP logo was designed to reflect this innovation. The sleek and modern design retains elements of the original logo, connecting us to our past and exemplifying how the Association will continue to adapt and change as we support the boards of pharmacy and their missions, now and in the future.

What Is a Brand?

In today’s digital world, where we are always connected and inundated with information, brand is a familiar concept. Specifically, a brand is the corporate image as a whole. For example, an audience may feel an organization is trustworthy, fun, trendsetting, caring, adventurous, or have any other type of emotional reaction to the business. A brand’s identity encompasses the visual aspects of the overall brand, including logos, which are intended to quickly and visibly identify a business or product. The brand identity forms a part of the overall brand and also includes the voice of its publications, the look and feel of its website, and the look of program promotional materials – to name just a few items.

To focus the NABP brand, working with consultants, NABP took an in-depth look at the Association, its members, customers, and competition. NABP has a strong mission and vision statement that guides us and explains who we are,

what we do, and who we serve, but it was important to re-examine these basic truths due to the growth of the Association and changes in the practice of pharmacy and pharmacy regulation. Confirming NABP's value and offerings was key to the rebranding efforts.

Understanding the NABP Audience

Understanding an audience is a key component to any branding review process. When NABP's previous logo was released, the Association's business focus was much narrower. Today, the primary audience is still our member boards of pharmacy; however, the Association now has more audiences that it must speak to so that it may support and expand the programs and services provided for the benefit of the member boards. By creating successful programs and services for others in the pharmacy industry, NABP can better protect public health as well as fund services that assist the boards.

For example, as part of this process, NABP staff reviewed the audiences that the Association is currently reaching out to with its messaging. NABP audiences span a wide spectrum, from boards of pharmacy executive directors and staff, to pharmacists, pharmacy students, and pharmacies; to wholesale distributors and industry experts; to legislators and consumers.

In examining the Association's strengths, NABP staff determined the value the Association brought to each audience type. For example, for boards of pharmacy, the Association works to provide support for their work and overall mission. Consumers, on the other hand, receive education and peace of mind regarding things like their ability to safely buy medications online or to learn about medication safety.

Some of the shared value offerings NABP provides to all audiences includes trustworthiness and our focus on protecting public health.

In considering the future of NABP branding, staff determined it was important to convey these values and traits in a new way because of the consistent growth in programs and the changes in the way NABP delivers its services.

Branding the Future NABP

A major achievement for the Association was the launch of the NABP e-Profile system in 2011, and the relaunch of the e-Profile system in 2018. The participation of pharmacists, technicians, the member boards, and other stakeholders has created a wealth of data that NABP can now serve back to these audiences to make their professional lives easier. This data also creates valuable information that NABP and the boards of pharmacy can use to further protect the public health.

Combining the old with the new, NABP's updated brand design elements aim to convey the Association as a future-focused thought leader that is informed by a rich history. Through the rebranding, the Association strives to ensure NABP is recognized for all that it offers throughout the pharmacy industry, including support for its member boards of pharmacy as examination developer and administrator, license transfer facilitator, accreditation provider, and a protector of public health.

The new, modernized NABP logo takes all the elements from the traditional logo and presents them in a streamlined, 21st century aesthetic. The updated logo will become a primary branding element for the Association, making it easier for audiences to tie together all the programs and services that NABP has to offer. NABP looks forward to rolling out newly designed pieces that reflect the new branding over the next several months. ■



- The serpent represents medicine dating back to ancient Greece.
- The Bowl of Hygieia represents good health and hygiene.
- The Rod of Asclepius represents compliance and authority.

The above is NABP's master symbol. The symbol reminds us that the Association's important work will continue to adapt and change as it supports the boards of pharmacy and public health now and in the future.



NABP's logo, shown left, is a combination of a wordmark and a symbol. Together, they represent the NABP brand attributes and personality. While these two elements complement each other, they may also stand on their own.

New NABP Accreditations and Verifications

The following entities were recently granted NABP verification or accreditation through the select programs noted below. Full listings of .Pharmacy Verified Websites can be found in the Find a Safe Site section at www.safe.pharmacy, and full listings of Verified Internet Pharmacy Practice Sites® (VIPPS®)-accredited facilities can be found in the Programs section at www.nabp.pharmacy. ■

Accredited VIPPS Facility

Millennial Benefit Management Corporation, dba

MailMyPrescriptions.com
www.mailmyprescriptions.com

.Pharmacy Verified Websites

Accredo Health Group, Inc

<http://accredo.pharmacy>
www.accredo.com

AllyScripts, LLC

www.allyscripts.pharmacy
www.allyscripts.com

AON Pharmacy, LLC

www.aon.pharmacy
www.aoncology.com

Brightwater Laboratories, Inc

www.vetmedics.pharmacy
www.vetmedicspharmacy.com

BSB Veterinary Corp

www.petvm.pharmacy
www.petvm.com

Casella California Inc

www.desert.pharmacy
www.desertrx.com

Confidential Drug, LLC

www.confidentialdrug.pharmacy
www.confidentialdrug.com

Creech & Gibbs Pharmacy

www.creechngibbs.pharmacy
www.creechngibbs.com

Empire Pharmaceutical Associates, Inc

www.empirehealthpharmacy.pharmacy
www.empirehealthpharmacy.com

EntirelyPets Pharmacy, LLC

www.entirelypetspharmacy.pharmacy
www.entirelypetspharmacy.com

GoodRx, Inc (AAA)

www.aaa.pharmacy
www.aaarx.pharmacy
www.aaarx.com

GoodRx, Inc (Iodine)

<https://iodine.pharmacy>
www.iodine.com

GoodRx, Inc (Kroger Rx Savings Club)

www.krogersc.pharmacy
www.krogersc.com

Grassy Sprain Pharmacy Inc

www.grassysprainpharmacy.pharmacy
www.grassysprainpharmacy.com

Henry Ford Health System

<https://pharmacyadvantagerx.pharmacy>
www.PharmacyAdvantageRx.com

Honeybee Health, Inc

www.honeybeehealth.pharmacy
www.honeybeehealth.com

Hope Specialty Pharmacy

www.pharm-assist.pharmacy
www.pharm-assist.com

Kester Drugs Inc

www.oswalds.pharmacy
www.oswaldspharmacy.com

Lambert Vet Supply

www.lambertvetsupply.pharmacy
www.petsupplies4less.pharmacy
www.petchoicepharmacy.pharmacy
www.lambertvetsupply.com

London Drugs Ltd

www.londondrugs.pharmacy
www.londondrugs.com

Lynnfield Drug, Inc

www.freedomfertility.pharmacy
www.freedomfertility.com

Managed Health Solutions LLC

www.mhs.pharmacy
www.managedhealthsolutionsrx.com

MedImpact Healthcare Systems

www.medimpactdirect.pharmacy
www.medimpactdirect.com

MedImpact Healthcare Systems, Inc

www.medimpact.pharmacy
www.medimpact.com

Mills Specialty Pharmacy, LLC

www.millsspecialty.pharmacy
www.millsspecialty.com

Pet's Choice Pharmacy

www.petschoicepharmacy.pharmacy
www.petschoicepharmacy.com

PharmacyNC

www.pharmacync.pharmacy
www.pharmacync.com

Raley's

<http://raleys.pharmacy>
www.raleys.com

Revival Animal Health

www.revivalanimal.pharmacy
www.revivalanimal.com

SMP Acquisition Co, Inc

www.smp.pharmacy
www.smppharmacy.com

Valisure, LLC

www.valisure.pharmacy
www.valisure.com

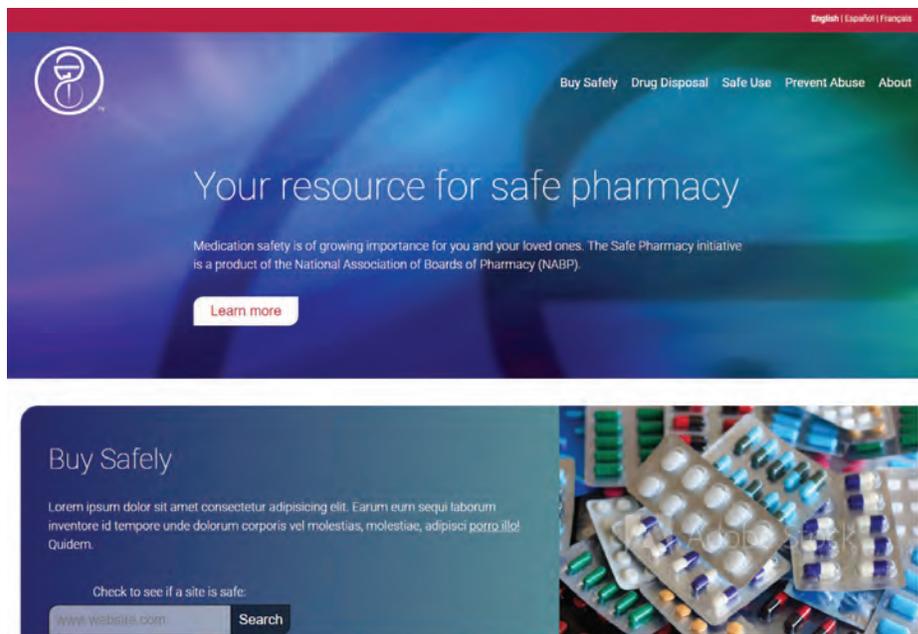
VMC Grace

www.gateway.pharmacy
www.mygatewaypharmacy.com

New *Safe.pharmacy* Site to Launch, Providing Information on Safe Drug Disposal Opportunities for Consumers *Website Changes Set the Focus for New Consumer Education Campaign*

In early September 2019, NABP will be updating its *safe.pharmacy* consumer website and consolidating a wealth of information about safe online pharmacies, prescription drug safety, and safe drug disposal in one place for consumers. The *safe.pharmacy* site will contain content for the .Pharmacy Verified Websites Program as well as the AWA_xE[®] Prescription Drug Safety Program, which will be moving from the Initiatives section of *nabp.pharmacy*. The .Pharmacy Program helps consumers find safe and legitimate websites for purchasing medication online and obtaining medication-related information, and the AWA_xE program educates consumers about buying, using, and disposing of medications safely, and allows users to quickly and easily find permanent drug disposal locations near them. By aggregating the content for these programs onto one website, NABP has created a one-stop shop for consumers to find a vast array of information related to prescription drug safety.

“By aggregating the content for these programs onto one website, NABP has created a one-stop shop for consumers to find a vast array of information related to prescription drug safety.”



Pictured above is the new *safe.pharmacy* home page. The website will offer consumers a wealth of information about safe online pharmacies, prescription drug safety, and safe drug disposal in one place.

Another component of the *safe .pharmacy* website changes is the website's redesign. For several years, the site has featured the branding of the .Pharmacy Program. Now, the site will be redesigned using the new NABP brand components. For more information about the NABP branding changes, see pages 8-9 of this newsletter.

New Consumer Education Campaign

In conjunction with the website update, NABP will launch its 2019 consumer education campaign, which focuses on the Association's locator tool for permanent prescription drug disposal sites. The Association is building on the success of its 2018 campaign, which focused on educating consumers about the role that NABP and the state boards of pharmacy take in ensuring safe medication use. The 2018 campaign included public service

announcements (PSAs), web banner ads and video ads, and a satellite media tour that included interviews with NABP Past Presidents Jeanne D. Waggener, RPh, DPh, and Joseph L. Adams, RPh. Year-end results from the 2018 campaign were strong. Some examples include the television and radio PSAs, which received over 163.3 million audience impressions and nearly \$5 million in donated media value. In addition, web banner ads and video pre-rolls that appeared on WebMD led thousands to the *safe .pharmacy* website.

This year's campaign will include several similar components, including television and radio PSAs, online banner display ads, and video ads. The PSAs will be played in large and small markets throughout the United States and at various times of day,

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Consumer Website

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enabling NABP to reach millions of consumers with important information about disposing of medications the safe way. Banner display ads and video ads will be shown to specific consumers on *WebMD.com* based on their keyword and topic searches, providing a targeted approach to reaching individuals with a need for information about medication disposal. In addition, NABP video ads will be played across premium video content sites with national distribution and will be targeted to specific individuals based on demographic characteristics and keyword searches. The various campaign components all direct consumers to the revamped *safe.pharmacy* website, where they can find detailed information about safe, proper disposal of unused, unwanted, and expired prescription and over-the-counter medications as well as all aspects of safe medication use and purchasing.

Drug Disposal Locator Tool Continues to Add Locations

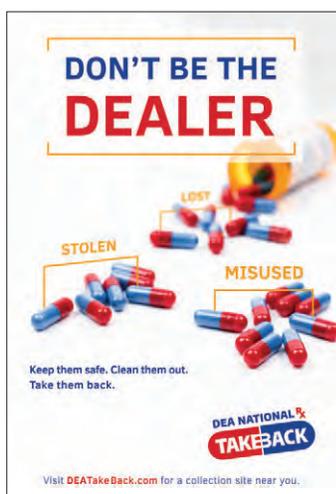
Many individuals end up with unneeded or expired medications but have no idea how to safely dispose of them. The AWAR_xE Drug Disposal Locator Tool gives consumers a quick,



NABP's 2019 consumer awareness campaign includes television and radio public service announcements, online banner display ads, and video ads. Targeted to specific individuals based on demographic characteristics and keyword searches, the video ads will be played across premium video content sites with national distribution.

easy way to find a permanent drug disposal location near them. AWAR_xE's nationwide database currently contains more than 7,000 drug disposal sites, including independent pharmacies, retail pharmacies, and law enforcement agencies with disposal boxes. Additionally, some locations include information on the types of medication they accept, such as controlled substances. NABP is continuously adding more sites to the Drug Disposal Locator Tool to provide consumers with a safe way to dispose of medications and help prevent

misuse and abuse of prescription drugs. If no permanent disposal sites are available near the search location, consumers are directed to information about other methods of safe disposal that can be done at home. The searchable database of US drug disposal locations will be available on the new *safe.pharmacy* website under Drug Disposal. Until the website launches in September, consumers can find the Drug Disposal Locator Tool in the Initiatives section of the NABP website. ■



DEA to Hold 18th Prescription Drug Take-Back Day on Saturday, October 26, 2019

Drug Enforcement Administration (DEA) will hold a National Prescription Drug Take-Back Day event on Saturday, October 26, from 10 AM to 2 PM, at participating locations nationwide. DEA will list collection sites on its website. Consumers unable to visit a location on the Take-Back Day can find permanent disposal locations using the AWAR_xE[®] Prescription Drug Safety Program's Drug Disposal Locator Tool, which will be soon moving from the Initiatives section of the NABP website to the Drug Disposal section at www.safe.pharmacy. Pharmacies that offer permanent disposal sites are encouraged to submit their location for inclusion in the locator tool by downloading and emailing the form per the instructions on the site. ■

MPJE Review Committee Convenes in June 2019

Members of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee met at NABP Headquarters in June 2019 to review MPJE questions to ensure compliance with pharmacy law as it applies to contemporary practice. ■



(Above) Susan McCoy, RPh, Mississippi Board of Pharmacy (left), and Alan M. Shepley, RPh, Mount Vernon, IA.

(Below) Mark Brown, MBA, RPh, Lahaina, HI (left), and Debra Glass, BPharm, RPh, Tallahassee, FL, Advisory Committee on Examinations representative.



NABP's *Innovations* Receives Award for Editorial Excellence

NABP received a 2019 EXCEL Award during Association Media & Publishing's (AM&P's) 39th Annual EXCEL Awards Gala, held June 24, 2019, at the National Housing Center in Washington, DC. AM&P's prestigious EXCEL Award program recognizes excellence and leadership in nonprofit association media, publishing, marketing, and communications.

NABP received the honor in the Editorial Excellence (Print) category for the April 2018 issue of *Innovations*. NABP received the Bronze award level.

AM&P's 2019 EXCEL Awards program drew 750 entries in seven broad categories ranging from digital publishing

and magazines to books and promotional campaigns. Of those, the judges selected 248 entries to receive EXCEL Awards. During the Awards Gala, AM&P announced the award levels for each of the awards (Gold, Silver, and Bronze). The 2019 EXCEL Award winners will be featured in the August/September issue of AM&P's *Signature* magazine. ■



Model Act Updates Address Suspicious Orders, PMP Reporting for Veterinarians, and More



NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to provide the state boards of pharmacy with model language that may be used for developing state laws or board rules for purposes of protecting the public health. Amendments to the *Model Act* were incorporated as a result of the NABP Executive Committee-approved recommendations suggested by the Suspicious Orders Work Group, the Task Force to Develop Regulations Based on Standards of Care, the NABP

PMP InterConnect® Steering Committee, and the 2019 Committee on Law Enforcement/Legislation. The following is a summary of the *Model Act* changes.

“Committee members also ensured the *Model Act* is consistent with the Drug Supply Chain Security Act by adding ‘manufacturer, repackager, and third-party logistics provider’ in the applicable places where ‘wholesale distributor’ appears.”

Suspicious Orders

The Committee on Law Enforcement/Legislation approved the *Model Act* amendments suggested by the Suspicious Orders Work Group with revisions.

The committee’s amendments account for the recently passed SUPPORT for Patients and Communities Act, which puts into place a process to develop a suspicious order reporting system at the federal level. For example, committee members recommended that manufacturers, repackagers, third-party logistics providers, and wholesale distributors that do not distribute controlled substances (CS) or drugs of concern be able to apply for an exemption from this federal reporting system, if it is established.

Committee members also ensured the *Model Act* is consistent with the Drug Supply Chain Security Act by adding “manufacturer, repackager, and third-party logistics provider” in the applicable places where “wholesale distributor” appears.

Committee members agreed that it is imperative to require truthful reporting regarding orders to prescription drug suppliers when asked. Therefore, the Committee on Law Enforcement/Legislation recommended that the responsibility to provide truthful information should be shared by the pharmacist-in-charge and the pharmacy

permittee/owner. To further enforce this responsibility, the willful misreporting of purchase order information was added to the *Model Act's* Unprofessional Conduct section.

The Committee on Law Enforcement/Legislation reviewed the definitions recommended by the Suspicious Orders Work Group and further revised the definitions of “diversion activity,” “drug of concern,” and “suspicious order.”

The Committee on Law Enforcement/Legislation also updated the *Model Act* in order to limit barriers, so that in cases of emergency, needed medications may be dispensed by pharmacies in a timely manner. The *Model Act* was amended to provide for pharmacies that need a CS or drug of concern outside of their normal ordering pattern to submit documentation of an emergent need for a specific patient. Also, manufacturers, repackagers, third-party logistics providers, and wholesale distributors should have procedures for responding to customers who submit purchase orders for patients with emergent needs.

Standards of Care-Based Regulations

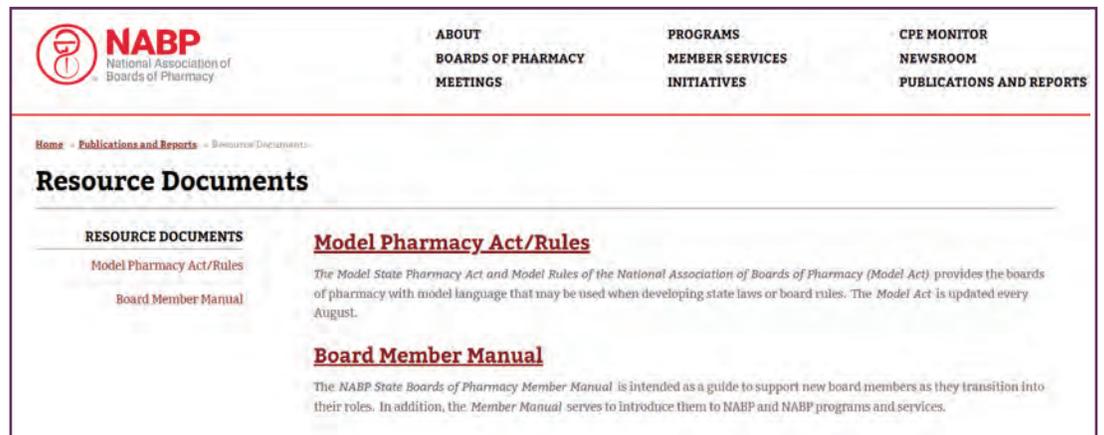
The *Model Act* now contains a definition for “standard of care” due to the input of both the Task Force to Develop Regulations Based on Standards of Care and the Committee on Law Enforcement/Legislation. The new definition was made broad to not be pharmacist-specific, so it can apply to other licensees, such as pharmacy technicians. In addition, amendments were made to the footnote regarding objectives of pharmacist care

services to include a reference to standards of care.

Veterinary Submissions to PMPs

The PMP Steering Committee suggested amendments to the *Model Act*, which were revised by the Committee on Law Enforcement/Legislation, in order to address the trend where drug seekers harm their pets or mislead the veterinarian in order to obtain CS. This type of misuse and abuse has caused many states to require veterinary prescriptions to be reported to the state’s prescription monitoring program (PMP).

One issue that has contributed to this problem is that veterinarians are not required to get Drug Enforcement Administration registrations to prescribe drugs of concern, and veterinarians are also not eligible for a National Provider Identifier. This makes it hard to find a consistent way to identify veterinarian prescribers in PMP reporting. This led to the decision to add to the footnote in Appendix F, Model Prescription Monitoring Program Act, to specify using the veterinarian’s state license number for prescriber identification purposes.



The *Model State Pharmacy Act and Rules of the National Association of Boards of Pharmacy (Model Act)* is available as a free download in the Publications and Reports section of the NABP website under Resource Documents. The updated 2019 *Model Act* will soon be available.

The two committees also decided that when a veterinarian is submitting information to a PMP for a patient that is a pet, the veterinarian should submit the pet owner’s name, address, telephone number, gender, and date of birth.

Biological Products

The Committee on Law Enforcement/Legislation made minor updates to the *Model Act* to align it with Food and Drug Administration rules for biological products and interchangeable products. This includes an addition of a footnote in the prescription labeling section, which states that if an interchangeable biologic is dispensed, the phrase “interchangeable for [reference product]” should be included on the prescription’s label.

The complete reports of the Committee on Law Enforcement/Legislation, Suspicious Orders Work Group, and Task Force to Develop Regulations Based on Standards of Care may be found by visiting the Publications and Reports section of the NABP website under Reports.

The updated *Model Act* will soon be available in the Publications and Reports section on the NABP website under Resource Documents. ■

Interview With a Board Member



**Richard M. Indovina, Jr,
MBA, RPh,
Louisiana Board of Pharmacy**

Richard M. Indovina, Jr, MBA, RPh Louisiana Board of Pharmacy

When were you appointed to the Board of Pharmacy? Are you a pharmacist, technician, public member, or other type of member?

I was appointed to my first term in 2010. I am a pharmacist.

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

For myself, the preparation started before being appointed to the Board. I attended – as a public person – all the regulation revision committee meetings and all the quarterly Board meetings for almost 10 years before being appointed to the Board, so I was very familiar with the way the Board works, the process by which things come about, and the topics the Board was taking on. I also think it is important to be active in both state and professional associations. I was active in the Louisiana Pharmacists Association and represented Walgreens with the National Association of Chain Drug Stores. Once appointed to the Board, the most important thing you can do is get involved and volunteer to serve on committees.

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

Our state legislature passed medical marijuana legislation that mandated that the Board promulgate rules and regulations to regulate medical marijuana through pharmacies. That was a big one and took a lot of time. Also, the Board took on pharmacy benefits manager (PBM) regulations. The Board's proposed regulations were killed in the legislature last year, but the legislature passed PBM legislation this year mandating licensure and regulation. That's going to come back to us to write PBM regulation. Another big change has been how we license technicians in training and, therefore, technicians. The education requirements have changed relative to how to become a technician in Louisiana.

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

Absolutely! What's not controversial about PBM regulations, medical marijuana, and education requirements for technicians? I don't think any of the PBMs want to be regulated by the Board of Pharmacy. That's been contentious at times. Everybody tends to look at that from their own angle: Are PBMs practicing pharmacy or are they not? Are they affecting the public's health and well-being by the things they do with regard to prior authorization, formulary requirements and restrictions, and eliminating the patient's choice of using their local pharmacy? Attitudes toward medical marijuana are often based on personal belief for many people. There are some who want recreational marijuana legalized, or even free marijuana. Then, you have people who want to protest everything because the word "marijuana" is in it. Being somewhat constrained by legislation that says exactly how we are to regulate medical marijuana has been a challenge. With regard to changing technician education, in our state, a lot of people fear that it is going to cause a technician shortage. There are also those who see it as imposing on what they have always done. As boards of pharmacy, we are going to struggle as we try to

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Louisiana Board of Pharmacy

Number of Board Members: 16 pharmacist members and 1 public member

Number of Compliance Officers/Inspectors: 6

Rules and Regulations Established by: Board of pharmacy

Number of Pharmacist Licensees: 8,780

Number of Pharmacies: 1,988

Number of Wholesale Distributors: Board of pharmacy does not license

Around the Association

Board Member Appointments

- **Heather C. Harris, PharmD, RPh**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Harris' appointment will expire June 30, 2025.

Board Member Reappointments

- **Edmund Sperry** has been reappointed a public member of the Idaho State Board of Pharmacy. Sperry's appointment will expire June 30, 2023.
- **Kevin Holland, RPh**, has been reappointed a member of the Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy. Holland's appointment will expire November 30, 2021.
- **Linda Varrell** has been reappointed a public member of the Maine

Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy. Varrell's appointment will expire November 30, 2020.

- **Timothy D. Fensky, RPh, DPh, FACA**, has been reappointed a member of the Massachusetts Board of Registration in Pharmacy. Fensky's appointment will expire November 7, 2020.
- **Stuart T. Williams, JD**, has been reappointed a public member of the Minnesota Board of Pharmacy. Williams' appointment will expire January 1, 2023.
- **Gayle Cotchen, MBA, PharmD, RPh**, has been reappointed a member of the Pennsylvania State Board of Pharmacy. Cotchen's appointment will expire May 23, 2024.
- **Terry A. Blackmon, RPh**, has been reappointed a member of the South Carolina Board of Pharmacy.

Blackmon's appointment will expire June 30, 2024.

- **Rebecca L. Gillespie, PharmD, RPh**, has been reappointed a member of the South Carolina Board of Pharmacy. Gillespie's appointment will expire June 30, 2022.
- **Diane Dady, RPh**, has been reappointed a member of the South Dakota State Board of Pharmacy. Dady's appointment will expire October 1, 2020.
- **Philip Trapskin, PharmD, RPh**, has been reappointed a member of the Wisconsin Pharmacy Examining Board. Trapskin's appointment will expire July 1, 2021.
- **Cathy Winters, RPh**, has been reappointed a member of the Wisconsin Pharmacy Examining Board. Winters' appointment will expire July 1, 2021. ■

Board Member

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expand what we allow technicians to do. Where is that balance between opening up the practice and ensuring that these individuals are properly trained and educated? Pharmacy seems to be the last holdout that is resisting the idea that technicians should have certain education or credentialing to practice. At the same time, we are looking to expand what it is that we allow them to do.

What advice would you give a new board member?

It goes back to being involved. Before I was appointed to the Board, I attended a lot of Board meetings, knew the Board members, and was familiar with the process. Being involved in NABP and in state associations – all those things exposed the different challenges the profession is facing and the different areas where the Board serves a vital function in ensuring that pharmacies practice in the best interest of patients.

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings? If so, in your experience, what are the benefits of participating in these NABP activities?

I served on the Task Force on Prescription Drug Abuse four years ago. Knowing that other states faced the same challenges as my state and looking at what we could do was an eye-opening experience. The time that I spent on that task force working with the other members was very helpful in my real job educating prescribers in my state about opioids and the addiction problem that we were facing. Most recently, I attended an NABP Interactive Member Forum. The ability to see – especially right now with telepharmacy, telehealth and a lot of technology outpacing regulation – how different states are approaching regulatory changes to address technology was pretty interesting. ■

PDMP Registration Now Required in DC

On April 11, 2019, D.C. Law 22-288 went into effect, mandating all practitioners who are registered to prescribe and/or dispense controlled substances (CS) or other covered substances in the District of Columbia to register with the District of Columbia Prescription Drug Monitoring Program (PDMP).

DC Releases Naloxone Policy Statement

DC Health has established a policy statement to allow pharmacists to dispense naloxone without a prescription pursuant to a standing order. The policy will allow national pharmacy organizations (NPOs) to use their own training programs and standing orders to dispense naloxone to District of Columbia residents. The NPO standing order must be signed by a District of Columbia-licensed physician. The training program must meet the requirements outlined in the policy statement.

Pharmacies that are not members of an NPO can dispense naloxone if the pharmacists have completed DC Health's naloxone training program and have signed the DC Health standing order. The DC Health training program can be found on the DC Center for Rational Prescribing (DCRx) website, <https://dchealth.dc.gov/dcrx>. Additionally, the pharmacist-in-charge (PIC) will need to complete the written standing order from DC Health and provide a certificate of completion from the DCRx course.

If there is a change in the PIC, a new DC Health standing order will need to be completed. A copy of the standing order must be maintained at the pharmacy and be readily available upon request by the District of Columbia Board of Pharmacy. For more information, visit www.dchealth.dc.gov/bop.

New Legislation in Idaho Addresses License Portability and Prescription Authority

The following pharmacy-related bills were passed by the Idaho Legislature and signed into law by Governor Brad Little with an effective date of July 1, 2019.

- **House Bill (HB) 10:** Creates a more mobile pharmacy license to allow pharmacists, technicians, and student pharmacists to better practice across state lines.
- **HB 12:** Prescriptive Authority for Naloxone allows any licensed or registered health professional to independently prescribe an opioid antagonist to certain individuals, such as those at risk for an opiate-related overdose, and those in a position to assist those at risk of experiencing such an overdose.
- **HB 182:** Removes the necessity for the Board to specifically authorize certain drugs, drug categories, and devices that may be prescribed. Idaho pharmacists can now prescribe any drugs that are in accordance with Food and Drug Administration (FDA)-approved labeling and are limited to conditions that do not require a new diagnosis, among other requirements. CS, compounded drugs, and biological products cannot be prescribed by a pharmacist.

Tennessee Updates Opioid Limiting Law

Governor Bill Lee approved changes to Public Chapter (PC) 1039 regarding the TN Together opioid law on April 9, 2019, which were designated as PC 124. Some of those updates are as follows.

- All prescriptions (written/printed/electronic) for a Schedule II CS must contain all the legal requirements, including a signature on the day the prescription is issued.
- Emergency prescriptions are not specifically mentioned in PC 124. However, this legislation does mention that verbal orders are permitted when following the proper requirements. Therefore, an emergency verbal prescription is still allowed.
- Updated language clarifies that the ICD-10 code on no more than a three-day supply of opioid treatment and a maximum of 180 morphine milligram equivalent (MME) dosage is not required.
- Starting January 1, 2021, it will be mandatory for Schedule II through Schedule V CS prescriptions to be sent electronically. If issued by an advanced practice nurse or physician assistant, the prescription must include the name, address, and telephone number of the collaborating physician.
- Regarding partial fills, any subsequent fill must remain and be completed at the pharmacy where it originally initiated. A partial fill must be completed within the six-month time frame from the date of issuance (unless required to be filled in less time under federal law).
- The requirement to fill opioids for "more than minimally invasive" procedures has been increased from the maximum of 20 days/850 MME to a maximum of 30 days/1200 MME.
- Opioid-containing preparations for cough and upper respiratory symptoms, approved by FDA for such use, may now be prescribed for a maximum of 14 days with no requirements regarding MME. The ICD-10 codes for these preparations are no longer required to be recorded on the prescription.

Review the complete PC 124 at <https://publications.tnsosfiles.com/acts/111/pub/pc0124.pdf>.

West Virginia Establishes Reciprocity for Pharmacy Technicians

A pharmacy technician who has obtained a national certification and practiced in another jurisdiction for at least a year is eligible to apply for reciprocity in West Virginia. The individual must be in good standing in the original state of jurisdiction. He or she must still apply as a pharmacy technician trainee and complete the 20-hour, site-specific training program. The applicant will then apply to be a pharmacy technician by providing satisfactory proof to the West Virginia Board of Pharmacy of his or her licensure status with the board of pharmacy in the state in which the individual was licensed and proof of national certification. In states where there is no technician licensure, a notarized document with proof of satisfactory employment by the previous PIC is sufficient. ■

CMS Proposes Updates to Medicare Part D e-Prescribing Standards

The Centers for Medicare & Medicaid Services (CMS) has issued a proposed rule that updates the prior authorization process and e-prescribing program for Medicare Part D. The prior authorization process requires that providers supply additional clinical information to verify that medications will be covered under Part D. It also promotes better clinical decision making and helps ensure that patients receive the drugs they need.

The proposed rule would update the e-prescribing program by adopting standards that ensure secure transmissions and expedite prior authorizations. If adopted, the proposed rule would allow clinicians to complete prior authorizations online, providing a more streamlined process for performing prior authorization for Part D prescriptions, as required by the SUPPORT for Patients and Communities Act.

The proposed standards would begin in January 2021. If finalized, all Medicare Part D plans would be required to support electronic prior authorization transaction standards that were developed by the National Council for Prescription Drug Programs. The full rule is available in the *Federal Register*.

PTCB Offers Streamlined Recertification Process for CPhTs via NABP e-Profile

Recognizing the demands that certified pharmacy technicians (CPhTs) have on their time, the Pharmacy Technician Certification Board (PTCB) has streamlined the recertification application process for CPhTs who meet their continuing education (CE) hours and have recorded them through CPE Monitor®. The new process eliminates the need to manually enter CE information as long as it is already in CPE Monitor. It also provides instant recertification/reinstatement and a quicker, more efficient application. To participate in the streamlined process, CPhTs must set up an NABP e-Profile on NABP's website by October 1, 2019, and add their PTCB certification number to the credentials section of their e-Profile. More information about CPE Monitor and creating an NABP e-Profile is available on the NABP website.

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products Sold at Retail Pharmacies

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc. is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies due to a lack of sterility assurance. Administration of nonsterile products intended to be sterile may result in serious and possibly life-threatening infections or death. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through a series of press releases, available on the recall section of the Food and Drug Administration (FDA) website at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.

Adverse reactions or quality problems experienced with the use of these products may be reported to FDA's MedWatch Adverse Event Reporting program.

FDA Warns Women of Possible Safety Risks of Dietary Supplements Containing Vinpocetine

FDA is warning consumers about possible safety risks concerning an ingredient known as vinpocetine, which is found in certain dietary supplements and often marketed to enhance memory, focus, or mental acuity; increase energy; and assist in weight loss. Specifically, women of childbearing age who take such supplements may be at increased risk of miscarriage or disruptions to fetal development.

Vinpocetine may be referred to on product labels as Vinca minor extract, lesser periwinkle extract, or common periwinkle extract. FDA advises pregnant women and women who could become pregnant not to take vinpocetine. They also advise firms marketing dietary supplements containing vinpocetine to evaluate their product labeling to ensure that it provides safety warnings against use by pregnant women and women who could become pregnant.

Adverse events related to these supplements may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program. ■

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.



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UPCOMING EVENTS

NABP/ACCP Districts 1 and 2 Meeting

September 19-21, 2019
Burlington, VT

2019 Tri-Regulator Symposium

September 26-27, 2019
Frisco, TX

FPGEE Administration

October 1, 2019

NABP Interactive Executive Officer Forum

October 1-2, 2019
NABP Headquarters

NABP/ACCP Districts 6, 7, and 8 Meeting

October 6-9, 2019
Boise, ID

NABP/ACCP 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
Hyatt Regency O'Hare Chicago

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