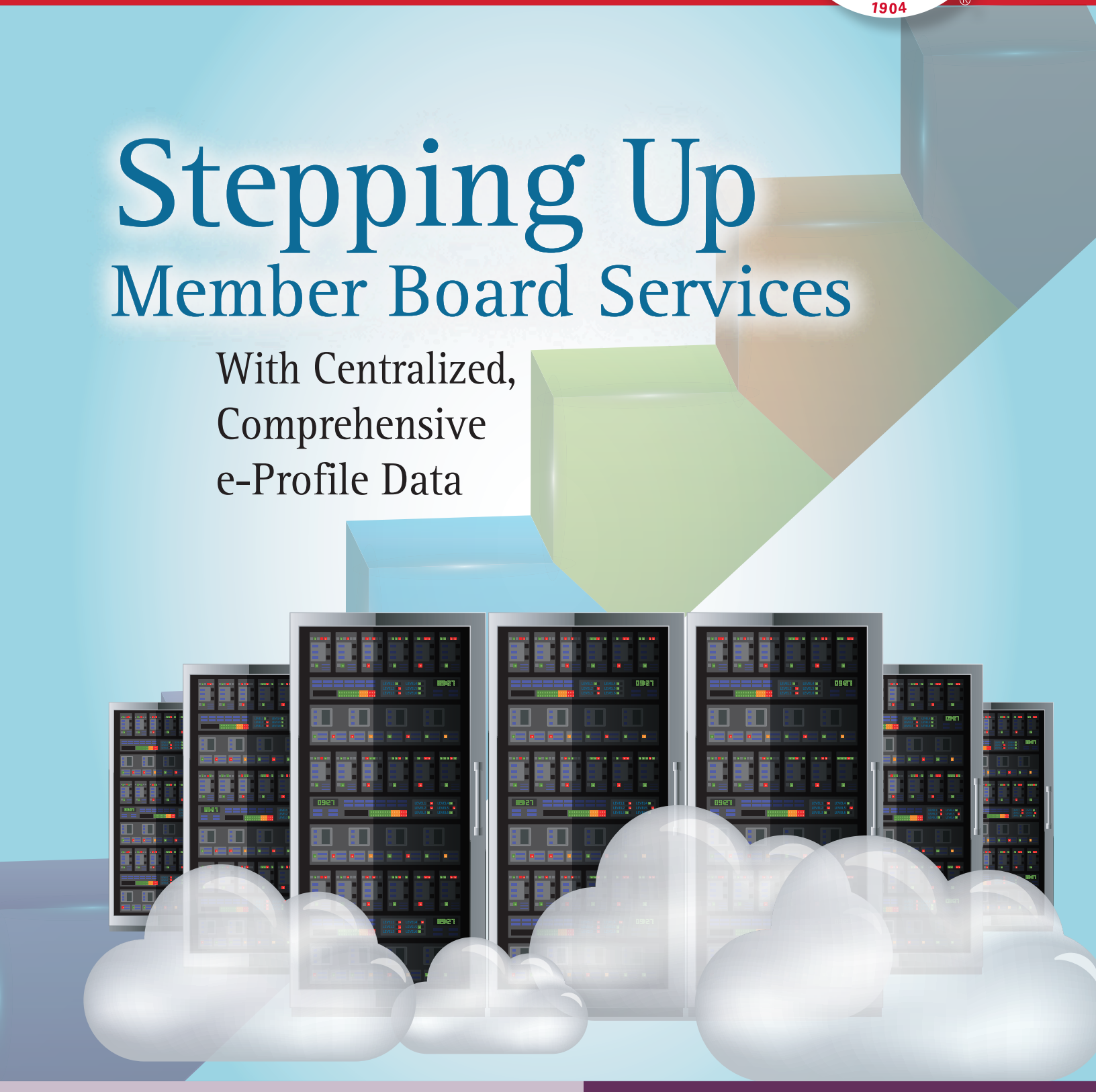
NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS®

Stepping Up
Member Board Services
With Centralized, Comprehensive e-Profile Data



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EXECUTIVE COMMITTEE

Innovations
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The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $70 per year.

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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.

Desktop Version of CPE Monitor Plus Plan Coming Soon

A desktop version of the CPE Monitor® plus plan, which has enhanced features that enable pharmacists to easily monitor their continuing pharmacy education (CPE) credits for one or more licenses, will be available soon. Previously, the plus plan was available only via the NABP mobile app.

Pharmacists who have been enjoying the time-saving features of the plus plan on their mobile device will soon be able to use those same features on their desktop at no extra charge. (The annual fee for the plus plan is $29.95.) Those who upgrade to the plus plan are able to:

- verify how much CPE credit they must earn to satisfy license renewal requirements;
- receive alerts when their license is nearing the end of a CPE cycle;
- upload non-Accreditation Council for Pharmacy Education (ACPE) credits to their e-Profile;
- view detailed transcripts for each state license;
- connect to My CPD, which allows them to maintain their continuing professional development (CPD) in one place; and
- connect to Pharmacists' Learning Assistance Network, where they can easily search for ACPE-approved courses.

The plus plan tracks renewal requirements for all 50 states and the District of Columbia.

The standard plan is free and includes all the basic features pharmacists have enjoyed through the CPE Monitor service since it was launched. The standard plan is also available for use on both desktop and mobile devices. Features include automatic transmission of ACPE-accredited activity from the provider to the user's NABP e-Profile and the ability to view a consolidated transcript and monitor their CPE activity. All CPE Monitor users are automatically set up with the standard plan upon entering a license in their e-Profile.

More information about the two plans CPE Monitor offers – standard and plus – is available at *www.nabp.pharmacy/plans*.

Committee on Law Enforcement/Legislation Convenes

In January 2019, the Committee on Law Enforcement/Legislation convened at NABP Headquarters to review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy. Pictured are (left to right) Jenny Downing Yoakum, RPh, member, Texas State Board of Pharmacy; Nicole L. Chopski, PharmD, BCGP, ANP, NABP Executive Committee liaison; Laura Forbes, RPh, member, Virgin Islands Board of Pharmacy; Kimberly "Kim" Tanzer, BSP, PharmD, RPh, member, Massachusetts Board of Registration in Pharmacy; Jeenu Philip, RPh, member, Florida Board of Pharmacy (chairperson); Kari Shanard-Koenders, RPh, executive director, South Dakota State Board of Pharmacy; Linda Witzal, RPh, member, New Jersey State Board of Pharmacy; Kevin Dang, PharmD, RPh, member, Arizona State Board of Pharmacy; and Paul Brand, PharmD, RPh, member, Montana Board of Pharmacy.

Politics Prompts Problematic Policymaking

Libby Baney, JD,
Faegre Baker Daniels Consulting

> **"A January 2019 POLITICO-Harvard poll found 90% of Democrats and 82% of Republicans saying that taking action to lower prescription medicine prices is extremely important, ranking as a top issue for both parties."**

If political predictions hold, this year it may be easier to track states that do not consider prescription drug importation policies than those that do. The same sentiment is already playing out on Capitol Hill. As discussed below, popular opinion and political pressure are driving policymakers toward importation despite the objections of drug safety experts, including NABP, state boards of pharmacy, former Food and Drug Administration (FDA) commissioners, and others.

Why Now?

A January 2019 POLITICO-Harvard poll found 90% of Democrats and 82% of Republicans saying that taking action to lower prescription medicine prices is extremely important, ranking as the top issue for both parties. In Congress, the Democratic House majority has made drug prices a top priority, an issue where they could find some common ground with President Donald J. Trump. In the Senate, the new chairman of the powerful Senate Finance Committee, Senator Chuck Grassley (R-IA), is a longtime supporter of drug importation. As leader of Finance, he has new abilities to advance his priorities, including drug importation, and no shortage of willing Democratic pro-importation allies. This holds for statehouses, too, where governors and state legislatures feel pressure to act. The 2020 election strongly contributes to politicians' motivation, as every elected official will need to show how he or she has delivered on constituents' most pressing concerns. In sum, at both the state and federal levels, politicians are motivated to do something to show constituents that they are responding to the bipartisan call for action on drug pricing before they "hit the trail" again for the 2020 election.

In the States

In 2018, nine states considered bills to authorize some form of prescription drug importation, according to the National Academy for State Health Policy (NASHP). One state, Vermont, passed the bill and is moving toward implementation in 2019. We expect this and more in 2019 for the reasons discussed.

This year, governors and state legislatures have already been working on importation proposals. Earlier this year, four new Democratic governors in Colorado, Maine, Michigan, and Wisconsin said they would be interested in exploring importing drugs from Canada, according to the NASHP. While state attorney general, Maine's new governor, Janet Mills, was a defendant in a 2013 lawsuit that resulted in a federal judge striking down a state law that authorized personal prescription importation in 2015. On the campaign trail for governor, however, Mills said she would "closely watch" the implementation of a Vermont law passed in May 2018 that instructs the state to develop a plan to safely execute wholesale drug importation from Canada.

In Washington, DC

Two federal importation bills were introduced during the first full week of January 2019, signaling policymakers' prioritization of this policy. Both bills authorize personal importation of prescription drugs from Canada.

1. Safe and Affordable Drugs from Canada Act of 2019 (Senate Bill [SB] 61) – Introduced by Senators Grassley

and Amy Klobuchar (D-MN). A summary of the bill can be found at *www.grassley.senate.gov/news/news-releases/grassley-klobuchar-introduce-legislation-permit-personal-importation-rx-drugs*.

2. Affordable and Safe Prescription Drug Importation Act (SB 97, House Resolution 447) – Introduced by Representatives Elijah Cummings (D-MD), Ro Khanna (D-CA), Peter Welch (D-VT), and Joe Neguse (D-CO), and Senator Bernie Sanders (I-VT). A summary of the bill can be found at *www.sanders.senate.gov/download/final_-affordable-and-safe-prescription-drug-importation-act-of-2019?id=3AC157ED-B4F5-4B7E-8B64-F980132A856C&download=1&inline=file*.

Unlike in 2017 – the last time there was a significant federal legislative importation threat – this year, Democrats control the House and a top-ranking Republican, Chairman Grassley, co-sponsored the bill upon introduction. Since Chairman Grassley controls the agenda for the Finance Committee, and as new House Democrats campaigned on drug importation, it is almost guaranteed that importation legislation will be taken up in both chambers. (Indeed, it may have been already as of the time you read this).

In addition to legislation, the Executive branch has also been eyeing importation solutions to drug pricing concerns. Last summer, the Administration announced an FDA working group on drug importation. The working group is charged with considering focused drug importation policy options to address access challenges related to certain sole-source medicines with limited patient availability, but no blocking patents or exclusivities.

AMA's New Importation Stance

In November 2018, the American Medical Association (AMA) adopted a policy supporting personal importation of prescription drugs from Canada. The policy expresses support for in-person drug imports from licensed brick and mortar Canadian pharmacies, so long as drugs imported are a limited quantity for personal use only. The medications also must be approved by Health Canada, which reviews the safety, effectiveness, and quality of prescription drugs sold in Canada. The new policy does not apply to prescription drugs imported via online or mail-order pharmacies. AMA says it opposes online imports until the safety of such drugs can be assured.

Drug Safety Leaders Raise Concerns

Dozens of pharmacy, pharmacist, and health care organizations have historically opposed importation, citing patient safety risks from sourcing medicine from foreign countries whose drug regulatory and distribution systems are not capable of protecting Americans from unsafe products. Even Canadian authorities agree. Some of these listed organizations follow; this does not include the myriad individual consumers, academics, health care providers, and economists who have also written in opposition to importation. Letters from these groups and other information can be found at *https://buysaferx.pharmacy/public-awareness-campaigns/drug-importation/letters.*

- Alliance for Safe Online Pharmacies
- American Pharmacists Association
- American Society of Health-System Pharmacists
- Americans for Tax Reform
- Boards of pharmacy from Arizona, California, Kentucky, Louisiana, Oklahoma, Virginia, and West Virginia
- College of Pharmacists of Manitoba
- Former FDA commissioners
- NABP
- National Association of Chain Drug Stores
- National Association of Pharmacy Regulatory Authorities (Canada)
- National Consumers League
- Newfoundland and Labrador Pharmacy Board
- Partnership for Safe Medicines
- The Pew Charitable Trusts
- Shatterproof
- US Chamber of Commerce

Conclusion

We expect this policy to continue to gain state and national attention, including votes in legislatures around the country, as the 2020 election nears. Drug safety experts will continue to be critical in helping to educate policymakers on the impact importation could have on Americans.

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

2018 Examinations and Assessments Volume Stable

NABP has announced the totals for the 2018 administrations of the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®). Below is a chart showing the administration totals.

With a steady number of school graduates, the number of NAPLEX administrations decreased only slightly when compared to 2017 data. And the Pre-NAPLEX®, which serves as the practice examination for the NAPLEX, saw a sizable increase compared to 2017. The majority of administrations, 68%, were purchased by individuals. The remaining 32% were purchased by schools and colleges of pharmacy, who provided them to students. Often, the school of pharmacy will have the students take the Pre-NAPLEX in a group setting to further provide the NAPLEX "experience" to students.

The number of MPJE administrations showed an increase in 2018, which is likely related to the steady number of license transfer requests. In 2018, 49 jurisdictions required the MPJE for initial licensure and license transfer.

In 2018, NABP launched a new online application for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) certification and the FPGEE, and the Association migrated hundreds of records to the new centralized database. While the number of applications to the FPGEC program remains steady, with technological and processing changes, less applicants were approved to test in 2018. The year 2019 will likely see the balance of the FPGEE volume.

In addition, a total of 19,887 students from 137 schools and colleges of pharmacy participated in the 2018 testing windows for the PCOA. The table below includes the breakdown of PCOA administrations by program year. NABP continues to cover the cost of one-time PCOA administrations to students nearing the completion of their didactic curriculum for compliance with *ACPE Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree*. More information on the PCOA administrations will be available in an upcoming issue of *Innovations*.

More information on NABP examinations and assessments is located in the Programs section of the NABP website at *www.nabp.pharmacy*. ■

Volume of Examination and Assessment Administrations

	2017	2018	% Change
NAPLEX	18,193	18,089	-0.6%
Pre-NAPLEX	12,249	13,266	+8%
MPJE	32,561	33,897	+4%
FPGEE	1,540	1,118	-27%
Pre-FPGEE	609	315	-48%
PCOA	18,466	19,887	+7%
Program Year 1	1,751	2,046	+17%
Program Year 2	2,099	2,635	+25%
Program Year 3	14,400	15,032	+4
Program Year 4	216	174	-19%

NABP Facility Programs Continue to See Steady Number of Applicants, Help Protect Public Health

With the Association's mission to protect the public health at the forefront, NABP's accreditation and verification programs help ensure the safety of the United States drug supply chain and that patients receive quality care and products from US pharmacies. In 2018, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) providers; pharmacies with an internet presence; and facilities engaged in distributing prescription and over-the-counter (OTC) drugs and devices continued to seek the appropriate accreditation to demonstrate compliance with state and federal requirements and to distinguish their companies as providers of high-quality products and services.

As a means to help protect the public from the threat of counterfeit drugs infiltrating the US medication supply chain, Verified-Accredited Wholesale Distributors® (VAWD®), launched in 2004, verifies suppliers' compliance with criteria based on state and federal laws and best practices for entities engaged in prescription drug and device distribution. By December 31, 2018, a total of 644 facilities were accredited by the VAWD program. Entities continue to seek VAWD accreditation or reaccreditation each year, and the number of states requiring or recognizing VAWD is four and 20, respectively.

In September 2016, NABP launched the Verified-Accredited Device Integrity Program® (VDIP®) as a means to expand efforts to protect the integrity of the medication distribution system. VDIP accreditation is for business entities that distribute diagnostic OTC medical devices that may be dispensed pursuant to a prescription. As an extension of the VAWD program, VDIP was launched to help prevent diverted or substandard diagnostic OTC medical devices from entering the US medical supply chain. The Association began accepting applications for VDIP accreditation in 2017.

Since 2006, the DMEPOS accreditation program has assisted numerous pharmacies seeking to meet the Centers for Medicare & Medicaid Services DMEPOS requirements. At the program's peak in 2009, the DMEPOS program had accredited over 1,000 companies representing over 30,000 facilities. Despite legislative changes made in 2010 that exempt certain pharmacies from having to obtain DMEPOS accreditation, the DMEPOS program continues to receive a steady number of applications, resulting in 119 new accreditations and reaccreditations in 2018. Today, the program has nearly 246 accredited DMEPOS companies representing almost 25,000 facilities.

Since 1999, the Verified Internet Pharmacy Practice Sites® (VIPPS®) program has accredited companies that operate pharmacies in the US offering interactive pharmacy services over the internet that meet a comprehensive set of criteria, including compliance with state and federal laws and regulations. In 2018, VIPPS accredited 18 companies and reaccredited 15 companies. By end of 2018, 72 companies were VIPPS-accredited.

In September 2017, VIPPS-accredited companies were required to register and use a .pharmacy domain name to maintain their accreditation status to further assist consumers in finding safe pharmacy websites and expand the secure pharmacy community.

The .Pharmacy Verified Websites program offers a superior means of identifying legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies. As of December 31, 2018, NABP has verified the websites of 325 customers, and 623 .pharmacy domain names were registered, including 470 pharmacies, 53 boards of pharmacy and regulatory agencies, 29 resource and referral sites, 29 professional sites, 26 associations and consumer advocacy sites, nine pharmacy automation distributors, four manufacturers, one pharmacy benefits manager, one wholesale drug distributor, and one school or college of pharmacy.

Newly Accredited VAWD Facilities

The following facilities were accredited through the NABP Verified-Accredited Wholesale Distributors® (VAWD®) program:

Aqua Pharmaceuticals, LLC
Exton, PA

Dispensary of Hope, LLC
Nashville, TN

KY Meds, Inc
Louisville, KY

MD Logistics, Inc
Plainfield, IN

Numed
Brooklyn, NY

Pharmaceutical Returns Service
Sugar Grove, IL

A full listing of more than 600 accredited VAWD facilities is available on the NABP website at *www.nabp.pharmacy*.

Stepping Up Member Board Services With Centralized, Comprehensive e-Profile Data

With the launch of NABP's new e-Profile system in April 2018, the Association merged multiple program databases to a centralized database, improved data quality, and brought additional NABP programs and services into the online environment. These improvements mean that the e-Profile data NABP holds is more comprehensive, accurate, and robust than ever before. And for member boards of pharmacy, this means the boards have access, through e-Profile Connect, to more data and better data in support of licensure decision making and other board responsibilities.

"With the launch of NABP's new e-Profile system in April 2018, the Association merged multiple program databases to a centralized database, improved data quality, and brought additional NABP programs and services into the online environment."

One way to understand the comprehensiveness of the data stored in the enhanced e-Profile Connect is to see it as layers that are gradually built up over time, as shown in the steps in the infographic on pages 10-11. The primary piece of information into the database is demographic data coming in from pharmacy students who are registering to take the Pharmacy Curriculum Outcomes Assessment® (PCOA®). That first step of demographic data then begins to build as PCOA scores are recorded by NABP (second step), followed by North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination® application and score information after the student graduates (third step). Americans with Disabilities Act accommodation requests, intern licenses, and any updated demographic data are also added, with the history of the demographic data being retained in each individual e-Profile.

Pharmacist licensure data, along with continuing pharmacy education (CPE) data, is then added over time. Currently, pharmacists are self-reporting much of their licensure data in order to ensure that they receive the CPE activity credit needed for each license. For subscribers to CPE Monitor® Plus, NABP also verifies licensure data entered by licensees. Soon, NABP will also be able to batch receive licensure data from the boards to ensure that records are complete, correct, and synching with board information. Some member boards are already piloting licensure data exchanges with NABP. CPE activity data flows in to the system from the Accreditation Council for Pharmacy Education (ACPE) after it is reported by the CPE provider and verified by ACPE. Currently, boards may access individual CPE activities through e-Profile Connect, and can request batch reports from NABP staff for auditing or other board purposes.

The Electronic Licensure Transfer Program® (e-LTP™) is one of the key avenues for boards to benefit from licensure data. With the database changes last year, the e-LTP process went entirely online. Applicants apply online, and NABP staff

can review and verify licensure data and run disciplinary data checks all from the same system. When the full process is complete, the official application for licensure is provided electronically to the relevant board within the e-Profile Connect system. Centralizing the e-LTP data helps data quality and streamlines processes.

Clearinghouse data, a vital part of the e-LTP verification process, is also referenced by NABP staff when reviewing candidate examination eligibility for the states that have opted to have NABP perform the eligibility process, and when evaluating organization accreditation and verification applications.

Technician e-Profiles bring demographic data, licensure/registration data (when applicable), Pharmacy Technician Certification Board certification data, employment data, and CPE data for pharmacy technicians into the system, making it an even more robust source.

Bringing the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification program online in 2018 also further enhanced the data available. FPGEC is the program for pharmacists educated in a non-ACPE-accredited pharmacy school and seeking a license from one of the member boards of pharmacy. These pharmacists must submit their credentials and education for review, pass the FPGEE, and pass the Test of English as a Foreign Language Internet-Based Test. All the associated data, along with electronic copies of the verified documents are saved to the pharmacist's e-Profile for access by NABP staff. Therefore, the e-Profile data of those pharmacists who earn the FPGEC certification is now stored in the same e-Profile Connect database for cross reference by other NABP programs, such as licensure transfer. Boards of pharmacy use e-Profile Connect to check whether or not a candidate for licensure holds the FPGEC certification.

By 2020, similar e-Profile data will be available for organizations that apply for any of NABP's accreditation or verification services. Organization license numbers, registration information, permits, board and Verified Pharmacy Program® inspection reports, NABP accreditation dates, and disciplinary actions are some of the key data points that will be recorded. In addition, by bringing the organization data into the same database, the power to cross-reference data profiles is on the horizon. For example, when completing an organization e-Profile, the pharmacist-in-charge and other pharmacist and technician employees may need to be identified. With the permission of these employees, their pharmacist or technician e-Profiles may then be linked to their names in the organization e-Profile. Another future feature will include the ability for pharmacists and technicians to initiate this process, by adding the employer to the employment history in the e-Profile and requesting through the system for the employer to verify them as an employee.

As e-Profile Connect is a vital and significant data source, NABP is constantly ensuring that the highest security measures are in place to protect data and that the best data quality practices are employed. In addition, the customer experience on the application side as well as the board staff experience on the e-Profile Connect side are consistently being evaluated for further improvements in function and ease of use. Further, data quality has been at the forefront of e-Profile development from the beginning, and continues to be a

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NABP e-Profile Definitions

NABP e-Profile: an online profile held by pharmacists, technicians, students, pharmacies/facilities, and others. The e-Profile contains the individual's demographic and professional data, including licenses, examination scores, continuing pharmacy education activity, history of NABP program and services purchases.

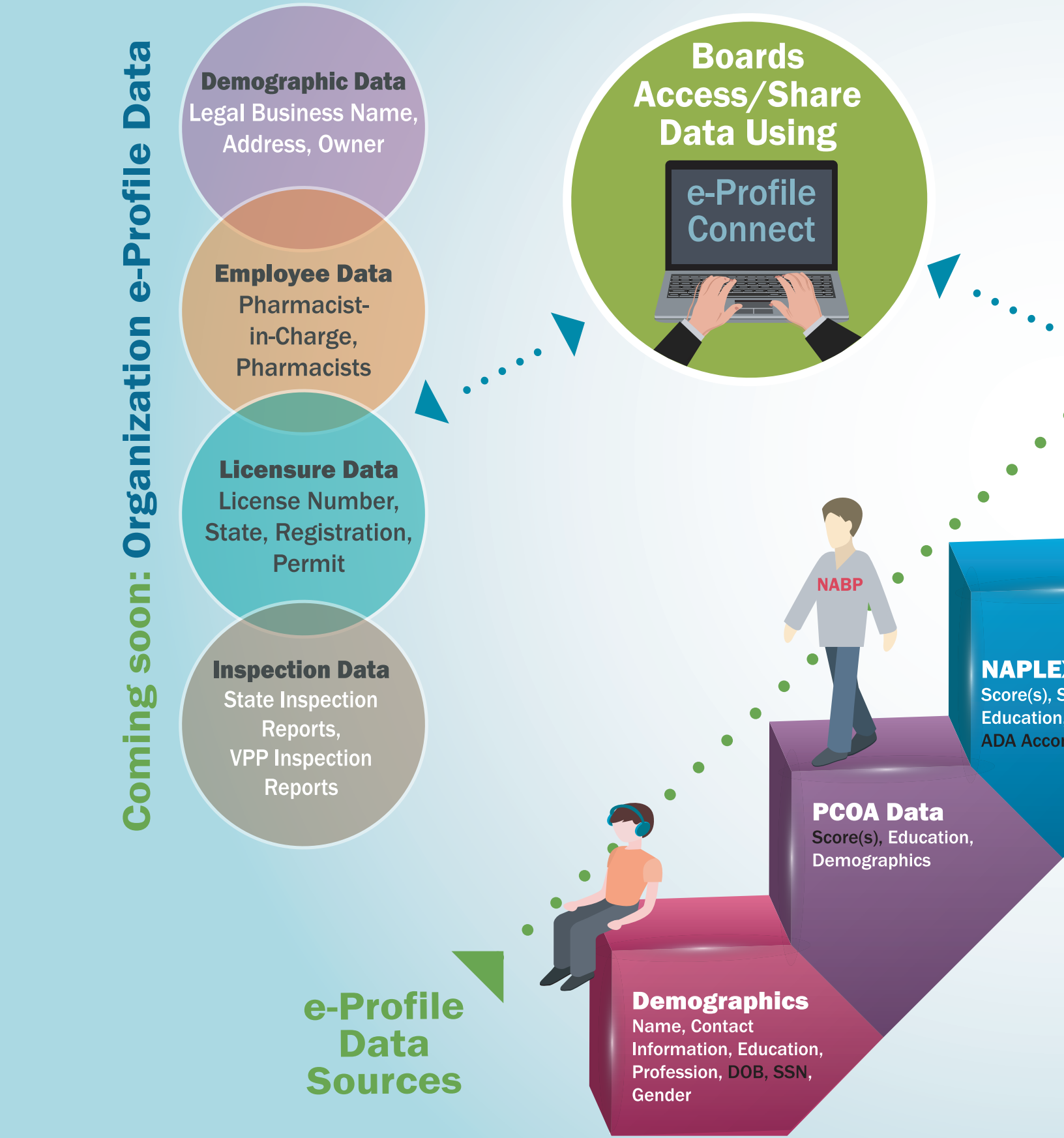
NABP e-Profile ID: a unique number used to identify an individual or facility that holds an NABP e-Profile.

NABP e-Profile System: encompasses all things related to e-Profile – user profiles, customer store where programs and services are purchased, administrative services provided to boards of pharmacy, NABP e-Profile Connect, etc.

NABP e-Profile Connect: the online tool used by boards of pharmacy and schools/colleges of pharmacy to access information on e-Profile holders. This is also where NABP staff, boards, and schools/colleges process customer applications and transactions for NABP programs and services including examinations, licensure transfer, CPE Monitor®, and soon accreditations. ■

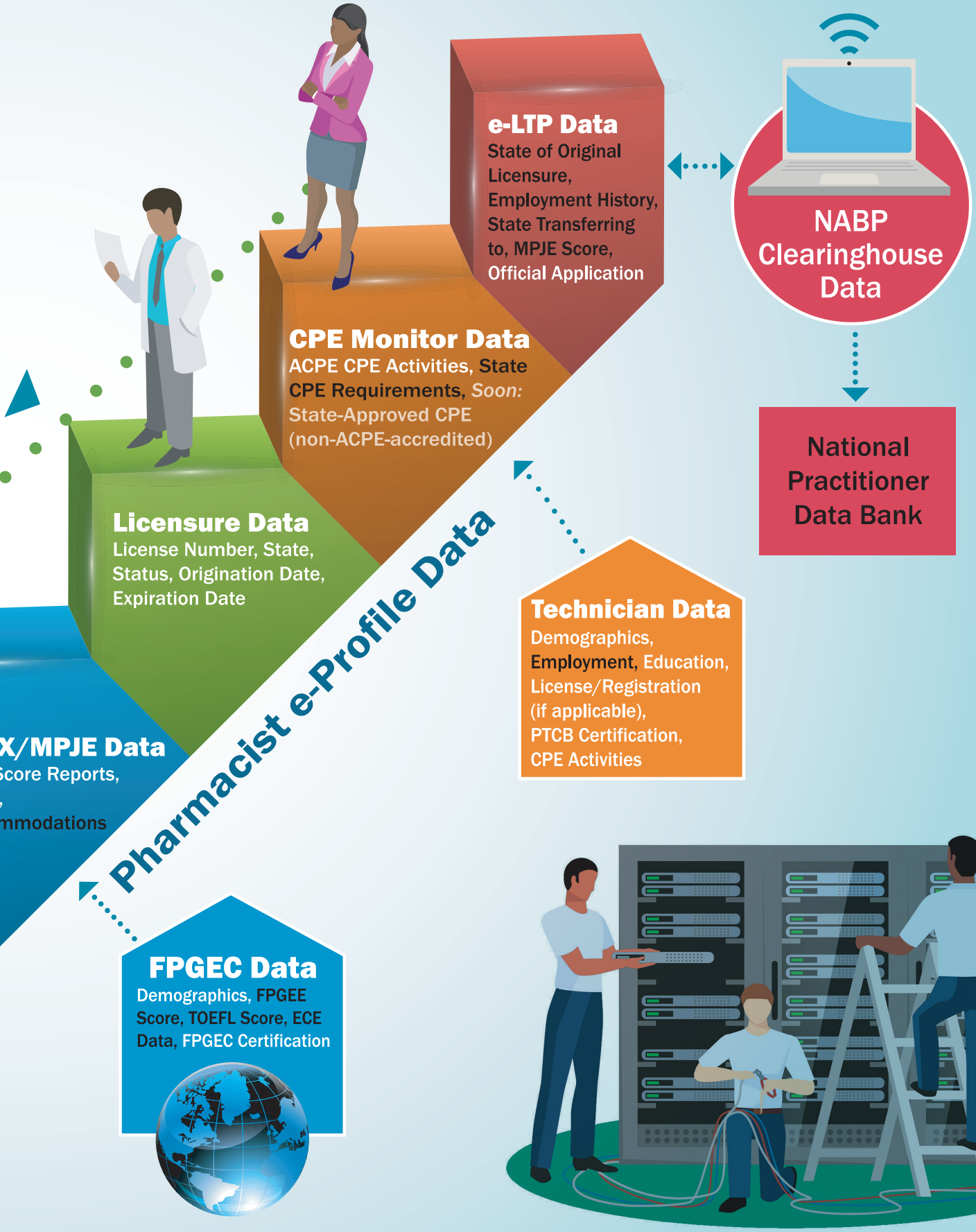
NABP Data Secured in Centrali

NABP e-Profile data is more comprehensive, accurate, and robust than ever before. For member boards of pharmacy, this means that e-Profile Connect provides more data and better data in support of licensure decision making and other board responsibilities. And more data will be accessible soon with organization e-Profile data to be added by 2020. The steps



zed e-Profile Connect Database

below represent the layers of data, from student demographic and exam data, to licensure and CPE data. Also shown is how e-LTP draws on the clearinghouse and all other data to verify transfer requests. *Data accessible for view by boards of pharmacy through e-Profile Connect is shown in white text (information current as of February 2019).*



NABP e-Profile Connect – Did You Know?

Clearinghouse Is a Vital Component to Protecting the Public Health

Board of pharmacy participation in reporting actions to the NABP Clearinghouse is required as part of a board's membership to the Association. The following are important things to consider:

- Reporting disciplinary actions to the Clearinghouse is vital to protecting the public health as these reports allow boards of pharmacy to screen for licensees who have failed to uphold professional and public safety standards and make informed decisions regarding who qualifies to practice pharmacy in their respective states.
- Timely reporting is essential to maintaining the integrity of the licensure transfer program for boards of pharmacy. Failure to participate may negatively impact licensure decisions made by other members based on incomplete information.
- The Clearinghouse is not exclusive to determining qualifications of candidates requesting transfer of examination scores. The Clearinghouse is also used during NABP's accreditation processes for screening applicants to the Verified-Accredited Wholesale Distributors®, Verified Internet Pharmacy Practice Sites®, and durable medical equipment, prosthetics, orthotics, and supplies programs.

- e-Profile alerts are available to boards via e-Profile Connect. If a licensee is licensed in multiple states, each board where the individual is licensed will receive an alert when actions are taken.

Training videos on using the NABP Clearinghouse are available to the boards via the Help link in e-Profile Connect. For more information, contact eltp@nabp.pharmacy.

NABP e-Profile System

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high priority as organization data is brought in, from creating data fields that will sync with board processes to scrubbing data to avoid duplication and ensure accuracy.

Training videos are available to boards via the Help Link under e-Profile Connect. Should your board staff need training on e-Profile Connect or have suggestions for enhancing the system, please contact the Member Relations and Government Affairs department by sending an email to MRGA@nabp.pharmacy. Updates on e-Profile Connect, including the board data exchanges and organization e-Profiles, will be provided at the 115th Annual Meeting and in future issues of *Innovations*.

New Reports Examine 2017 and 2018 PCOA Outcomes

NABP has published two reports that present descriptive statistics for Pharmacy Curriculum Outcomes Assessment® (PCOA®) scores from five testing windows during the 2016-2017 and 2017-2018 administrations:

- *PCOA School Outcomes for Students Nearing the End of Their Didactic Curriculum: 2017*
- *PCOA School Outcomes for Students Nearing the End of Their Didactic Curriculum: 2018*

The reports review results of the 2017 and 2018 Accreditation Council for Pharmacy Education reporting cohorts, which are comprised of students from more than 130 schools and colleges of pharmacy who have completed their didactic coursework (typically in their third year). More details can be found in the two reports, which are available in the Research Briefs and Papers section on NABP's website at *www.nabp.pharmacy.*

2019-2020 MPJE Review Committee Members Announced

Commending 12 returning members, NABP is pleased to announce the 2019-2020 Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee.

Dedicated to reviewing and safeguarding the integrity and validity of the MPJE, the committee is composed of experts in pharmacy law and regulation authorities who are representative of the diversity of pharmacy practice. The committee shares the responsibility for developing and reviewing the items in the MPJE. This team of dedicated volunteers acts under the policy and planning guidance of the Advisory Committee on Examinations (ACE) and the NABP Executive Committee. Responsibilities include reviewing the examination questions to ensure compliance with pharmacy law as it applies to contemporary practice and participating in meetings.

NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. ACE recommends appointments to the committee, and the NABP Executive Committee approves the appointments. Committee members, whose terms began February 1, 2019, are as follows:

- Mark Brown, MBA, RPh, Lahaina, HI
- Katie Busroe, RPh, Kentucky Board of Pharmacy
- Grace Cheung, RPh, Kent, WA
- Mark T. Conradi, JD, RPh, PC, Clanton, AL
- Amy Mattila, PharmD, RPh, Washburn, WI
- Susan McCoy, RPh, Mississippi Board of Pharmacy
- Michael A. Moné, JD, RPh, Powell, OH
- Charles W. Sauer, JD, RPh, Sycamore, IL
- Alan M. Shepley, RPh, Mount Vernon, IA
- John D. Taylor, RPh, Tallahassee, FL
- Dean Wright, RPh, Goodyear, AZ
- David C. Young, PharmD, RPh, West Bountiful, UT ■

Volunteers Convene to Write and Review Exam Items

Volunteer item writers evaluated and developed new test questions for the Foreign Pharmacy Graduate Equivalency Examination® and the Pharmacy Curriculum Outcomes Assessment® during a workshop in January 2019 at NABP Headquarters. ■

(Below, left to right) Bruce Waldrop, PhD, Samford University McWhorter School of Pharmacy and William "Bill" Kolling, PhD, RPh, Southern Illinois University Edwardsville School of Pharmacy.

(Above, left to right) Melissa Badowski, PharmD, RPh, BCPS, University of Illinois at Chicago College of Pharmacy, and Lynn Kassel, PharmD, RPh, Drake University College of Pharmacy & Health Sciences.

US Defense Health Agency Participating in NABP's PMP InterConnect Data Sharing System

Recognizing the need for military and community treatment providers to deliver appropriate health care based on best-available information, the United States Department of Defense's Defense Health Agency (DHA) signed a memorandum of understanding (MOU) to participate in NABP PMP InterConnect®. The MOU was executed and DHA began sharing data with other PMP InterConnect participants in January 2019.

There are DHA military hospitals and clinics available to active duty military and their families across the US. While the military hospitals and clinics shared data through an internal network, DHA recognized that more data sharing was necessary to combat the opioid crisis facing the US today. Therefore, DHA created a prescription monitoring program (PMP) to collect prescription data from all its locations so that it could be positioned to begin sharing data with state entities and began investigating the best vehicle for sharing PMP data.

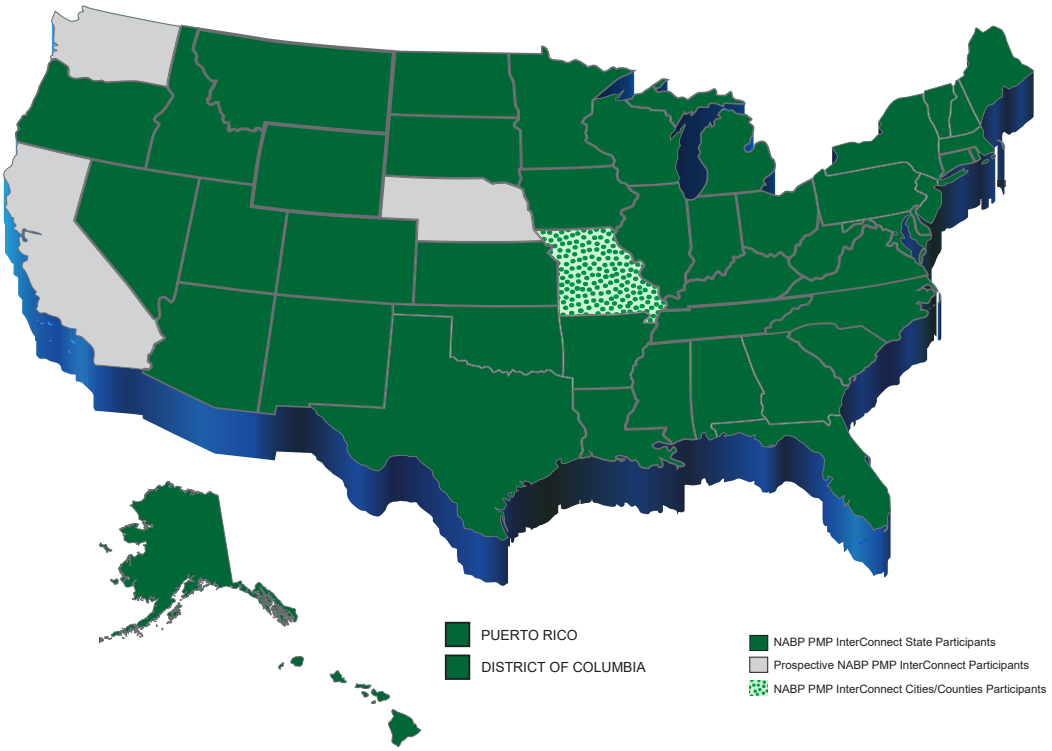
"By participating in NABP's PMP InterConnect, DHA demonstrates that the military is serious about partnering with the states to address the opioid crisis," said NABP President Susan Ksiazek, RPh, DPh. "PMP InterConnect is a secure national network of PMPs that allows authorized prescribers and pharmacists to access information about their patients' controlled substance prescriptions across state lines."

A report from the President's Commission on Combating Drug Addiction and the Opioid Crisis highlights PMPs as an important tool to aid in the fight against opioid abuse. Such systems can be used for early detection and prevention of drug abuse and addiction, and a national network like PMP InterConnect allows for a secure exchange of prescription data between states. It can also help identify patients who cross state lines to purchase drugs for the purposes of misuse or diversion.

Currently, 50 PMPs are actively using PMP InterConnect or have signed MOUs – 46 states, the District of Columbia, Puerto Rico, the St Louis County PMP collaborative, and the DHA. These PMPs make up the Steering Committee, which is the governing and advisory body of PMP InterConnect.

Additional information about PMP InterConnect is available in the Initiatives section of the NABP website at *www.nabp.pharmacy*.

PMP InterConnect Participation Overview



VPP Builds on Inspection Service Achievements in 2018, Expands Verified Data Available for Boards

As NABP continues to roll out enhancements to its inspection service and information sharing network to better assist the state boards of pharmacy, NABP's Verified Pharmacy Program® (VPP®) remains a valuable tool for boards to find verified pharmacy license data via the pharmacy's e-Profile ID. Through the NABP e-Profile Connect platform, boards of pharmacy have access to a facility's interstate licensure details, inspection reports, disciplinary history, and more.

In 2018, 110 pharmacies applied to VPP as renewal applicants, which is an increase of 69.23% compared to 2017's total of 65 renewal VPP applications. In addition, 285 VPP inspections were performed in 2018 and provided new inspection reports, viewable through the pharmacy e-Profiles. See the table (right) for a breakdown of the inspection totals.

NABP continues to be in close discussions with the state boards of pharmacy to further develop VPP so that it meets their needs. States can make licensing or renewal decisions based on the complete information and verified data found in the pharmacy's e-Profile.

For more information about VPP, contact the NABP Accreditation department at vpp@nabp.pharmacy.

Additional details are also available in the Programs section of the NABP website at *www.nabp.pharmacy.* ■

VPP Inspections*	2018	Since Inception (2013)
General Retail Pharmacy Only	47	153
General and Nonsterile Compounding Only	102	423
General and Sterile Compounding Only	38	171
General, Nonsterile, and Sterile Compounding	81	373
Nuclear	17	34

*The totals above represent pharmacies whose inspections have already been completed in 2018 and do not include applicants who are awaiting an inspection or who recently submitted an application.

Sixty-Four State Inspectors Earn Sterile Compounding Certification in 2018

In 2018, NABP and The Pew Charitable Trusts helped educate a total of 64 state inspectors about the standards for inspecting sterile compounding facilities for compliance by offering tuition and travel assistance to attend one of the three on-site training sessions held at the CriticalPoint Center for Training and Research in Totowa, NJ. As part of the Sterile Compounding Inspector Training program offered by CriticalPoint, LLC, the credentialed inspectors from various state boards of pharmacy, health departments, and other agencies in the United States and Canada participated in informative classroom sessions and cleanroom practicums held at the United States Pharmacopeia 797- and 800-compliant plant on July 16-19, 2018, October 8-11, 2018, and November 5-8, 2018. Twenty-one state inspectors earned certification during the July offering, followed by another class of 21 inspectors in the October offering, and 22 inspectors participated in the last on-site training session in November 2018.

Participants who successfully completed the entire Sterile Compounding eLearning Series prior to taking the live training, attended the entire on-site training, and successfully passed a test earned the certification. NABP partnered with CriticalPoint to launch this certificate program in 2016, in an effort to assist state boards of pharmacy in their goal to protect public health and safety by improving the quality of inspections of sterile compounding facilities through more comprehensive and targeted training.

In 2019, the Sterile Compounding Inspector Training program is scheduled for July 9-12, 2019, and October 29-November 1, 2019. To learn more, visit *www.criticalpoint.info/sterile-compounding-inspector-training.* ■

Travel Grants to Attend Annual Meeting Still Available

Are you an active board of pharmacy member or administrative officer who is attending the NABP 115th Annual Meeting? NABP still has travel grant opportunities available for qualified individuals that cover up to $1,500 of the costs related to travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

- Each active NABP member board of pharmacy is eligible for one grant to be awarded to a current board member or administrative officer as designated by the board's administrative officer.
- To receive reimbursement, active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions.

To obtain a grant application, board administrative officers may contact the NABP Executive Office at ExecOffice@nabp.pharmacy. ■

Online Registration Is Available at *www.NABPAnnualMeeting.pharmacy*

Important Deadlines

- Proposed CBL Amendments – Due April 1, 2019
- Early Registration Rate – Ends April 15, 2019
- Voting Delegate Submissions – Due April 16, 2019
- Early Hotel Reservation Rate – Ends April 22, 2019

Support Minneapolis Charity Phillips Neighborhood Clinic: Purchase Annual Meeting T-shirts or Make a Donation

Annual Meeting attendees can support Phillips Neighborhood Clinic (PNC) in Minneapolis by purchasing an Annual Meeting t-shirt for $20 when registering for the Annual Meeting at *www.NABPAnnualMeeting.pharmacy* or at the meeting, or by making a donation. A limited quantity of t-shirts is available. All proceeds will go to PNC, which offers free health care services to patients in Minneapolis with unmet needs. PNC is operated by University of Minnesota health professional students who are supervised by licensed clinicians. The charity was selected by the Minnesota Board of Pharmacy.

Attendees are encouraged to wear their t-shirts during the AWAR$_x$E Fun Run/Walk, which takes place Friday, May 17, at 7:30 AM. Space is limited for this event. To hold a place in the event, select the Fun Run/Walk session during the online meeting registration process. ■

Schedule of Events

Wednesday, May 15, 2019

5 - 7 PM
Registration Desk Open

Thursday, May 16, 2019

7 AM - 5 PM
Registration Desk Open

7:30 - 8 AM
Annual Meeting Program Orientation

8:30 - 11:30 AM
Hospitality Brunch and Educational Table Top Displays

9 - 11 AM
CPE
Educational Poster Session: The Value of Teamwork to Protect Public Health

Noon - 3:30 PM
First Business Session
Presiding: Susan Ksiazek, RPh, DPh, NABP President

- Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
- Presentation of Colors
- National Anthem
- Call to Order
- Keynote Address
  Robin Farmanfarmaian, Entrepreneur and Health Care Investor
- Greeting From the Host State
  Minnesota Board of Pharmacy
- Report of the Executive Committee
  Jeanne D. Waggener, RPh, DPh, Chairperson, NABP Executive Committee
- President's Address
  Susan Ksiazek, RPh, DPh, NABP President
- Announcement of Candidates for Open Executive Committee Officer and Member Positions

3:45 - 5:15 PM
CPE
Shared Discussion Topics

6 - 9 PM
President's Welcome Reception
Honoring NABP President Susan Ksiazek, RPh, DPh

Friday, May 17, 2019

7 AM - 3:30 PM
Registration Desk Open

7 - 9:30 AM
NABP Breakfast

7:30 - 9 AM
NABP AWAR$_X$E Fun Run/Walk

9:30 - 10:30 AM
CPE
Artificial Intelligence – Reality and Possibilities in Improving Patient Care

10:45 - 11:45 AM
CPE
How to Make a Case in a Standards of Care World

1 - 3 PM
Second Business Session
Presiding: Susan Ksiazek, RPh, DPh, NABP President

- Report of the Treasurer
  Timothy D. Fensky, RPh, DPh, FACA, NABP Treasurer
- Report of the Executive Director/Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
- Report of the Committee on Resolutions
  Jack W. "Jay" Campbell IV, JD, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  – First Reading of the Resolutions
- Report of the Committee on Constitution and Bylaws
  Cynthia L.W. Warriner, RPh, CDE, Chairperson, Committee on Constitution and Bylaws
- Candidate Speeches for Open Executive Committee Officer and Member Positions

3 - 3:30 PM
Informal Member/Candidate Discussions

Saturday, May 18, 2019

7 - 11 AM
Registration Desk Open

7 - 8 AM
NABP Continental Breakfast

8:30 - 11:30 AM
Final Business Session
Presiding: Susan Ksiazek, RPh, DPh, NABP President

- Election of the 2019-2020 Executive Committee Officers and Members
- Remarks of the Incoming President
  Jack W. "Jay" Campbell IV, JD, RPh, NABP President-elect

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Schedule of Events

continued from page 17

- Installation of the 2019-2020 Executive Committee Officers and Members
- Final Report of the Committee on Constitution and Bylaws
  Report of the Committee on Constitution and Bylaws
  Cynthia L.W. Warriner, RPh, CDE, Chairperson, Committee on Constitution and Bylaws
  – Discuss and Vote on Amendments
- Final Report of the Committee on Resolutions
  Jack W. "Jay" Campbell IV, JD, RPh, 2019-2020 NABP President and Chairperson, Committee on Resolutions
  – Discuss and Vote on Resolutions
- Invitation to the 2020 Annual Meeting in Baltimore, MD

12:45 - 2:30 PM
Annual Awards Luncheon
Presiding: Jack W. "Jay" Campbell IV, JD, RPh, 2019-2020 NABP President

- Presentation to 2019 Honorary President
- Presentation to Susan Ksiazek, RPh, DPh, 2019-2020 Chairperson, NABP Executive Committee
- Presentation of the 2019 Fred T. Mahaffey Award
- Presentation of the 2019 Henry Cade Memorial Award
- Presentation of the 2019 John F. Atkinson Service Award
- Presentation of the 2019 Lester E. Hosto Distinguished Service Award

Note: The 115th Annual Meeting schedule is subject to change. The final schedule will be posted prior to the meeting at *www.NABPAnnualMeeting.pharmacy.*

The knowledge-based continuing pharmacy education (CPE) activities presented at the Annual Meeting are developed specifically for the Association's member boards of pharmacy, which are composed of executive officers, board staff, board members, compliance staff, and board counsel. Activities are also relevant to other attendees in the practice of pharmacy. By actively participating in the meeting's CPE programming, at the conclusion of the Annual Meeting participants should be able to:

- *Identify the latest legislative and regulatory issues being addressed by the state boards of pharmacy.*
- *Explain how the changing regulatory environment impacts the state boards of pharmacy and the practice of pharmacy.*
- *Identify gaps in regulatory oversight and best practices for state pharmacy boards to overcome them.*
- *Discuss emerging roles of pharmacists and pharmacy technicians with respect to the public's access to quality health care.*
- *Discuss how poster session research findings further the protection of the public health.*
- *Describe best practices for regulating pharmacist care services in a changing health care environment.*
- *Analyze licensing standards between state boards of pharmacy.*

Contact NABP Professional Affairs staff at 847/391-4406 or via email at Prof-Affairs@nabp.pharmacy for more details.

NABP and NABP Foundation® are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of CPE. ACPE provider number: 0205. Learning objectives and descriptions for each CPE session will be available on the CPE page of the Annual Meeting website. Instructions for claiming CPE credits, including continuing legal education credits, will also be provided.

NABP Members Shape Direction of Association Through District and Annual Meeting Business Processes

District meetings provide a voice for each district to take part in the decision-making processes of the Association and, in turn, shape the business processes for the Annual Meeting.

It All Starts at the District Meetings

Much of the foundation for issues addressed at the Annual Meeting is laid at the district level. During the district meetings, board delegates vote on candidates who decide to run for NABP Executive Committee open member positions representing their district. Also, during these meetings, members may submit resolutions for consideration by their district. Resolutions are then submitted by the district to NABP and are reviewed by the Committee on Resolutions before being voted on at the Annual Meeting. These resolutions have the potential to result in NABP actions such as the development of task forces to explore or address an issue or revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, which provides the boards with model language that may be used when developing state laws or board rules. In addition, once approved by the full membership, resolutions document the Association's stance on issues affecting the practice of pharmacy and public health. They can also express NABP's intention to work with other key stakeholders.

Voting

As previously noted, most of the business conducted at the Annual Meeting starts at the district level. When there is an open NABP Executive Committee member position for a district, the district may nominate up to two candidates at its district meeting. After the district meeting, there is also an opportunity for individuals to be nominated outside the district process. Nominees for Executive Committee officer positions of president-elect and treasurer submit their interest and qualifications for these positions directly to NABP. NABP then determines if they meet the criteria to be candidates. At the Annual Meeting, the membership votes on the slate of candidates, including the open member positions and officer positions of president-elect and treasurer. The president and chairperson positions are progressively assumed.

Amendments to the NABP Constitution and Bylaws are also voted on at the Annual Meeting. These amendments may be submitted by any active member board, the Committee on Constitution and Bylaws, or the Executive Committee within a specific time frame prior to the Annual Meeting. Although newly proposed amendments to the Constitution may be presented during any Annual Meeting business session, they may not be discussed and voted on until the next succeeding Annual Meeting. By contrast, proposed amendments to the Bylaws may be presented and voted on at the same Annual Meeting.

Finally, resolutions that were submitted by the districts, active member boards, or NABP committees are discussed and voted on at the Annual Meeting. As previously noted, these resolutions have the potential to be carried out as single-issue task forces or revisions to the *Model Act*, among other activities. Last year, NABP commissioned two task forces, the Task Force to Develop Regulations Based on Standards of Care and the Task Force on Mutual-Recognition Licensure. These task forces were established in response to resolutions voted on during the 114th Annual Meeting in Denver, CO, in 2018.

Business Sessions

So that the member boards can be provided with the opportunity to thoroughly review what the Association has accomplished and plans to accomplish for the upcoming year, business processes have been divided into three sessions at the Annual Meeting. At the First Business Session, attendees will hear the reports of the NABP Executive Committee chairperson and president. Attendees are also introduced to the candidates running for the open Executive Committee officer and member positions.

During the Second Business Session, attendees will hear the reports of the NABP treasurer and executive director/secretary. The resolutions that were submitted by the districts, active member boards, or committees of the Association, and proposed amendments to the Constitution and Bylaws (if any) are also presented during this session. Finally, attendees hear the candidate and seconding speeches for the open Executive Committee positions. After the business session, attendees have the opportunity to interact with the candidates during the Informal Member/Candidate Discussion and share their thoughts about each candidate with their board's voting delegate.

The third session, known as the Final Business Session, is held on the last day of the Annual Meeting. This is when all voting takes place and

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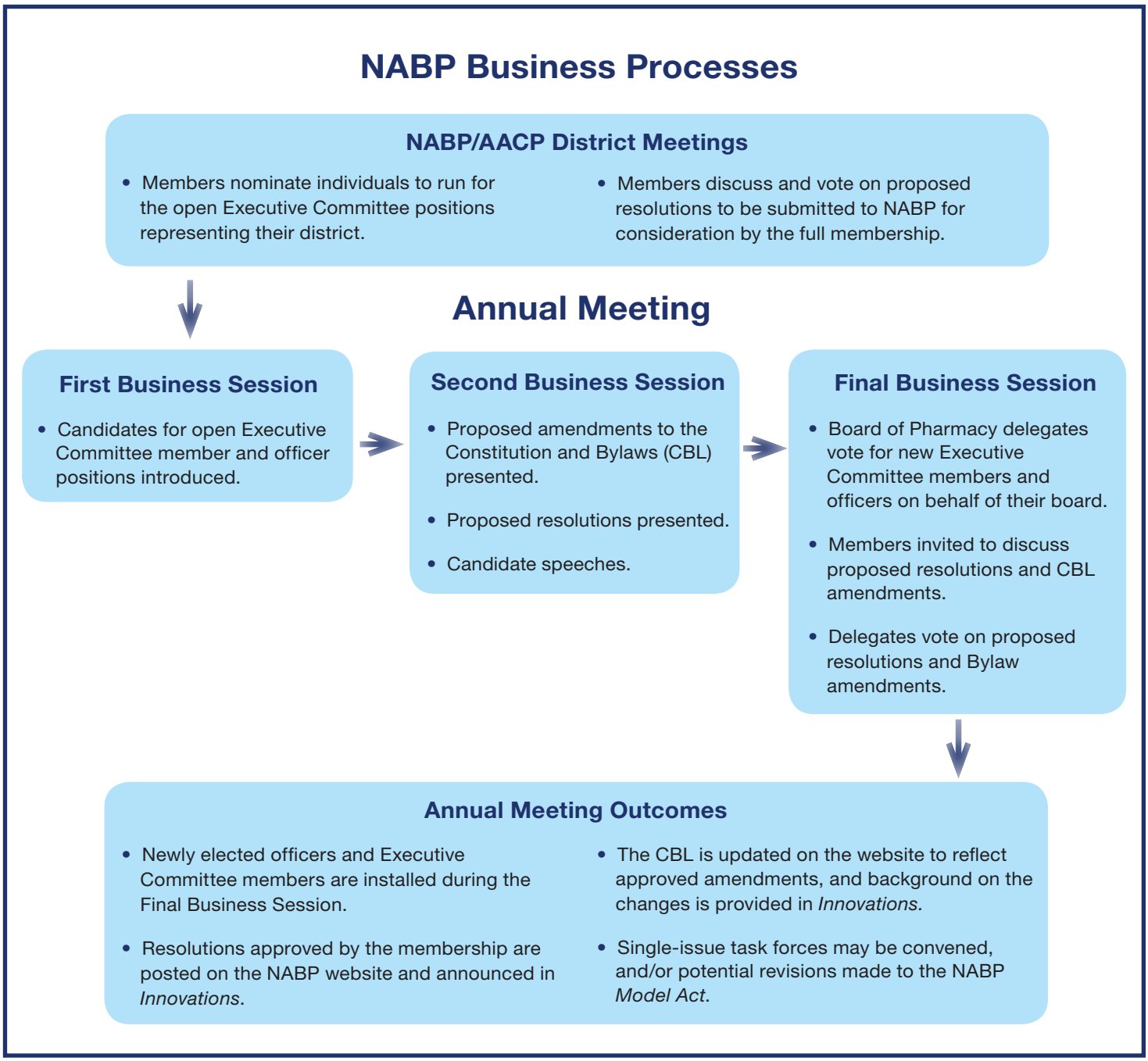
Orientation for Annual Meeting Attendees

Annual Meeting attendees have the opportunity to learn about NABP business processes and procedures in an orientation session on Thursday, May 16.



AM Business Processes

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when the new Executive Committee officers and members are elected and installed. Attendees also hear the remarks of the incoming president and the final reports of the Committee on Constitution and Bylaws and the Committee on Resolutions. During these reports, the proposed amendments and resolutions that were read during the Second Business Session are discussed and voted on. Although only designated voting delegates from active member boards may vote, any affiliated member may participate in the discussion portion of the Final Business Session's agenda. An affiliated member is any individual who is a current or former member or administrative officer of an active or associate member board of the Association.

With important outcomes such as new Executive Committee officers and members, amendments to the NABP Constitution and Bylaws, and adoption of policy-setting resolutions, attendees can see the significance of the business sessions to the NABP member boards. It is through participation in these sessions that members have the opportunity to help shape the Association's actions for the coming year. ■

Around the Association

Executive Officer Changes

- **Dmitry Kunin, PharmD, MBA, RPh,** has been named program director of the Colorado State Board of Pharmacy, replacing Interim Program Director Joseph Liber. Prior to assuming the position, Kunin was pharmacy market manager – Market 716 at Sam's Club Health and Wellness. Kunin's previous positions include Health and Wellness director – Market 130 and pharmacy clinical services manager at Walmart Health and Wellness; pharmacy manager at Walgreens Pharmacy and Safeway Pharmacy; and pharmacist at SuperValu. Kunin received his doctor of pharmacy from St Louis College of Pharmacy and master of business administration from the University of Missouri.
- **Norma Torres-Delgado** has been named executive director of the Puerto Rico Board of Pharmacy, replacing Agustin González-Rivera. ■

(Above) Members of the North American Pharmacist Licensure Examination® (NAPLEX®) Competency Statement Review Committee met at NABP Headquarters in January 2019 to review and revise the competency statements that will be used for the NAPLEX National Pharmacy Practice Survey of Practitioners. Pictured are Adam Pate, PharmD, RPh, BCPS, University of Mississippi; Neal Walker, RPh, Hill City, MN; Susan Lutz, RPh, Altoona, IA; and William A. "Bill" Hopkins, Jr, PharmD, RPh, Big Canoe, GA. ■

Newly Accredited DMEPOS Facilities

The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

Aeva Specialty Pharmacy
Las Vegas, NV

Highland Specialty Pharmacy
Hattiesburg, MS

Kremer Pharmacy - Altamont
Altamont, IL

Medical Home Pharmacy
Trenton, NJ

A full listing of approximately 250 DMEPOS-accredited companies representing almost 25,000 facilities is available on the NABP website at *www.nabp.pharmacy*.

Delaware Legislation Affects Pharmacy Practice

Delaware Governor John Carney has signed three bills into law regarding emergency prescriptions, benzodiazepine and non-benzodiazepine hypnotics, and expedited partner therapy (EPT). Because of the delay in the prior authorization process by pharmacy benefits managers, many patients end up waiting days or weeks for medications to be filled. Prescriptions that often involve long waits to be filled are medications prescribed on an emergency basis and medications that have been previously prescribed for chronic and long-term conditions that must go through the prior authorization process again. To reduce the delays and hardships of this waiting process, House Bill (HB) 441 will establish specified time tables to fill emergency prescriptions and make subsequent prior authorizations for chronic and long-term conditions filled more readily.

Further, HB 331 creates regulations concerning the use, distribution, and education of benzodiazepine and non-benzodiazepine hypnotics. This bill requires practitioners to obtain consent from a minor's parent or guardian prior to prescribing these drugs and requires the pharmacist to include a cautionary statement explaining the risks associated with the long-term use of these drugs.

Under Senate Bill (SB) 157, EPT, the clinical practice of treating the sex partners of patients diagnosed with a sexually transmitted disease without clinical assessment of the partners, is now permissible in Delaware. The act requires health care professionals to provide information developed by the Delaware Department of Health and Social Services when providing EPT and provides immunity to health care practitioners and pharmacists acting in compliance with the statute. SB 157 also provides immunity to health care practitioners who do not provide EPT and pharmacists who do not fill a prescription written under this statute if doing so would violate any law that governs them.

Massachusetts Establishes New Tobacco Regulation

As of December 31, 2018, any retail stores containing pharmacies licensed by the Massachusetts Board of Registration in Pharmacy may no longer sell tobacco products.

Ohio Colleges and Universities Receive Access to PDMP Training Tool for Students

Ohio's colleges and universities now have access to a new training program designed to simulate the use of the state's prescription drug monitoring program (PDMP), Ohio Automated Rx Reporting System (OARRS). OARRS Academy is a demonstration system designed to educate students in the health care professions on the process and value of including OARRS in the professional decision-making process. OARRS Academy is the first of its kind in the country and will provide Ohio students with an opportunity to simulate the use of OARRS in the classroom setting. The simulation comes preloaded with data for a variety of sample patients and allows for the creation of additional sample patients. This tool is available at no cost to all Ohio colleges and universities engaged in the training of pharmacists and prescribers. For more information, visit *www.oarrsacademy.ohio.gov*.

Utah Addresses New Rules Governing Cannabidiol Products

During the 2018 legislative session, the Utah Legislature passed two laws that address industrial hemp and cannabidiol (CBD). Utah allows for the "sale or use" of a CBD product provided it is registered with the Utah Department of Agriculture and Food (UDAF). The law specifies that CBD products must be in one of the following medicinal dosage forms: capsule, tablet, concentrated oil, sublingual, liquid suspension, or transdermal preparations. Additionally, the law allows UDAF to establish labeling and testing requirements for CBD products.

The rule requires that labels for CBD products meant for human consumption follow the federal guidelines for the labeling of dietary supplements, including the usage of a supplement facts panel and not a nutrition facts panel. Additionally, the label should include a barcode or QR code, which will link to the certificate of analysis (COA) performed for that specific batch of product. The rule does not allow medical claims to be made.

UDAF requires that these products undergo third-party testing. These third-party tests must establish and show the cannabinoid profile and test for residual solvents, pesticide residue, heavy metals, and microbials. A copy of the COA for each product must be attached to the label with the product being registered with UDAF. UDAF will periodically check these products against the COA filed with the product to check the accuracy of the labels and the COA. It is the responsibility of retail owners to ensure that the products in their stores are registered. UDAF is committed to educating retailers about the rules before issuing citations. ■

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

FDA to Modernize Oversight and Reporting of Inspections for Sterile Injectable Drugs

According to a November 9, 2018 statement, Food and Drug Administration (FDA) Commissioner Scott Gottlieb, MD, announced the agency's plans to modernize its inspections program with a new way of assessing, recording, and reporting data from surveillance and pre-approval inspections for sterile drug products. A new FDA tool – New Inspection Protocol Project (NIPP) – uses standardized electronic inspection protocols to collect data in a structured manner for more consistent oversight of facilities as well as faster and more efficient analysis of the agency's findings. Gottlieb said FDA has been applying this new tool to its inspectional work related to sterile injectable drugs, which have been the subject of sterility problems and shortages in the past.

The first phase of NIPP was aimed at developing a protocol that could be used during aseptic processing surveillance and pre-approval inspections. FDA conducted multiple pilots of the NIPP protocols to ensure that they would be consistent with current program objectives and integrate into the way investigators conduct inspections. As the agency integrates learnings from these pilots and field activities, FDA's goal is to have them ready for full implementation within the next two years. More details can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625601.htm*.

FDA Warns About Recalls Affecting Valsartan, Losartan, and Irbesartan Products

In November 2018, FDA alerted health care professionals and patients about angiotensin II receptor blocker (ARB) recalls affecting valsartan, losartan, and irbesartan products. FDA continues to investigate the presence of N-Nitrosodiethylamine and N-Nitrosodimethylamine, which are probable human carcinogens, in ARBs. With the investigation ongoing, FDA has been updating its drug safety statement. At press time, the agency issued the following alerts:

- November 27, 2018: Teva Pharmaceuticals recalls all lots of valsartan-containing products manufactured using an active pharmaceutical ingredient (API) from Mylan Pharmaceuticals.
- November 21, 2018: Mylan recalls 15 lots of valsartan-containing products.
- November 9, 2018: Sandoz, Inc, recalls one lot of losartan potassium and hydrochlorothiazide tablets made using an API manufactured by Zhejiang Huahai Pharmaceutical Co Ltd, which is on import alert.

FDA notes the agency is taking swift action when it identifies unacceptable impurities in APIs and finished drug products, indicates the statement, which is available at *www.fda.gov/Drugs/DrugSafety/ucm613916.htm*.

IHS Enables Providers to Apply for Designation to Prescribe OUD Treatment via Telemedicine

On November 1, 2018, the Indian Health Service (IHS), an agency within the United States Department of Health and Human Services, announced the release of a new Internet Eligible Controlled Substance Provider Designation policy, which is designed to increase access to treatment of opioid use disorder (OUD) for American Indians and Alaska Natives living in rural or remote areas. This policy enables IHS, tribal, and urban Indian organization health care providers to apply to be designated by IHS as Internet Eligible Controlled Substance Providers, allowing them to prescribe controlled substances for medication-assisted treatment through telemedicine.

More information is available in a November 2018 IHS blog post, which can be found in the Newsroom section at *www.ihs.gov*.

ASHP Updates Handling Hazardous Drugs Guidelines

In the updated "ASHP Guidelines on Handling Hazardous Drugs," the American Society of Health-System Pharmacists (ASHP) outlines new and continuing concerns for health care workers handling hazardous drugs and provides recommendations and requirements.

Developed through the ASHP Council on Pharmacy Practice, the new guidelines provide a framework for health care teams to develop policies and procedures to minimize the risks that hazardous drugs pose to health care workers. The updates align with US Pharmacopeia (USP) General Chapter *800 Hazardous Drugs — Handling in Healthcare Settings* and provide guidance on topics not addressed in USP Chapter 800, including the safe use of robotics in both the preparation and proper disposal of hazardous drugs. These guidelines supersede the ASHP guidelines on handling hazardous drugs dated January 12, 2006. Published online on October 25, 2018, and in the December 15, 2018 issue of *American Journal of Health-System Pharmacy*, the guidelines can be located at *https://doi.org/10.2146/ajhp180564*.

More information is also available in an October 17, 2018 news release available in the News and Press Releases section at *www.ashp.org*. ■

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

Committee on Constitution and Bylaws
April 8, 2019
Teleconference

FPGEE Administration
April 10, 2019

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

NABP Program Review and Training
June 18-19, 2019
NABP Headquarters

PMP InterConnect Steering Committee Meeting
July 16-17, 2019
NABP Headquarters

NABP/AACP District 5 Meeting
August 7-9, 2019
Duluth, MN

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