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iNNOVATiONS

Passing the Leadership Torch:

NABP Names New Executive Director

NABP
National Association of Boards of Pharmacy

iNNOVATiONS

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Lemrey "Al" Carter
Executive Director/Secretary

Amy Sanchez
Communications Manager

NABP Mission Statement
NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP
National Association of Boards of Pharmacy

Oregon State Board of Pharmacy

Number of Board Members:
5 pharmacist members and 2 public members

Number of Compliance Officers/Inspectors:
6

Rules & Regulations Established by:
State Board of Pharmacy

Number of Pharmacist Licensees:
8,522

Number of Pharmacies:
1,535

Number of Wholesale Distributors:
788

Joseph 'Joe' Schnabel, PharmD, RPh

Executive Director, Oregon State Board of Pharmacy

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

I have been executive director of the Oregon State Board of Pharmacy since February 4, 2019. Prior to working with the Board, I was director of pharmacy at Salem Health in Salem, OR. I worked at Salem Health for 31 years – the first 24 years as the clinical pharmacy manager and the last seven years as director of pharmacy.

Early in my pharmacy career, I served as a Board member for eight years. This experience enabled me to realize the important role that boards play in the public protection and regulation of pharmacy practice. For the past 18 years, I have also taught the pharmacy law course at Oregon State University/Oregon Health & Sciences University College of Pharmacy.

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

During the interview process and after I was hired, it was clear that the Board was very eager to begin a strategic planning process to clearly articulate, prioritize, and execute change in areas needing regulatory updates. Several of these issues, particularly technician and technology regulations, had been in discussion over the past several years. The continued evolution of technicians' assistance in the practice of pharmacy will be critical to the evolution of a pharmacist's provision of patient care services, such as prescribing under statewide protocols. Many technologies have emerged that would allow improved access and efficiency without compromising patient safety.

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

The Board and staff leadership solicited input from pharmacy association and academic stakeholders, then met over two days to discuss the current state of pharmacy regulation and to prioritize areas in need of updated rules.

Five major goal areas were identified: technicians, technology, licensing, regulation, and communication. Each of these areas was determined to be critical for creating a regulatory structure that provides the highest level of public protection, while allowing pharmacists to incorporate emerging patient care services into their practices.

What other key issues has the Board been focusing on?

The legislature has passed bills requiring pharmacies to improve the labeling of prescription medications for people with visual impairment and limited English proficiency. Bills were also passed requiring continuing education in cultural competency, adding the diagnosis code and "reason for the prescription" to the prescription drug monitoring program, and reducing barriers to licensure for immigrants and spouses or domestic partners of military service personnel.

Two years ago, the Oregon Legislature gave the Board statutory authority to adopt statewide drug therapy management protocols and a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a health care practitioner. Developed by the Public Health and Pharmacy Formulary Advisory Committee, both have been presented for adoption by rule of the Board.

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

Every state has unique challenges it must meet to achieve its mission to protect the public. One key is to maintain open communication with Board members to make sure that the Board and staff are working in concert to carry out the statutory directives and public protection mission in the most effective ways possible. The Board and staff should also try to maintain open communication with licensees to facilitate understanding of each other's perspectives on regulations and compliance. ●

Washington's Response to COVID-19 and the Impact on Pharmacies and Pharmacists

As the nation and world contended with the emergence and spread of coronavirus disease 2019 (COVID-19) this spring, policymakers in Washington, DC, responded with unprecedented speed by enacting and implementing multiple sweeping laws and regulations to combat the virus. From major cash assistance for businesses and individuals to sweeping health care reforms, policies impacting every facet of American life were driven by the COVID-19 public health emergency. Not surprisingly, pharmacists have proved to be key to helping ensure safe and timely access to medications, tests, and other products and services during the pandemic. This article provides an overview of the initial federal COVID-19 relief packages and highlights just some of the major policy changes that have impacted the practice of pharmacy during the COVID-19 pandemic thus far.

Megan S. Herber, MPH
Faegre Drinker Biddle & Reath LLP

Sarah-Lloyd Stevenson
Faegre Drinker Biddle & Reath LLP

Three Phases of Pandemic Relief Laws in March

In March 2020 alone, Congress passed, and President Donald J. Trump signed into law, three major relief bills to fund public health activities, ensure access to health care, support businesses, and send relief to individuals.

Phase 1 – The first law, the Coronavirus Preparedness and Response Supplemental Appropriations Act, signed into law on March 6, focused primarily on public health protection and response. The act deployed $8.3 billion in emergency funding for response to the outbreak by federal agencies, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, the Small Business Administration, and the United States Department of State. The law also provided funds for the Public Health and Social Services Emergency Fund at the US Department of Health and Human Services (HHS) to support the health care workforce and made changes to Centers for Medicare & Medicaid Services (CMS) policy allowing for more reimbursement of telehealth services.

Phase 2 – With the second law, legislators turned their attention from the immediate public health response to worker and family protections during the public health emergency. The Families First Coronavirus Response Act, signed into law on March 18, mandated and funded paid sick leave and emergency leave for employees of certain companies. The act also infused money into federal agencies for federal safety programs, such as food assistance and unemployment benefits. It also required and subsidized paid sick leave and emergency leave for employees, as well as free COVID-19 testing.

Phase 3 – By the end of March, it was clear to Congress and the Trump Administration that the public health emergency had evolved into an economic crisis. In response, the third law, the Coronavirus Aid, Relief, and Economic Security (CARES) Act, was enacted on March 27 and allocated an unprecedented $2.2 trillion in relief funding. The act appropriated more funding intended to support workers, businesses, and the health care system. It created the Paycheck Protection Program, through which small businesses could benefit from $349 billion in forgivable loans; authorized direct payments to individuals; appropriated $100 billion in relief funding for health care providers; and funded payments to distressed industries, among other policies and forms of relief funding.

Not surprisingly, pharmacists have proved to be key to helping ensure safe and timely access to medications, tests, and other products and services during the pandemic.

Top 10 COVID-19 Federal Actions and Policies Impacting Pharmacy

With new authority from Congress and the emergency declarations, federal agencies like HHS have moved to loosen regulations and provide guidance to providers in the field. Through guidance documents, new regulations, and the enacted laws, many policies in Washington, DC, have directly impacted pharmacists and the practice of pharmacy during the COVID-19 public health emergency.

1. **COVID-19 Tests and Pharmacist Protections** – HHS authorized licensed pharmacists to order and administer

COVID-19 tests approved by Food and Drug Administration (FDA). This policy allows pharmacists to qualify as "covered persons" under the Public Readiness and Emergency Preparedness Act, affording them immunity to claims for losses caused by, arising out of, relating to, or resulting from the administration or use of the FDA-approved COVID-19 tests.

2. **Remote Prescribing of Controlled Substances** – Drug Enforcement Administration loosened remote prescribing restrictions during the public health emergency, enabling providers to prescribe controlled substances using telemedicine.
3. **Protecting Pharmacists From Exposure** – CDC issued guidance on how pharmacists can take precautions to minimize risk of exposure to themselves and their patients.
4. **Encouraging Practice Across State Lines** – HHS Secretary Alex Azar wrote to all governors asking them to work with other states to allow for licensed or certified health professionals to practice across state lines.
5. **Part D and Out-of-Network Pharmacies** – CMS issued guidance directing Medicare Part D to reimburse enrollees for prescriptions obtained from out-of-network pharmacies if access to network pharmacies is disrupted.
6. **Compounding for Hospitalized Patients** – FDA announced the agency will not take action against compounding facilities that make a medicine that is a copy of an approved drug, use bulk ingredients not on an approved list, or fail to meet good manufacturing requirements for stability testing during the public health emergency, as long as the drug is in shortage and certain criteria are met.
7. **Compounding Hand Sanitizer** – FDA also updated guidance to allow for and provide support for temporary compounding of alcohol-based hand sanitizers by pharmacists during the pandemic.
8. **90-Day Prescription Supply** – The CARES Act requires that Medicare Part D plans provide a 90-day supply of prescription medication when requested by the patient during the public health emergency.
9. **HIPAA Guidance** – The CARES Act directs HHS to issue guidance on the sharing of patients' protected health information during the COVID-19 public health emergency. Due within 180 days of the legislation's enactment, the guidance should address compliance with existing Health Insurance Portability and Accountability Act (HIPAA) regulations, including any policies that may come into effect due to the national emergency.
10. **Drug Shortages** – The CARES Act enacted several new policies to help avert future drug shortages. The law directs FDA to prioritize and expedite reviewing generic applications for drugs in shortage. The act also expands manufacturers' reporting requirements around shortages and mandates the inclusion of certain medical supplies and drugs in the nation's Strategic National Stockpile.

The top 10 policy changes described are only temporary policies put in place during the pandemic. In addition, the CARES Act permanently made the first meaningful reform to FDA's treatment of over-the-counter (OTC) drugs in nearly 50 years. Now, FDA may designate or approve changes to OTC monographs administratively, rather than going through full notice and comment rulemaking. Under this new, faster administrative process, decisions rest with agency scientists, which is more in line with the current procedure for prescription drug label updates. This new process should make it much easier for FDA to revise OTC monographs to reflect the latest science and respond to safety issues. To support this new OTC drug review, the law established a new FDA OTC user free program.

Congress also reversed a policy from the Affordable Care Act that required individuals to obtain a prescription to use health savings accounts and health reimbursement accounts to purchase OTC drugs. Now patients can use these accounts for OTC drugs, medical supplies, and menstrual products.

Practice of Pharmacy and the Continued Federal Response to COVID-19

Congress and the Administration acted swiftly in March 2020 by providing funding and implementing policies to mitigate the COVID-19 pandemic, attempting to allow health care providers to address the crisis in creative ways, without regulatory barriers. The fight against the pandemic is not over, and continued involvement from the federal government will be required both to address the pandemic and to adjust policies to the "new normal" as we emerge from it.

NABP will continue to be flexible and responsive to boards of pharmacy needs by engaging with Congress and the Administration in the months to come. Meanwhile, pharmacists will continue to be on the front lines of this pandemic providing both COVID-19-related and other health services, including if and when a vaccine is approved. As boards of pharmacy and pharmacists respond to the urgent health needs during and after the public health emergency, it will be critical that federal policies enhance – and do not impede – their work. ●

This article was written by Megan S. Herber, MPH, and Sarah-Lloyd Stevenson with Faegre Drinker Biddle & Reath LLP. Please note, the opinions and views expressed by Faegre Drinker Biddle & Reath do not necessarily reflect the official views, opinions, or policies of NABP or any member board unless expressly stated.

Passing the Leadership Torch:
NABP Names New Executive Director

The NABP Executive Committee is pleased to announce that Lemrey "Al" Carter, PharmD, MS, RPh, assumed the position of executive director/secretary at the close of the Association's 116th Annual Meeting, which was held virtually on May 14, 2020. He succeeds Carmen A. Catizone, MS, RPh, DPh, the fourth NABP executive director. Catizone, who is retiring from NABP after serving the Association for 35 years, will serve in an advisory capacity until December 31, 2020.

Carmen A. Catizone, MS, RPh, DPh

Lemrey "Al" Carter, PharmD, MS, RPh

Prior to joining NABP, Carter served as the divisional vice president of pharmacy operations and professional affairs for Walgreens. In this position, he was responsible for the day-to-day operations and pharmacy regulatory oversight of more than 9,200 pharmacies in the United States as well as oversight, management, and execution of all commercial, Medicare Parts B and D, and state Medicaid plans. In addition, Carter was serving his second term as a member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy.

"NABP is excited to welcome Dr Carter as the next executive director/secretary," said Search Committee Chair and 2019-2020 NABP Chairperson Susan Ksiazek, RPh, DPh. "His commitment to community, excellence, and innovation will foster responsible stewardship of the Association's resources. Dr Carter will lead with passion and integrity as he serves NABP's membership and works tirelessly to support our shared mission of protecting public health."

"I am humbled and excited by the opportunity to lead NABP and will continue to be an unyielding advocate for the protection of public health while preserving the long-standing success of NABP," said Carter.

Reporting to the NABP Executive Committee, Carter's responsibilities as executive director/secretary will include leadership of the Association, budget oversight and development, and strategic planning and analysis. In addition, he will collaborate with professional organizations and stakeholders at the state and federal levels to advance public health protection.

In addition to serving on the Illinois State Board of Pharmacy, Carter was appointed by the Illinois House of Representatives to serve two terms on the Illinois Collaborative Pharmaceutical Task Force. He is a member of the American Association of Colleges of Pharmacy Council of Deans Task Force on Community-Based Pharmacy Practice and has served on numerous task forces and committees for pharmacy organizations, including NABP. Carter earned his master of science degree with studies focused on pharmacy regulation and policy from the University of Florida and his doctor of pharmacy degree from Xavier University of Louisiana, College of Pharmacy. ●

Carter's Three-Year Plan

1. Develop and strengthen relationships with the Executive Committee, and all state executives and board members to better understand how NABP can best serve its member boards
2. Continue focusing on NABP programs and make improvements that foster a culture of innovation through technology and the utilization of data and digital solutions to assist member boards in regulating for the purpose of protecting public health
3. Focus on data integration and the opportunities that exist with the enhanced collection and utilization of NABP e-Profile data

For more information about Catizone's 35 years of service to the Association, see "Looking Ahead: Association Prepares for Leadership Changes," from the November/December 2019 issue of *Innovations*.

2019-2020 Annual Report on Association Legal Affairs

The extraordinary challenges everyone is facing in 2020 present opportunities to achieve new goals and provide greater support for members, colleagues, and the public. The NABP Legal Affairs team has endeavored to accomplish both while assisting the Association in its pandemic initiatives, including collating the latest regulatory information and preparing for a virtual Annual Meeting.

Since the 2019 Annual Meeting, Legal Affairs has provided guidance and partnered with colleagues to support Association growth:

- In December 2019, NABP expanded its accreditation portfolio by acquiring key assets of a compounding pharmacy accreditation program; and
- In April 2020, NABP deployed a new telecommunications system that will foster enhanced customer data analysis.

Board Support

In December 2019, NABP hosted the Interactive Compliance Officer and Legal Counsel Forum. Legal Affairs curated the educational programming for board counsel, which included several attorneys who discussed their individual state's administrative review cases. Detailed case summaries were created by the Legal Affairs team and shared with participating board counsel. Legal Affairs is looking forward to offering an educational webinar for board attorneys, slated for fall 2020.

In support of the California State Board of Pharmacy, NABP (joined by eight boards of pharmacy) filed an amicus curiae brief in the *Fusion IV Pharmaceuticals, Inc v. California State Board of Pharmacy* appellate case. Fusion IV Pharmaceuticals, Inc (Fusion) filed an appeal with the United States Court of Appeals for the Ninth Circuit. Fusion is a California-based 503B outsourcing facility that contended federal law preempts state law regulating outsourcing facilities, among other claims. NABP and the boards of pharmacy that joined the brief set forth numerous arguments in opposition to the preemption claims. In June 2020, the Appellate Court rejected all of Fusion's claims and affirmed the decision of the lower court that the 503B outsourcing facility regulations of the California State Board of Pharmacy are not preempted by the federal Drug Quality and Security Act. The Appellate Court Memorandum Decision is available on the Court's website at *https://cdn.ca9.uscourts.gov/datastore/memoranda/2020/06/17/19-55791.pdf*.

Litigation Update

Currently, NABP is a party to three lawsuits:

- In January 2020, the Association sued an individual who allegedly engaged in copyright infringement related to an NABP examination. The individual has not yet responded to the claims in NABP's lawsuit, and the case is still pending.
- NABP is a defendant in a case involving its Drug Distributor Accreditation. Three applicants to the accreditation program claim, among other things, that NABP is a state actor, and its accreditation program criteria are preempted under federal law. The applicants withdrew their petition for a preliminary injunction, which asked the court to halt the operation of NABP's accreditation program. The applicants amended their claims and now seek monetary damages, all of which NABP is seeking to dismiss. The accreditation program continues to operate without restriction. NABP denies the allegations in this case.
- In August 2019, an organization that accredits international pharmacies that ship medications to the US sued the Association and four other organizations that support safe online pharmacy practice. The international pharmacy accreditor argued that NABP conspired with the others to exclude it from internet search engine results and reduce consumer choice, among other claims. The accreditor sought a preliminary injunction to require NABP to remove its name from a list of "not recommended" websites that the Association maintains; the court denied the preliminary injunction petition. The accreditor revised its lawsuit, and NABP recently filed a request to dismiss the case. NABP denies the allegations in this case.

NABP is vigorously protecting its assets and operations in all three cases, but it is not able to comment otherwise on the pending litigation.

Since the 2019 Annual Meeting, Legal Affairs has provided guidance and partnered with colleagues to support Association growth.

Deep Gratitude and Exciting Future

NABP staff sincerely thanks former NABP Executive Director/Secretary Carmen A. Catizone for his unwavering commitment to the Association and its membership, and congratulates him for 35 years of exceptional leadership. Catizone's incredible legacy is the foundation for the data-driven and innovative public health protection initiatives that will be launched as envisioned by NABP's new executive director/secretary, Lemrey "Al" Carter. NABP staff is thrilled to team with Carter as it advances the Association and strengthens its partnership with member boards in service to the public. ●

NABP Announces 2020-2021 ACE Appointments

NABP is pleased to announce the roster of individuals appointed to serve on the 2020-2021 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations.

ACE oversees the development and administration of all the Association's examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically convenes twice per year. The committee consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers, individuals who have served within the last five years as a member or administrative officer of a board of pharmacy, and non-affiliated individuals who are practicing pharmacists or serving as pharmacy school faculty. Members serve three-year terms and ex officio members serve one-year terms. The following members began their terms on June 1, 2020. Jeffrey J. Mesaros, PharmD, JD, RPh, NABP Executive Committee member, is serving as the Executive Committee liaison.

Michael A. Burleson, RPh
Kentucky

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

Debra B. Glass, RPh
Florida

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

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

Theresa M. Talbott, RPh
Pennsylvania

Anita M. Young, EdD, RPh
Massachusetts

N. Katie Busroe, RPh
Kentucky (ex officio member, one-year term, Multistate Pharmacy Jurisprudence Examination® program)

Kimberly "Kim" Burns, JD, RPh
Pennsylvania (ex officio member, one-year term, Foreign Pharmacy Graduate Equivalency Examination®/ Pharmacy Curriculum Outcomes Assessment® programs)

Eric F. Schneider, PharmD, BCPS
North Carolina (ex officio member, one-year term, North American Pharmacist Licensure Examination® program)

Color denotes new member

Additional State Boards of Pharmacy Opt to Utilize NABP's Exam Eligibility Service

NABP has expanded its exam eligibility service to include two additional member boards of pharmacy – Kentucky and Rhode Island. The service allows NABP to confirm candidates' eligibility to take the North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination®. In addition, NABP's enhanced e-Profile system now allows for greater automatization of the eligibility review process by eliminating paper applications and requiring candidates to upload requests for accommodations under the Americans with Disabilities Act during the online examination application process.

Kentucky and Rhode Island join the following additional boards in utilizing this service: Colorado, Maine, Michigan, Nebraska, Oregon, and Utah.

State boards interested in utilizing this service may contact the Member Relations and Government Affairs department via email at GovernmentAffairs@nabp.pharmacy for more information. ●

New Streamlined Application for NABP Accreditation and Inspection Programs Offers Benefits for Businesses, Boards

NABP is launching a streamlined application process for its accreditation and inspection programs that enables pharmacies and other licensees – wholesale distributors, third-party logistics providers, and manufacturers – to more easily apply for these programs via the NABP e-Profile system. The application will be connected to the Association's e-Profile system, which has been expanded to include any pharmacy-related business. (See "NABP e-Profiles Now Available to Pharmacies, Other Pharmacy-Related Businesses" on this page for more information about NABP's business e-Profile.)

The improved application process was launched for the Verified Pharmacy Program® and Supply Chain Inspection in April 2020. All NABP accreditation and inspections programs are expected to be integrated into the new and improved application process by fall 2020.

Streamlining the Application Process

Previously, businesses were required to complete separate applications for each accreditation and inspection program. As a result, when applying for multiple programs, applicants often spent considerable time reentering the same information into each application. Businesses that complete their e-Profile prior to submitting a program application can further reduce the amount of time spent as the system automatically pulls relevant information from the applicant's business e-Profile to prepopulate data fields in the application (ie, the more robust the data in an applicant's e-Profile, the more information there is to prepopulate the application's data fields). Once the application is prepopulated with available data, the business will be asked to provide additional data pertinent only to the program for which it is applying.

The prepopulated information can be updated as needed during the application process. By regularly updating and augmenting the information in their e-Profiles, businesses can ensure a more efficient application experience when applying for an NABP accreditation or inspection program in the future.

More Robust Data Available to Boards

As businesses continue to build upon their e-Profiles, more robust data will be accessible to member boards via NABP e-Profile Connect (eg, information about businesses' licensing and disciplinary history, business practice models, as well as information about employees such as pharmacist-in-charge, pharmacy technicians, and more). Access to comprehensive business data continues to support boards of pharmacy making licensing decisions and ultimately, better protecting the public health.

In addition, in 2019, NABP introduced an application programming interface (API) for e-Profile Connect that allows participating states to automatically access NABP-provided information. The NABP API enables the NABP e-Profile system to share data with systems used by individual boards, and vice versa. By using the API to support data exchanges, states gain the ability to update their systems with relevant information from NABP at any time. Boards are encouraged to require licensees, including businesses, to obtain an NABP e-Profile ID in order to participate in these data exchanges. By doing so, boards will ensure that information in their systems is matched to NABP data and reduce data inconsistencies and errors as well as the burden on board staff time and resources. For more information about NABP's data exchange capabilities, including the benefits to member boards, see "NABP Enhances e-Profile Connect Technology, Offers Member Boards New Method for Improved Data Sharing" in the June/July 2019 issue of *Innovations*. ●

NABP e-Profiles Now Available to Pharmacies, Other Pharmacy-Related Businesses

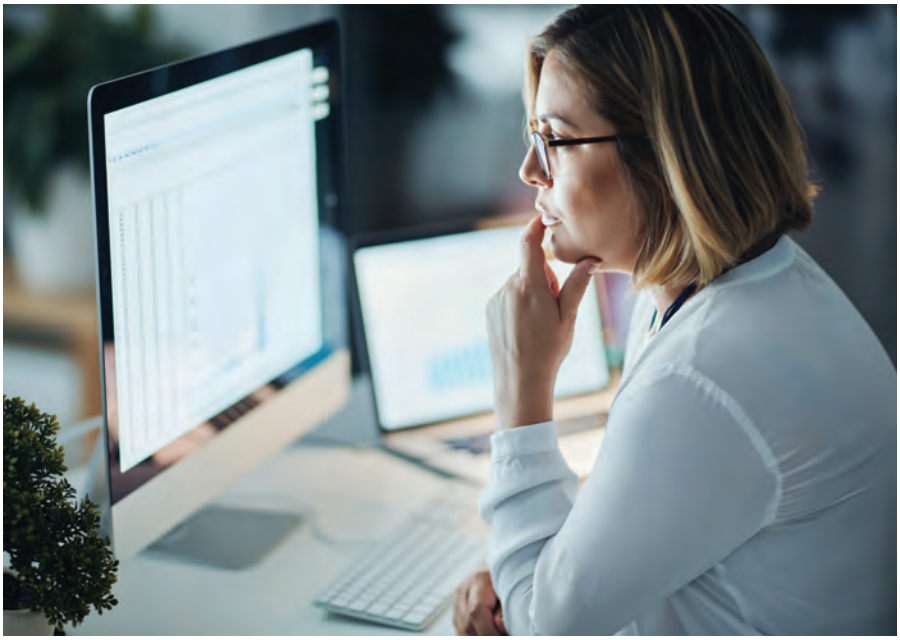
Boards of pharmacy may now direct pharmacies and other licensees, such as wholesale distributors, third-party logistics providers, and manufacturers, to the NABP website to create NABP e-Profiles for their businesses. The business NABP e-Profile contains information relevant to a licensee's demographics, licensure, business hours, activities (eg, compounding, long-term care, specialty, wholesale distribution, etc), inspection and accreditation histories, and ownership information.

Boards of pharmacy are encouraged to have their facility licensees create e-Profiles and provide the e-Profile IDs to the board. Doing so will position member boards to take advantage of data sharing opportunities with NABP. Benefits of data sharing with NABP include real-time updates of inspection and accreditation data, decreases in data inconsistencies and errors, and reduced processing time for the boards and the Association.

Facility licensees can request a business NABP e-Profile, free of charge, via the NABP e-Profile Login link on *www.nabp.pharmacy*. Additional information, including steps to initiate a new business NABP e-Profile, can be found on the NABP Help page at *www.nabp.pharmacy/help*.

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

The annual Multistate Pharmacy Jurisprudence Examination® (MPJE®) state-specific item pool review and new item selection will take place **August 10-September 11, 2020**. State board participation is critical to ensure that the MPJE maintains the highest validity standards with the most up-to-date and defensible items. NABP requests that all MPJE-participating jurisdictions schedule resources and time to complete this important set of tasks.



Remote Review

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

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

1. select new items to be pre-tested, which will become scored items in the future, and
2. review their current operational (scored) item pool to confirm it is still valid.

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

Regulatory Changes May Impact MPJE

State laws and regulations pertaining to the practice of pharmacy must be reviewed regularly, as changes may impact the MPJE. Such regulatory changes that may impact the MPJE item pool include, but are not limited to, changes to:

- the list of vaccines that pharmacists are permitted to administer, or changes in the defined patient population to which pharmacists may administer vaccines;
- statute language, official titles, definitions, etc, that would render MPJE language invalid;
- initial license, renewal, or continuing education requirements;
- collaborative practice agreements;
- state drug schedules;
- pharmacists' right to refuse prescriptions;
- requirements regarding prescription expiration dates;
- pharmacist-to-technician ratio requirements;
- permissions for accessing emergency kits; and
- changes to requirements for dispensing syringes.

New federal- and state-specific items to test the pharmacy jurisprudence knowledge of candidates seeking licensure were developed by board of pharmacy-designated item writers during the MPJE Item Development Workshop held March 11-13, 2020. To date, 48 boards utilize the MPJE and are asked to participate in at least one State-Specific Review meeting each year to determine the appropriateness of items in the MPJE for candidates seeking licensure. ●

NABP encourages your designated remote reviewers to schedule specific days and times to complete the review, just as if they were traveling to NABP Headquarters.

NABP Accreditations and Verifications

NABP awarded a total of 140 accreditations and verifications from January 1 to March 31, 2020. The breakdown by program is as follows:

Drug Distributor Accreditation: 84

formerly known as Verified-Accredited Wholesale Distributors®

Digital Pharmacy Accreditation: 4

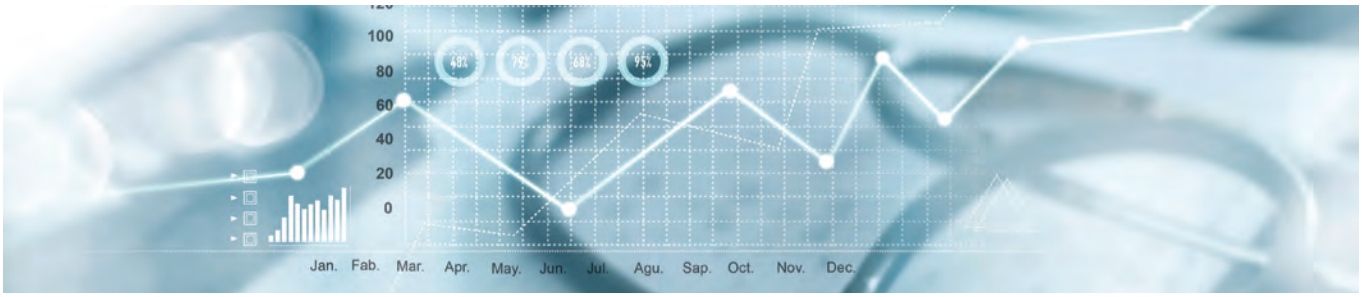
formerly known as Verified Internet Pharmacy Practice Sites®

DMEPOS Pharmacy Accreditation: 9

.Pharmacy Verified Websites: 43

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

First Quarter 2020 NABP Clearinghouse Totals Announced



During the first quarter of 2020, a total of 1,285 disciplinary records were submitted by the state boards of pharmacy on 1,100 individual and organization e-Profiles. The majority of disciplinary records submitted were for pharmacists, pharmacies, and pharmacy technicians. Please note that a disciplinary record can have multiple "actions" and "bases for actions," which explains why there will always be more actions and bases for actions than records reported.

Contained in the 1,285 disciplinary records, there were 1,558 actions reported to the NABP Clearinghouse. Of the 1,558 actions, the three most reported actions in the first quarter were publicly available fine/monetary penalty (556 or 35.7% of all actions); other actions not classified (146 or 9.3% of all actions); and reprimand or censure (141 or 9.1% of all actions).

Timely reporting to the Clearinghouse is essential to maintaining the integrity of the licensure transfer program. Boards may access the Clearinghouse using NABP e-Profile Connect.

Of the 1,507 bases for actions cited in first quarter 2020, violation of federal or state statutes, regulations and rules, or health and safety requirements (470 bases or 31.2%); other bases not classified (144 bases or 9.6%); and failure to comply with continuing education or competency requirements (117 bases or 7.8%) were the top reasons why disciplinary actions were taken during the quarter.

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

Robert Frankil, RPh

Member, Pennsylvania State Board of Pharmacy

Pennsylvania State Board of Pharmacy

Number of Board Members: 5 pharmacist members and 2 public members, plus 2 ex officio members

Number of Compliance Officers/Inspectors: 6

Rules & Regulations Established by: State Board of Pharmacy, General Assembly, and various other regulatory review agencies

Number of Pharmacist Licensees: 23,838

Number of Pharmacies: N/A

Number of Wholesale Distributors: N/A

When were you appointed to the Board of Pharmacy? What type of member are you (pharmacist, technician, public member, other)?

I was appointed in 2014 to a six-year term. I am a pharmacist member.

What steps should a board member take to be successful in his or her role?

I would suggest board members make all meetings, attend NABP Annual Meetings, read all notices and emails, be engaged, and listen to licensees in your state.

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

We are wrapping up regulatory revisions to our Pharmacy Act to stay current. In addition, we updated the compounding regulations and wrote regulations to reflect changes to our immunization laws (the flu age was lowered, and pharmacy students may administer injectables under the supervision of a pharmacist). We also addressed United States Pharmacopeia Chapter <800> in these revisions.

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

The Pennsylvania State Board of Pharmacy is not allowed to weigh in on legislation until it has passed into law. Once legislation has passed that affects the Pharmacy Act, the Board chimes in and begins to write regulations to make it work and be sensible. The regulatory process in Pennsylvania is very sluggish and slow, so it takes a long time to get a law passed. And once a law is passed, it takes a long time for the regulations to get written and approved. For example, in 2015, the immunization act, or Act 8 of 2015, was passed to allow pharmacists to administer immunizations. A two-part law was passed to amend it. One part lowered the immunization age for a flu shot to nine years. The other part allowed students to administer immunizations and injectables under the supervision of a pharmacist. The Board got those regulations written within a couple of meetings, and the governor approved the part about lowering the immunization age because it was considered an important public safety issue. Meanwhile, the other part has been sitting for several years. What happens in Pennsylvania now is that students get their training to administer injectables and immunizations in their fourth year of school. They can practice while in school, but once they graduate, they lose the ability to do so; and a year or two might lapse before they actually administer a shot.

Learn from senior board members, check your own agenda at the door, and act in the best interest of the public.

What advice would you give to a new board member?

Learn from senior board members, check your own agenda at the door, and act in the best interest of the public. Also, I would pay attention to the pharmacy profession in your state and strive to make it better and safer for all.

Have you served as a member of any NABP task forces or committees, or attended NABP or district meetings?

I have attended the NABP Annual Meeting and an interactive forum, which is my favorite event. You get to dig into what the other states are doing and have a lot of informal conversations with other attendees. The forum's format promotes interaction and hearing from others – all with the intent of enabling you to do your job as a board member better when you get home. ●

Arizona Eliminates Law CE Requirement for Pharmacists and Pharmacy Technicians

The Arizona State Board of Pharmacy is no longer requiring pharmacists and pharmacy technicians to obtain law continuing education (CE). The total amount of CE is still required per Board rule. The Board's CE requirements are as follows:

Pharmacists:

- 3 CE hours must be opioid related, substance-use related, or addiction related.
- 2 CE hours must be on immunization-related education (if you are an immunizer).
- A total of 30 Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) is required.

Technicians:

- 3 CE hours must be opioid related, substance-use related, or addiction related.
- 2 CE hours must be on remote dispensing site pharmacy practices, in addition to the required amount, if applicable.

A total of 20 ACPE-accredited CPE is required, plus 2 CE hours on remote dispensing site pharmacy practice, if applicable.

Idaho Rule Changes Impact Pharmacy Technician Certification, Pharmacist CE Requirements

In an effort to simplify current rules, combine five chapters of rules into one, and remove unnecessary barriers and restrictions to licensure/registration, the Idaho State Board of Pharmacy made the following changes to its rules.

- The categories of technicians have been collapsed into just two: pharmacy technician and certified technician. Upon the effective date of the rule, anyone currently registered as a grandfathered technician, a technician in training, or student technician will automatically be converted to a pharmacy technician registration. Current certified technicians will remain certified technicians. This rule change eliminates the requirement to become a certified technician after two years. The Board values technicians and encourages ongoing education and certification as evidenced by the expanded duties permitted over the past three years that are commensurate with the education, training, and experience of the technician to whom the tasks are delegated. The Board views certification as an employer decision, not a matter of law.
- Pharmacists may now use alternatives to the Board's CE requirement to renew their licenses, such as Board certification. This change provides a pathway for a pharmacist to substitute a current certification by a nationally accredited pharmacy practice-specific specialty certification program in lieu of CE credits.

The above rule changes became effective in March 2020. Additional details can also be found in the Board's March 2020 *Newsletter*.

New Mexico Updates Rules Related to Nuclear Pharmacies, Requires USP Chapter 825 Compliance

The New Mexico Administrative Code (NMAC) has been updated related to nuclear pharmacy requirements. Under 16.19.18 NMAC, training requirements have been updated to reflect current standards. The utilization of paper or electronic access to regulations has also been added. In addition, the minimum equipment requirements as appropriate for the scope of services provided have been added and are in addition to those found in 16.19.6.11 NMAC. All nuclear pharmacies must operate in conformance with United States Pharmacopeia (USP) Chapter <825> (once the chapter becomes official) and all applicable chapters below <1000>.

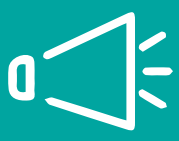
Additional details can be found in the New Mexico Board of Pharmacy's March 2020 *Newsletter*.

Virginia Classifies Gabapentin as Schedule V CS, Requires e-Prescribing of Opioids

The 2019 Virginia General Assembly passed legislation related to the scheduling of gabapentin and electronic prescribing of opioids.

House Bill (HB) 2557 classifies gabapentin as a Schedule V controlled substance (CS) as of July 1, 2019. The Virginia Board of Pharmacy notes that while this scheduling action occurred under state law, Drug Enforcement Administration (DEA) has not yet scheduled gabapentin; therefore, a prescriber is not required to hold a DEA registration in order to possess, dispense, or prescribe gabapentin. More information is available at *www.dhp.virginia.gov/Pharmacy/docs/Gabapentin06172019.pdf*.

HB 2559 amended §54.1-3408.02 and §54.1-3410 and requires any prescription for a CS that contains an opioid to be issued as an electronic prescription as of July 1, 2020. Several exceptions to this requirement are enumerated in §54.1-3408.02. Indicated in §54.1-3410, a pharmacist who receives a non-electronic prescription for a CS containing an opioid is not required to verify that one of the exceptions set forth in §54.1-3408.02 applies and may dispense such CS pursuant to such prescription and applicable law. ●



State Board News articles are selected from the newsletters of state boards that participate in the NABP State Newsletter Program. Five years' worth of issues are posted on the NABP website on each participating state's page.

NABP, Licensing and Regulatory Organizations Issue Joint Statement on COVID-19 Pandemic

NABP and several licensing and regulatory organizations across the country have issued a joint statement on the coronavirus disease 2019 (COVID-19) pandemic. Specifically, organizations involved in regulating the practice of pharmacy, medicine, nursing, physical therapy, psychology, occupational therapy, and social work expressed support for the efforts being undertaken by member boards and staff to help health care providers and other professionals deliver needed care during the pandemic. The statement placed emphasis on the ongoing coordination with county, state, and federal agencies and between partner organizations representing these professions.

As regulators, we share a common duty during this public health crisis to do what we can to ensure access to care across the country to those in need.

"As regulators, we share a common duty during this public health crisis to do what we can to ensure access to care across the country to those in need," the organizations stated. "While our healthcare professionals focus on providing the care that the public needs to manage and control the further spread of COVID-19, including through the appropriate use of telemedicine and telehealth technologies, we are working with our member boards to review existing and developing rules and regulations to facilitate the delivery of safe and effective care."

The complete text of the joint statement is available in the Newsroom section of the NABP website.

DEA Increases Aggregate Production Quotas for Controlled Substance Medications

In response to higher demand created by the COVID-19 pandemic, Drug Enforcement Administration (DEA) has increased aggregate production quotas (APQs) available to pharmaceutical manufacturers for certain controlled substance (CS) medications. Specifically, DEA issued a final order to increase the 2020 APQ by 15% for CS needed for the treatment of COVID-19. These include fentanyl, morphine, hydromorphone, codeine, ephedrine, pseudoephedrine, and certain CS intermediates, which are essential to their production. The agency also increased the APQ for methadone to ensure that opioid treatment programs have sufficient supplies to treat patients suffering from opioid use disorder and is increasing the authorized amounts of certain Schedule III and IV CS that may be imported to the US, which are necessary to treat patients using ventilators.

After the health emergency recedes, DEA states it will reevaluate demand and adjust APQ levels as needed. More information is available in a DEA press release at *www.dea.gov/press-releases/2020/04/07/dea-takes-additional-steps-allow-increased-production-controlled*.

NABP and FSMB Issue Joint Statement on Inappropriate Prescribing, Dispensing of Medications Related to COVID-19

NABP and the Federation of State Medical Boards (FSMB) issued a joint statement in response to actions by some health care providers that are abusing prescribing and dispensing privileges during the COVID-19 pandemic. Specifically, reports have found that some physicians are inappropriately prescribing medications (including chloroquine, hydroxychloroquine, and azithromycin) to prevent or treat COVID-19 for themselves or their family members, and that some pharmacies and hospitals may be stockpiling these medications in anticipation of future demand.

In the joint statement, NABP and FSMB remind health care providers that it is essential to carefully follow established guidance and clinical evidence in making decisions regarding prescribing, and that patients with appropriate needs have access to approved medications. In addition, the organizations note that physicians, pharmacists, pharmacies, and hospitals have an ethical duty to put the needs of patients first, and this includes observing strict prescribing guidelines.

Physicians, pharmacists, hospitals, and other organizations are encouraged to visit the COVID-19 web resource pages made available on the NABP website and on the FSMB website for questions about prescribing, licensing, and other regulatory matters.

The NABP and FSMB joint statement is available in the Newsroom section of the NABP website.

New Data Shows Significant Decline in Overdose Deaths

Overdose deaths involving prescription opioids declined by 13.5% from 2017 to 2018, according to new data from the Centers for Disease Control and Prevention's (CDC's) *Morbidity and Mortality Weekly Report*. The data also shows a 4% decline in heroin-related overdose deaths, and a 4.1% overall decrease in overdose deaths. Despite these declines, overdose deaths involving synthetic opioids (excluding methadone) increased by 10% during the same time period, once again illustrating the continued impact of the opioid overdose epidemic's "third wave."

More information about this data is available in a CDC press release at *www.cdc.gov/media/releases/2020/p0318-data-show-changes-overdose-deaths.html*. Additional information about the opioid epidemic and the impact of synthetic opioids is also available in the October 2019 issue of *Innovations* (pages 8-11). ●

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UPCOMING EVENTS

NABP/AACP District 5 Meeting
August 7, 2020 | Virtual Meeting

NABP/AACP District 3 Meeting
August 12, 2020 | Virtual Meeting

NABP/AACP District 1 and 2 Meeting
September 9-11, 2020 | Annapolis, MD

NABP Interactive Executive Officer Forum
September 29-30, 2020 | Location TBD

NABP/AACP District 4 Meeting
October 8, 2020 | Virtual Meeting

NABP/AACP District 6, 7, and 8 Meeting
October 11-13, 2020 | Carefree, AZ

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