INNOVATIONS



NABP e-Profile Facility Data to Further Streamline Board Compliance Processes





INNOVATIONS® table of contents

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NABP Executive Committee elections are held each year at the Association's Annual Meeting.

- Legal Briefs Student Rotates Out of Academic Program
- **Association News** Twelve Member Boards **Deemed Blueprint States**
- 10 Interactive Forum Compliance Officers, Legal Counsel Gather at Interactive Forum
- 18 State Board News New Nevada Laws Address Opioids, PMP, and Laboratory Tests
- **Professional Affairs** Update

DEA Announces Scheduling of Fentanyl-Related Substances



Feature News

NABP e-Profile Facility Data to Further Streamline Board **Compliance Processes**

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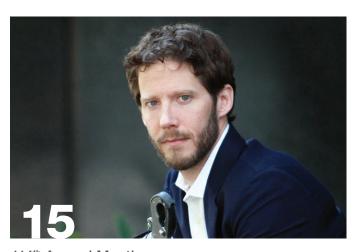
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National Association of Boards of Pharmacy

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.



114th Annual Meeting

Avid Adventurer to Share Lessons on Triumphing Over Insurmountable Odds During Keynote Address

Interview With a Board Executive Director



Marcie Bough, PharmD, RPh **Executive Officer,** Montana Board of Pharmacy

Marcie Bough, PharmD, RPh **Executive Officer, Montana Board of Pharmacy**

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

I have been the executive officer of the Montana Board of Pharmacy in the Montana Department of Labor and Industry since April 2013. I moved home to Montana after working for the American Pharmacists Association (APhA) in Washington, DC, from 2004 to 2013, where I served as senior director of government affairs, following several years as director of federal regulatory affairs. I enjoyed the work of being primary liaison and lobbyist to the federal agencies. Most of my time was spent working with Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services, and Drug Enforcement Administration, but I did some Congressional work, too. I started at APhA in practice affairs. Between undergraduate

and pharmacy schools in Montana, I first worked in Washington, DC, as staff for the United States Senate Committee on Indian Affairs, which helped guide the direction of my career.

My previous work provided a great opportunity to serve the pharmacy profession at the national level and to collaborate with multiple stakeholders and pharmacy associations, including NABP. I am grateful to bring such experiences to my work with the Board. In 2014, I was honored to receive from then FDA Commissioner Margaret Hamburg, MD, the Commissioner's Special Citation Award in recognition of the work I had done on behalf of APhA and the profession in helping FDA consider regulatory issues important to pharmacists.

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

Like other states, the Board had to address how wholesale drug distributors are licensed. The 2017 Montana Legislature passed the Board's bill to separate our single wholesale license into four license types to comply with Drug Supply Chain Security Act requirements. The new law also defines outsourcing facilities, so the Board can move forward with ways to better identify sterile compounders. Implementation of these changes will continue to be challenging, as we try to limit the administrative impact on current licensees. It is an interesting process to now be implementing at the state level some of the issues I had worked on at the federal level.

What other key issues has the Board been focusing on?

The Board administers the Montana Prescription Drug Registry, our prescription drug monitoring program, and is pleased with the implementation of delegate access and interstate data sharing enhancements, which have helped increase registration and utilization rates. We appreciate NABP's work in providing the NABP PMP InterConnect® program, which enables interstate data sharing. We are now moving forward with de-identification of data for research and analysis purposes and other improvements. In addition, the Board continues to collaborate with the Montana Department of Public Health and Human Services, law enforcement, and others to implement new 2017 laws increasing access to naloxone and

continued on page 7

Montana Board of Pharmacy

Number of Board Members: 4 pharmacists, 1 certified pharmacy technician, 2 public members

Number of Compliance Officers/Inspectors: 2

Rules and Regulations Established by: Board of Pharmacy

Number of Pharmacist Licensees: 2,205 Number of Pharmacies: 308 (in-state)

Number of Wholesale Distributors: 95 (in-state)

Student Rotates Out of Academic Program



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

66 Most boards of pharmacy engage in some form of assessment of good moral character as a prerequisite to licensure eligibility, whether for initial licensure. renewal. or licensure transfer. 77

ost boards of pharmacy engage in some form of assessment of good moral character as a prerequisite to licensure eligibility, whether for initial licensure, renewal, or licensure transfer. Such an assessment may involve criminal background checks, personal history, credit-worthiness, and the status of other professional licenses, if any, held by the applicant. If the applicant has graduated from an approved or accredited pharmacy education program, the education component of the licensure process will likely be determined to have been satisfied. If the applicant was subjected to disciplinary action within the education setting, is such information relevant to a board of pharmacy when making a licensure eligibility decision? If so, is such information able to be obtained by the board of pharmacy? Consider the following.

A pharmacy student (Student) at South College, a private, co-educational institution in Tennessee, was enrolled in the accelerated three-year program for a doctor of pharmacy degree. As part of the required curriculum, students must complete an **Experiential Education Program** (EEP) that involves taking and passing a number of clinical rotations at pharmacies or medical institutions. Students in the EEP work under the supervision of licensed pharmacists who are referred to as preceptors. EEP rotations are not only required to graduate from the education program, they also count as "contact hours" required by the

Tennessee Board of Pharmacy as one criterion for licensure eligibility.

The Student successfully completed three of the four required clinical rotations. In August 2012, the director for clinical rotations (Director) emailed the Student to schedule her 2013 clinical rotation. This particular rotation consisted of five, eighthour days at a pharmacy or medical institution, and the Student was given three options from which to choose. The Student chose the last option of the second year of the curriculum. According to the EEP handbook, the students are responsible for making contact with the preceptor prior to starting the rotation. The purpose of this contact is to obtain information about site location. parking, hours, and other logistics of participation. Furthermore, the student handbook and class conduct set forth policies emphasizing the importance of professionalism and noting attendance and timeliness as a hallmark of such professionalism.

The Student did not contact the preceptor prior to the commencement of the rotation. Further, the Student did not show up for the first day of the EEP. The Director and others within the administration of the school made multiple attempts to contact the Student, Such correspondence directed the Student to contact the preceptor and reschedule the EEP. but she failed to immediately do so. Subsequent testimony by the Student at her hearing before the relevant committee at the school revealed a rambling of excuses, including getting lost, being intimidated by the neighborhood, arriving before the

pharmacy opened, attempting to enter the wrong door, and that her chosen pharmacy was not a good fit for her.

The Director informed the Student that her actions constituted unprofessionalism, but the school, through the course director, continued to attempt to schedule the rotation. The Student attempted to negotiate her rotation with a preceptor with whom she previously participated, but the school policies prohibited repeating the use of a preceptor. Many negotiations ensued, but the school's final attempts to place the Student in an EEP were met with an email response from the Student to the course director stating, "Those who will not reason, are bigots, those who cannot, are fools, and those who dare not, are slaves-George Gordon Bryon."

The course director eventually gave the Student an "F" for the unattended rotation, which resulted in an automatic dismissal from the program under the progression requirement. That is, students must progress to the next academic quarter by successfully completing the previous requirements. The Student appealed the "F" grade and a hearing was scheduled. The Student did not show up for the hearing, citing car trouble. The proceeding was rescheduled and, after a hearing, her grade appeal was denied.

Those dismissed from the program are able to seek readmission through an application process. The Student sought readmission

and her application was denied by the Academic Standing and Progression Committee based upon the unprofessional conduct that occurred. The executive vice president upheld the denial and the Student filed a lawsuit against the school in United States District Court for the Eastern District of Tennessee. In her complaint, the Student alleged that the school breached its contract with her by assigning an "F" to the rotation. The Student also alleged the elements of promissory estoppel, arguing that the school personnel made certain promises to her that caused her to rely upon such representations.

The school filed a motion for summary judgment, arguing that there are no material issues of fact that demand a trial and, thus, the court can decide the case as a matter of law. The court agreed with the school and found in favor of the school. The court found that the school did not breach its contractual obligations to the Student, citing the various school handbooks. Specifically, the court noted the emphasis in the handbooks on professionalism as a core competency component and that the Student breached many of her own responsibilities. Under such circumstances, the Student cannot blame the school for her failure to comply with rudimentary requirements.

The court also rejected arguments that the school breached its contractual obligations by giving the Student an "F" on the rotation, failed to schedule another EEP, and that representations made by the

Director and course director created contractual obligations to secure another rotation option. In short, the court held that the back and forth "negotiations" between the Student and school personnel did not result in a contractual relationship as there was no offer and acceptance.

Finally, the court noted the elements of promissory estoppel which require a promise, inducement to act or not act, and avoidance of injustice available only through enforcement. The court found no unambiguous promise by the school that induced the Student to enroll in and attend classes and clearly no fraud. Thus, the court rejected the Student's arguments and entered judgment in favor of the school.

Under numerous circumstances, student activities will occur that may guestion the character of an applicant for licensure. As long as a student graduates, are activities that occurred in the academic program relevant to good moral character determinations by a board of pharmacy? State and federal laws protect the students and may prohibit the disclosure of information about activities that occurred within the educational setting. Boards may never know, unless they ask.

Sifuna v. South College of Tennessee, Inc, 2017 US Dist LEXIS 72699.

Twelve Member Boards Deemed Blueprint States

In-state Sterile Compounding Training Opportunities Available

Created in collaboration with member boards and NABP, the Multistate Pharmacy Inspection Blueprint Program continues to offer participating state boards an accessible database of consistent, current inspection information to help them make informed licensure decisions for nonresident compounding pharmacies. At press time, 12 states - Kentucky, Louisiana, Mississippi, New Jersey, North

Carolina, North Dakota, Ohio, South Dakota, Tennessee, Virginia, West Virginia, and Wyoming - have signed the Multistate Pharmacy Inspection Blueprint Program Participation Agreement. When states participate in the Blueprint Program, they utilize uniform inspection criteria as determined by NABP member boards. States participating in the Blueprint Program eliminate the need to perform their own inspections, thus alleviating

the burden on staff and easing concerns for public safety.

To become a "Blueprint State," boards of pharmacy agree to several processes for inspecting sterile compounding pharmacies that ship products to other states. Inspectors or compliance officers who inspect these pharmacies must have completed NABP-approved training. This includes, but is not limited to, CriticalPoint's

continued on page 7

New Class of Inspectors Earn CriticalPoint Credential, Promote Safety of **Compounded Medicines**

NABP and CriticalPoint, LLC, are pleased to announce a new class of inspectors who earned the Certification in Sterile Compounding for Inspectors as part of the Sterile Compounding Inspector Training program. The following inspectors earned their certification on October 24-27, 2017:

- · Reginal Bellamy, District of Columbia Department of Health
- · Tommy Roe, Georgia Drugs and Narcotics Agency
- Aarti Parikh, Illinois Department of Financial and Professional Regulation
- · Thomas Avery, State of Maine
- · Nancy Richard, Maryland Board of Pharmacy
- Michael Brosnan, Massachusetts Department of Public Health
- Joanne Trifone, Massachusetts Board of Registration in Pharmacy
- Mary Mayleben, Surveyor for NABP
- Mike Poblet, Surveyor for NABP

- Jim Velez, Surveyor for NABP
- · Jennie King, Nebraska
- Daniel Dodge, Nevada State Board of Pharmacy
- Robert Elder, New Hampshire Board of Pharmacy
- · Rachna Patel, New Jersey State Board of Pharmacy
- Tony Qi, New Jersey State Board of Pharmacy
- Adela Padilla, New Mexico Board of Pharmacy
- Algeste Marcellus, New York State **Education Department**
- · David Smith, New York State **Education Department**
- Summer Canoy, North Carolina Board of Pharmacy
- William Zupko, Pennsylvania State Board of Pharmacy
- Carol Smith, South Dakota State **Board of Pharmacy**

- · Carrie Phillips, Vermont Office of Professional Regulation
- Matthew Martineau, Wyoming State Board of Pharmacy

The Association and CriticalPoint will continue to offer training and certification in sterile compounding for inspectors throughout 2018 on the following dates: July 16-19, October 8-11, and November 5-8. Additional information will be forthcoming.

This training provides inspectors with hands-on experience with inspecting to United States Pharmacopeia Chapters <797> and <800> in a state-of-the-art classroom located in Totowa, NJ. Registration for classes is available at www.criticalpoint .info/sterile-compoundinginspectortraining/.

NABP is offering a scholarship to cover tuition for one inspector or compliance officer per state per year. For more details about the NABP funding, please contact the NABP Professional Affairs department at Prof-Affairs@nabp.pharmacy.

NABP Foundation Offering Grants to Attend APhA Institute on Alcoholism and Drug Dependencies

The NABP Foundation® is accepting grant applications from qualified board of pharmacy members or staff who would like to attend the American Pharmacists Association (APhA) Institute on Alcoholism and Drug Dependencies in Salt Lake City, UT, on May 30-June 3, 2018. This year, 10 grants will be awarded to assist with some of the costs associated with attending. The APhA Institute sessions will offer attendees educational information on alcohol and drug dependency and how to effectively support pharmacists who are in recovery. Because of the overwhelming interest in attending this program in 2017, the NABP Foundation Board of Directors approved additional grant funding for 2018.

More information about the APhA Institute is available at aphainstitute .pharmacist.com.

To apply for a grant, qualified board of pharmacy members and staff

should contact the NABP Executive Office at ExecOffice@nabp.pharmacv by February 15, 2018. Grants will be assigned on a first-come, first-served basis.

APhA Institute Provides Opportunity to:

- Participate in four days of education, networking, and personal development
- Help increase awareness of the health and social problems related to alcoholism and drug dependencies
- Gain information and instruction for providing programs to support pharmacists in recovery
- Earn continuing pharmacy education

Marcie Bough

continued from page 3

to develop a state opioid strategic plan. Also, the Board has a great working relationship with the Montana Pharmacy Association, and we will continue to monitor its achievements in helping pharmacists receive payment for services by utilizing the Board's existing Clinical Pharmacist Practitioners endorsement, issued in conjunction with the Montana Board of Medical Examiners.

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

I encourage states to remember that Boards are responsible for more than the key roles of issuing licenses and regulating the practice of pharmacy to ensure public safety. It is important for Boards to step out of potential regulatory silos and utilize opportunities to collaborate with others. We can be trusted and valued resources for state legislatures, state and federal agencies, Congress, associations, the public, and other medical, pharmacy, nursing, and related stakeholders. Collaboration is key in helping to drive the direction of health care laws and regulations.

Blueprint States

continued from page 6

Boot Camp, NABP and CriticalPoint Sterile Compounding Inspector Training, or NABP in-state inspection training. See page 6 of this newsletter for more information about the 2018 training opportunities offered through CriticalPoint.

In-State Training With NABP Surveyors

Through a grant administrated by NABP, The Pew Charitable Trusts is providing funding to assist state boards of pharmacy with the training necessary for strong oversight of sterile compounding. In 2018, funding is available to provide 11 states with in-state training by NABP surveyors. This training includes educational webinars, on-site observation of sterile compounding inspections, and a follow-up analysis. The states that will receive funding for training in 2018 will be announced in a future issue of Innovations.

To date, in-state training with NABP surveyors was provided to state pharmacy inspectors and compliance officers from Colorado, Michigan, Mississippi, New Hampshire, and Vermont. Participants completed the activities mentioned above and had an opportunity to practice sterile gowning and garbing for an inspection of a clean room, inspecting for all elements in the universal inspection sterile compounding module, and completing the inspection report.

To learn more about the sterile compounding inspector training through NABP or to become a Blueprint State, contact the NABP Member Relations and Government Affairs department at governmentaffairs@nabp .pharmacy.

NABP e-Profile Facility Data to Further Streamline Board Compliance Processes



In the past two issues of Innovations, NABP has taken an in-depth look at NABP e-Profile Connect and the advantages of using e-Profiles to their full potential. Articles have explored the type of data available in each pharmacist's NABP e-Profile, examined how the use of the e-Profile can streamline licensing and regulation tasks performed by the boards of pharmacy, and discussed current data-syncing and data-sharing pilot projects that point the way for seamless data exchange between NABP and the boards, and the subsequent increased efficiency, convenience, and security, for boards and licensees alike.

pilot project is designed to make concurrent progress on several goals, all of which are intended to strengthen NABP's support of the boards of pharmacy and protection of the public health at the same time that they support further development and utilization of e-Profile Connect.

In this third and final segment of the series, Innovations looks at the e-Profile Connect system as it relates to facilities, a new pilot project taking place involving NABP and multi-state licensed pharmacies, and some of the benefits that would come from more fully utilizing e-Profile IDs for pharmacies.

E-Profiles for Pharmacies

NABP currently maintains e-profiles for more than 80,000 pharmacies. Data contained on pharmacies may include demographic, ownership, and pharmacist-in-charge (PIC) information; current and previous licenses and current licensure status; inspection and disciplinary history; and accreditations. Facility e-Profile data is populated with information from accreditation and Verified Pharmacy Program® (VPP®) applications as well as with disciplinary Clearinghouse information from the state boards of pharmacy.

Thus far, no states require resident or nonresident pharmacies to obtain or use an e-Profile ID, or to provide this number to the state as a requirement of licensure. Boards of pharmacy can access relevant pharmacy data through NABP e-Profile Connect (such as when considering a licensure application from an out-of-state compounding pharmacy).

Ideally, one day e-Profile Connect will contain current information for every pharmacist, technician, and pharmacy licensed or registered with the state boards of pharmacy. This system will also be continuously updated and provide a seamless flow of data, allowing the boards easy access to the information they need to carry out their regulatory duties while also allowing pharmacists, technicians, and pharmacies to more easily maintain their licenses in good standing with their licensing boards.

Pilot Proiect – Phase One

Realizing the full potential of e-Profile Connect requires progress on several parallel tracks and will mean addressing numerous technical, procedural, and legal issues. The pilot projects NABP is conducting with some state boards in preparation for larger-scale data-synchronization and eventual data-sharing programs is one of these tracks. (See "Member Boards, NABP Working Toward Seamless, Automatic Data Exchange" in the January 2018 issue of *Innovations* for a discussion of these projects). On a different track, NABP has embarked on phase one of another pilot project, this one providing inspection and compliance services to 23 multi-state licensed pharmacy facilities.

The facilities participating in the pilot project are all mail-order or specialty pharmacies that have largely centralized operations and therefore must manage the separate license and regulatory requirements for each state into which they ship medications. Particularly because many laws regarding nonresident pharmacies have changed in recent years, especially in regard to inspections, these types of facilities often struggle to keep track of the different timetables and requirements for each license. NABP identified three areas that could be of particular value to these facilities and with which the Association is uniquely well-placed to assist: tracking inspection requirements and providing timely reminders, helping notify the boards of PIC changes, and providing facility-specific reports based on Clearinghouse disciplinary data, which can help ensure complete and accurate reporting to the boards. Moreover, by helping these facilities

avoid accidental lack of compliance, NABP simultaneously provides support to the licensing boards of pharmacy.

In phase one of the project, NABP is focusing largely on the inspection and disciplinary areas. (Facilitating reporting of PIC changes will occur in a later phase, as it relies on the still-inprogress technical modifications that will fully enable pharmacy e-Profiles.) The Association helps the facilities by tracking the inspection standards and interval requirements for each state in which a given pharmacy is licensed, and notifying the facilities of the need for a new inspection four months prior to a due date. This gives the facility time either to arrange an inspection with the relevant board of pharmacy or, alternatively, arrange for an inspection via VPP if a state cannot perform the inspection within the time period or does not inspect to United States Pharmacopeia <797> standards.

For disciplinary data, NABP is able to create a report for each participating facility that details disciplinary actions that have been reported to the Clearinghouse. This allows the pharmacy to match its information with that of the licensing state, eliminating time-consuming back-andforth communications as the facility endeavors to synchronize its records with the board's.

This initial phase of the pilot project involves essentially manual processes to collect and distribute data, but prepares the ground for subsequent stages, in which automations and enhanced features could be developed.

Parallel Paths

The facilities pilot project is designed to make concurrent progress on several goals, all of which are intended to strengthen NABP's support of the boards of pharmacy and protection of the public health at the same time that they support further development and utilization of e-Profile Connect. The

inspection and compliance services program is designed to offer these multi-state licensed pharmacies a valuable service that leverages the relationship they already have with NABP via its accreditation programs and allows the facilities to more easily navigate many of the challenges they face in maintaining pharmacy licenses in multiple states. As the program enables facilities to maintain their numerous licenses with fewer errors, the boards of pharmacy will have to expend fewer of their finite resources on following up on infractions caused by such administrative errors. And as NABP and the states continue their progress toward the e-Profile Connect ideal of seamless, secure data sharing and data syncing - with pharmacies as well as with pharmacists and technicians - the inspection and compliance services program will be able to both benefit from and contribute to the process.

In phase two of the inspection and compliance services program, much of the process would go online, and facilities would be able to access their e-Profile. This phase would rely on progress made on the process of building in the mechanism for pharmacies to be able to view and access limited fields (such as PIC information) in their e-Profile to make changes. Information on inspection renewal schedules and reminders can also be built into each pharmacy's e-Profile, allowing facilities to manage them online.

As NABP and the state boards of pharmacy develop and implement the standards and process for bidirectional data exchange, the program will evolve and improve. Progress in three additional areas - states' collection and incorporation of e-Profile IDs for pharmacies, continued adoption of universal inspection standards, and development of a universal online pharmacy licensure application - would further help maximize the program's potential. If sufficient progress is

continued on page 12



Connect & Protect

Educating, Sharing, and Leading

NABP Interactive Compliance Officer & **Legal Counsel Forum**

November 29-30, 2017



(Above) The Joint Compliance Officers/Legal Counsel Session on November 29 featured a discussion on the role of prescription monitoring programs. Pictured are (left to right) Hal Wand, MBA, RPh, NABP chairperson; session moderator Mark D. Johnston, RPh, DPh, member, NABP Executive Committee; S. Paul Edwards, JD, general counsel, Nevada State Board of Pharmacy; Nicole M. Schuster, JD, deputy attorney general, Indiana Board of Pharmacy; and Rebecca Moak, DPh, pharmacy investigator, Tennessee Board of Pharmacy.

(Right) Detecting diversion was also addressed during the Joint Compliance Officers/Legal Counsel Session on November 29. Panelists pictured are (left to right) Cheryl Lalonde, JD, general counsel, Kentucky Board of Pharmacy; Amanda Harding, RPh, pharmacy and drug inspector, Kentucky Board of Pharmacy; and session moderator Mark D. Johnston, RPh, DPh, member, NABP Executive Committee.



Compliance Officers, Legal Counsel Gather at Interactive **Forum to Address Common Challenges**

Continuing the 2017 forum theme "Connect & Protect: Educating, Sharing, and Leading," compliance officers and legal counsel gathered for two days of lively discussion on topics related to their roles at the boards of pharmacy. The NABP Interactive Compliance Officer and Legal Counsel Forum included breakout sessions tailored to each group and joint sessions for open discussion on topics suggested by the attendees. The event drew 51 compliance officers and 26 legal counsel from 45 member boards of pharmacy. Fifty-two attendees also participated in a Food and Drug Administration session on compounding facilities.



(Above) During the morning Compliance Officer Interactive Session on November 30, panelists focused on United States Pharmacopeia (USP) <797> and <800> and physician compounding standards. Panelists pictured are (left to right) James "Jay" Queenan, MBA, RPh, compliance investigator/inspector, New Hampshire Board of Pharmacy; session moderator Caroline D. Juran, RPh, DPh, member, NABP Executive Committee; Krystal Brashears Stefanyk, director of inspections, North Carolina Board Pharmacy; Jenni Wai, MBA, RPh, chief pharmacist, State of Ohio Board of Pharmacy; and Timothy Reilly, RPh, pharmacy inspector, Virginia Board of Pharmacy.



(Above) The morning Legal Counsel Interactive Session on November 30 examined the legality of cannabis and the hazards of USP Chapter <800>. Pictured are (left to right) session moderator Jack W. "Jay" Campbell IV, JD, RPh, NABP treasurer; Nicole Dehner, JD, chief legal counsel, State of Ohio Board of Pharmacy; Maggie Pagel, JD, staff attorney, Washington State Department of Health; and James Rutkowski, JD, assistant attorney general, Virginia Board of Pharmacy.

Interactive Forum



(Above) During the afternoon Compliance Officer Interactive Session on November 30, panelists focused on advanced practice requirements and patient safety, the expanded roles of technicians, and the Drug Supply Chain Security Act. Panelists pictured are (left to right) Eric Griffin, RPh, director of compliance and enforcement, State of Ohio Board of Pharmacy; Dennis DelaBarre, RPh, compliance officer, North Dakota State Board of Pharmacy; Gregg Jones, RPh, compliance senior manager, NABP; session moderator Gary W. Dewhirst, RPh, DPh, member, NABP Executive Committee; Bonnie Wilgus, RPh, pharmacist inspector, South Carolina Department of Labor Licensing and Regulation -Board of Pharmacy; and Brianne Efremoff, RPh, compliance director, Oregon State Board of Pharmacy.



(Above) The late morning Legal Counsel Interactive Session on November 30 provided attendees with a regulatory case update. Pictured are (left to right) Dale J. Atkinson, JD, NABP outside counsel, Atkinson & Atkinson, and session moderator Philip P. Burgess, MBA, DPh, RPh, member, NABP Executive Committee.



(Above) Richard B. Mazzoni, RPh, member, NABP Executive Committee (left) and Timothy D. Fensky, RPh, DPh, FACA, member, NABP Executive Committee (right) each moderated a session during which attendees discussed topics of interest to both compliance officers and legal counsel.

e-Profile Facility Data

continued from page 9

made over the next several years, the system could deliver further significant benefits to all pharmacies and boards of pharmacy. For example, real-time updates of a facility's PIC to the state boards, flow of licensure applications

into a board's licensing system for assessment, and easy disciplinary information submission via the universal application process are all potential future features. In addition, capture of reports for inclusion in the e-Profile, license verification and monitoring of facility and pharmacist licenses, and elements such as inspection monitoring and disciplinary

Clearinghouse reports could be made available via e-Profile Connect.

The merging of these various paths promises numerous efficiencies for both facilities and boards of pharmacy, as well as greater regulatory compliance. NABP will continue to report on their progress.

NABP Implements New Suite of Tools to Strengthen Web Application Security

In 2017, NABP implemented new software providing a suite of tools to continue reinforcing the security of its networks and online applications. The new software instantaneously identifies any threats to external- and internalfacing systems. As the Association prepares to transition its online applications and workflow programs (eg, e-Profile Connect) in April 2018, NABP has been actively taking measures to augment the security of its new infrastructures.

Programming Tools

Specifically, with cyber security challenges becoming more and more complex, the Association is taking preventative measures to address application vulnerabilities, data breaches, and cyber attacks. A key tool in the software provides NABP developers with insight into coding errors as the code is written. This immediate feedback allows staff to rectify the issue in real time and reduce the risk of vulnerabilities that could breach the security of NABP platforms.



In addition, the automatic detection of code-level flaws increases the efficiency of NABP staff by presenting them with an

inventory of the most critical and easily exploitable vulnerabilities, followed by recommendations to remediate the threats. Thus, NABP developers are acquiring increased knowledge in producing more reliable code and preventing any data breaches.

Into the Future

The Association will continue to deploy data security best practices and tools





VIRUS PROTECTION





and is committed to ensuring that its board-, college-, customer-, and stafffacing systems operate seamlessly and that the transmission of data via its online applications is secure. By integrating new security measures,

NABP is building on its prior data security initiatives, which are discussed in the Data Security Corner article found in the November/December 2017 issue of Innovations.

66 As cyber security challenges become more complex year after year, the Association is taking preventative measures to address application vulnerabilities, data breaches, and cyber attacks. 77

Schedule of Events May 5-8, 2018

Hyatt Regency Denver at Colorado Convention Center

Saturday, May 5, 2018

10 AM - 5 PM

Registration Desk Open

1:30 - 3:30 PM

Pre-Meeting CPE

4 - 5 PM

From District Meeting to Annual Meeting - Learning About NABP

6 - 9 PM

President's Welcome Reception Honoring NABP President Jeanne D. Waggener, RPh, DPh

Dinner will be served. Dress: business casual

Sunday, May 6, 2018

7:30 ам - 4:45 рм

Registration Desk Open

7:30 - 8:30 AM

NABP AWAR_xE Fun Run/Walk

8:30 - 11:30 AM

Hospitality Brunch and Educational Table Top Displays

9 - 11 AM

Joint CPE

Educational Poster Session

9:30 - 10:30 AM

Public Member Forum

Noon - 3:15 PM

First Business Session

3:45 - 4:45 PM

Joint CPE

Monday, May 7, 2018

7:30 AM - 12:30 PM

Registration Desk Open

7:30 - 9 AM

USP Update and Breakfast

Breakfast served plated from

7:30 - 8 AM

9:15 - 10:15 AM

Joint CPE

10:45 AM - 12:30 PM

Second Business Session

12:30 - 1 PM

Informal Member/Candidate

Discussion

Free Afternoon

(No programming)

Tuesday, May 8, 2018

7:30 AM - 4 PM

Registration Desk Open

7:30 - 8:30 AM

NABP Breakfast

8:30 - 10 AM

Executive Officer and Board

Member CPE

8:30 - 10 AM

Compliance Officer CPE

10:30 ам - Noon

Shared Discussion Topics

Noon - 1:30 PM

Lunch Break

(On your own)

1:30 - 4:15 PM

Final Business Session

6 - 6:45 рм

Awards Dinner Reception

7 - 9 PM

Annual Awards Dinner

Dress: semiformal

Note: The 114th 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) sessions 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. Sessions 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 at www.NABPAnnualMeeting.pharmacy. Instructions for claiming CPE credits, including continuing legal education credits, will also be provided.

Avid Adventurer to Share Lessons on Triumphing Over Insurmountable Odds During Keynote Address

Aron Ralston, an experienced outdoorsman whose harrowing wilderness survival story was the subject of the major motion picture 127 Hours, will inspire 114th Annual Meeting attendees with his keynote speech, "Between a Rock and a Hard Place." An avid hiker and climber. Ralston was hiking alone in Utah's remote canyonlands in 2003 when he accidentally dislodged a boulder that pinned his right hand to the canyon wall. He was trapped for more than five days and freed himself by severing his arm using a pocketknife. Ralston later returned to pursuing his outdoor passions, now accomplished with the aid of a prosthetic arm. During his keynote address, Ralston will reflect on the tough challenges he has faced since his ordeal and will share lessons he learned about the importance of examining one's life priorities and the value of relationships in overcoming even the most daunting obstacles.

Originally from Ohio and Indiana, Ralston's family moved to Colorado in 1987 when he was 12, giving him his first exposure to mountains and the wild outdoors. In 1997, he received his bachelor of science degree in mechanical engineering from Carnegie Mellon University in Pittsburgh, PA. After graduating, he moved west again to work for Intel Corporation as a mechanical engineer, living in Phoenix, AZ; Tacoma, WA; and Albuquerque, NM, all of which gave him further opportunities for enjoying mountain climbing and other outdoor sports. In 2002, he moved to Aspen, CO, to pursue outdoor adventuring full-time. Less than two years after his amputation, Ralston achieved his goal to solo climb all of Colorado's 59 peaks of over 14,000 feet during winter. This accomplishment had never been achieved by another climber.

In 2004, Ralston published his best-selling autobiography, Between a Rock and a Hard Place. The film adaptation, 127 Hours, directed by Danny Boyle and starring James Franco as Ralston, was released in 2011 and garnered six Academy Award nominations, including Best Picture and Best Actor. In more recent years, Ralston has led rafting expeditions through the Grand Canyon and ski mountaineering expeditions to Mt Elbrus in Russia. He has climbed five of the world's Seven Summits since his amputation, including summiting North America's highest peak, Denali, then skiing its descent.

In addition to his outdoor adventures, Ralston is an enthusiastic advocate for wilderness protection, lending his support to numerous environmental and conservation projects, including serving as a board member for the Wilderness Workshop, an organization devoted to protecting more than 3 million acres of public lands in western Colorado. He has also served as a volunteer with the Albuquerque Mountain Rescue Council and as an honorary ambassador for Paradox Sports, a nonprofit that provides adaptive equipment and opportunities for people with disabilities to enjoy outdoor sports.

Ralston will deliver the keynote address during the First Business Session of the NABP 114th Annual Meeting. More information will be available on the Annual Meeting website at www.NABPAnnualMeeting .pharmacy.



66 During his keynote address. Ralston will reflect on the tough challenges he has faced since his ordeal and will share lessons he learned about the importance of examining one's life priorities and the value of relationships in overcoming even the most daunting obstacles. 77

Annual Meeting Travel Grant Available

Travel grant opportunities are still available for the NABP 114th Annual Meeting. Eligible individuals may receive up to \$1,500 to cover the costs of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

- One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer.
- Active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

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



- Early Registration Rate March 30, 2018
- Voting Delegate Submissions April 6, 2018

Proposals Requested for Educational Poster Session

NABP seeks proposals for the annual Educational Poster Session to take place on Sunday, May 6, 2018, during the Annual Meeting. Proposed posters should reflect the theme of "Thinking Forward to Educate." Those selected to display posters have the opportunity to share information about policy development, public health initiatives, legislative issues, or other topics as they relate to this year's theme. Proposed posters may be descriptive, scientific, or informational.

For detailed instructions on submitting a poster concept for consideration, please contact NABP Professional Affairs staff via email at Prof-Affairs@ nabp.pharmacy. Proposals should include a short poster title highlighting the topic and a brief summary or abstract that explains how the poster

reflects the theme. Selected poster presenters must be available in March and April for correspondence with NABP staff and to submit required materials, and should be able to personally attend the Annual Meeting.

Board of pharmacy members and staff as well as schools and colleges of pharmacy are invited to submit poster proposals. Students are welcome to submit proposals and if selected, must be accompanied by a credentialed advisor or licensed pharmacist.

Poster Session participants may be eligible to earn Accreditation Council for Pharmacy Education (ACPE)accredited continuing pharmacy education (CPE) credit. Details will be provided to individuals selected to present at the session.

Educational Poster Session: Thinking Forward to Educate

- · Proposals must be submitted via email by February 28, 2018.
- Eligible for one contact hour (0.1 CEU) of ACPEaccredited CPE credit.

Around the Association

Board Member Appointments

- James Hansen, RPh, has been appointed a member of the Colorado State Board of Pharmacy. Hansen's appointment will expire July 1, 2019.
- Neill F. Piland, PhD, has been appointed a public member of the Colorado State Board of Pharmacy. Piland's appointment will expire July 1, 2019.
- · Kenneth VandenBussche, RPh, has been appointed a member of the Hawaii State Board of Pharmacy. VandenBussche's appointment will expire June 30, 2021.
- Jonathan Brunswig, PharmD, RPh, has been appointed a member of the Kansas State Board of Pharmacy. Brunswig's appointment will expire April 30, 2021.
- William Walden, RPh, has been appointed a member of the Kansas State Board of Pharmacy. Walden's appointment will expire April 30, 2021.
- · Melissa Ing (Huynh) Shake, PharmD, RPh, has been appointed a member of the Nevada State Board of

- Pharmacy. Shake's appointment will expire October 31, 2019.
- Michael Carroll, RPh, has been appointed a member of the Vermont Board of Pharmacy. Carroll's appointment will expire June 30, 2021.

Board Member Reappointments

- Wesley Hunter, RPh, has been reappointed a member of the Colorado State Board of Pharmacy. Hunter's appointment will expire July 1, 2021.
- Laura Rang, RPh, has been reappointed a member of the Colorado State Board of Pharmacy. Rang's appointment will expire July 1, 2021.
- Mary Jo Keefe, RPh, has been reappointed a member of the Hawaii State Board of Pharmacy. Keefe's appointment will expire June 30, 2021.
- Kerri Okamura, RPh, has been reappointed a member of the Hawaii State Board of Pharmacy. Okamura's appointment will expire June 30, 2020.

- LaDonna Gratias has been reappointed a member of the Iowa Board of Pharmacy. Gratias' appointment will expire April 30, 2020.
- Cheri Pugh has been reappointed a public member of the Kansas State Board of Pharmacy. Pugh's appointment will expire April 30, 2021.
- Jason Penrod, RPh, has been reappointed a member of the Nevada State Board of Pharmacy. Penrod's appointment will expire October 31, 2020.
- Shane R. Wendel, RPh, has been reappointed a member of the North Dakota State Board of Pharmacy. Wendel's appointment will expire May
- Ryan K. Logan, RPh, has been reappointed a member of the Virginia Board of Pharmacy, Logan's appointment will expire June 30, 2021.



Newly Accredited DMEPOS Facilities

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

City Rx Pharmacy Paterson, NJ

Mace Rx Pharmacy, LLC Houston, TX

Margaretville Memorial Hospital Margaretville, NY

MDS Capital LLC Bohemia, NY

A full listing of nearly 450 accredited DMEPOS companies representing almost 28,500 facilities is available on the NABP website at www.nabp.pharmacy.

State Board News

New Nevada Laws Address Opioids, PMP, and Laboratory Tests

During the 2017 Nevada Legislature, several bills that affect the practice of pharmacy, including Governor Brian Sandoval's broad opioid bill, Assembly Bill (AB) 474, became law. Effective January 1, 2018, AB 474 requires a practitioner to list days supply, International Classification of Diseases, Tenth Revision code, and Drug Enforcement Administration registration number on all Schedule II, III, and IV prescriptions. Prescriptions for Schedule II, III, and IV controlled substances (CS) must contain these elements to be valid. The bill also empowers occupational licensing boards that license practitioners who are authorized to prescribe CS to review and evaluate records and impose disciplinary action if the practitioner is unlawfully prescribing.

Another bill that became law is Senate Bill (SB) 59, which requires the uploading of Schedule V opioid medications into Nevada's prescription monitoring database. SB 59 also authorizes law enforcement agencies, coroners, and medical examiners to access the database to enter reports of CS violations, stolen prescription drugs, and prescription drug-related overdoses or deaths.

Further, SB 337, which authorizes a registered pharmacist to manipulate a person for the collection of specimens, was also passed during the 2017 Nevada Legislature. SB 337 authorizes a registered pharmacist to perform certain laboratory tests without obtaining certification as an assistant in a medical laboratory.

To view these laws, visit www.leg.state.nv.us/App/NELIS/ REL. Details about other bills that were passed can be found in the October 2017 Nevada State Board of Pharmacy Newsletter, available in the Boards of Pharmacy section of the NABP website.

North Carolina Board Issues Guidance on Implementation of the STOP Act

In an effort to combat the opioid abuse and misuse epidemic, Governor Roy Cooper signed into law the Strengthen Opioid Misuse Prevention ("STOP") Act during the 2017 North Carolina General Assembly. The STOP Act makes numerous changes to the laws governing CS prescribing, CS dispensing, and the North Carolina Controlled Substance Reporting System. Various sections of the STOP Act become effective at differing times. A frequently asked questions guidance document on the STOP Act's implementation is available on the North Carolina Board of Pharmacy website at www.ncbop.org/ PDF/GuidanceImplementationSTOPACTJuly2017.pdf.

Oklahoma Pharmacists Can Prescribe Naloxone and Refill Maintenance Medications

In Oklahoma, pharmacists are granted the authority to prescribe and dispense naloxone under House Bill (HB) 2039, which went into effect November 1, 2017. Naloxone must be dispensed by or under the direct supervision of a pharmacist, and no dispensing protocol is required. In addition, HB 2039 gives pharmacists in Oklahoma the right to use professional judgment when dispensing and refilling maintenance medications.

Pharmacists are allowed to vary quantities per fill when refills are authorized by a prescriber. A pharmacist may dispense up to a 90-day supply of a nonscheduled medication. Any controlled dangerous substance or other medication that requires prescription monitoring program reporting is prohibited. Additional information is available in the October 2017 Oklahoma State Board of Pharmacy Newsletter, available in the Boards of Pharmacy section of the NABP website.

Washington Adopts Pharmacy Inspection Rules

The Washington State Pharmacy Quality Assurance Commission adopted a rule that updates the inspection process for pharmacies and amends Washington Administrative Code 246-869-040 and 190. The new inspection rules support continuous quality improvement by removing the point scores and moving to an annual self-inspection and plan of correction for all deficiencies identified during a Commission inspection. The adopted rule specifically requires that all deficiencies are identified at the end of an inspection and noted on the inspection report/notice of deficiency. The pharmacy must remedy deficiencies promptly. The licensees must submit a plan of correction to the Commission for review. The Commission or its designee will notify the licensee if the plan of correction adequately addresses the deficiencies. Finally, the rule removes the requirement to post an inspection certificate in the pharmacy.

The rules also require pharmacies to perform and complete a self-inspection worksheet each March. A new selfinspection form is also required within 30 days of a change in a pharmacy's responsible manager. Additionally, the adopted rule makes changes regarding new pharmacy registrations, revising the language concerning what type of inspection needs to occur before an applicant will receive a new pharmacy license, rather than an achieved score, while framing the scope of services.

The rules are effective 31 days after filing with the Washington State Office of the Code Reviser. At press time, the filing status was pending. For more information, visit the Commission's website at www.doh.wa.gov.

Professional Affairs Update

DEA Announces Scheduling of Fentanyl-Related Substances

Drug Enforcement Administration (DEA) intends to schedule all fentanyl-related substances on an emergency basis. This action will make it easier for federal prosecutors and agents to prosecute traffickers of all forms of fentanyl-related substances. Under the Analogue Act, prosecutors must overcome cumbersome evidentiary hurdles to secure convictions of these traffickers. When DEA's order takes effect, anyone who possesses, imports, distributes, or manufactures any illicit fentanyl analogue will be subject to criminal prosecution in the same manner as for fentanyl and other controlled substances. The temporary scheduling will go into effect no earlier than 30 days after DEA publishes its notice of intent and will last up to two years, with a possibility of a one-year extension, if certain conditions are met.

The bulk of illicit fentanyl arrives in the United States through the mail or express shipping systems or is imported into the US across the southwest border. Overseas chemical manufacturers, aided by illicit domestic distributors, evade regulatory controls by creating structural variants of fentanyl that are not directly listed under the Controlled Substances Act. More information is provided in a Department of Justice press release (number 17-1268), which can be located at www.justice.gov.

PTCB Completes Beta Exam for the Sterile Compounding Certification Program

The Pharmacy Technician Certification Board (PTCB) has successfully completed the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program beta exam. The beta exam is a critical step in developing an exam for CSPT candidates that is psychometrically sound and meets industry standards for validity. The PTCB CSPT Exam Development Committee, which is comprised of pharmacists and PTCB-Certified Pharmacy Technicians (CPhTs), was responsible for the development of two 90-question forms for the CSPT beta exam. Internal and external consultants conducted a three-part analysis of the CSPT beta exam, which included item analysis, end of exam survey analysis, and time analysis.

"PTCB's standards are rigorous, and we are confident that those PTCB CPhTs who earn the CSPT™ will stand out as highly qualified to meet today's expectations in sterile compounding safety," said former PTCB Executive Director and Chief Executive Officer Everett B. McAllister, RPh, MPA, in a news release available at www.ptcb.org in the News Room section. The CSPT certification program launched in December 2017.

FDA Recognizes Eight European Drug Regulatory **Authorities Capable of Conducting Inspections**

Food and Drug Administration (FDA) has determined the agency will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in: Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 United States-European Union (EU) Mutual Recognition Agreement that enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at www.fda.gov/NewsEvents/Newsroom/ PressAnnouncements/ucm583057.htm.

One in Five Drivers Uses a Prescription Drug That **Can Impair Driving Despite Receiving Warnings**

A new study, which analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the Journal of Studies on Alcohol and Drugs on October 31, 2017, and can be found at https://doi.org/10.15288/jsad.2017.78.805.



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NABP Headquarters

Committee on Constitution and Bylaws March 28, 2018 **FPGEE Administration** April 18, 2018

NABP 114th Annual Meeting May 5-8, 2018 Denver, CO