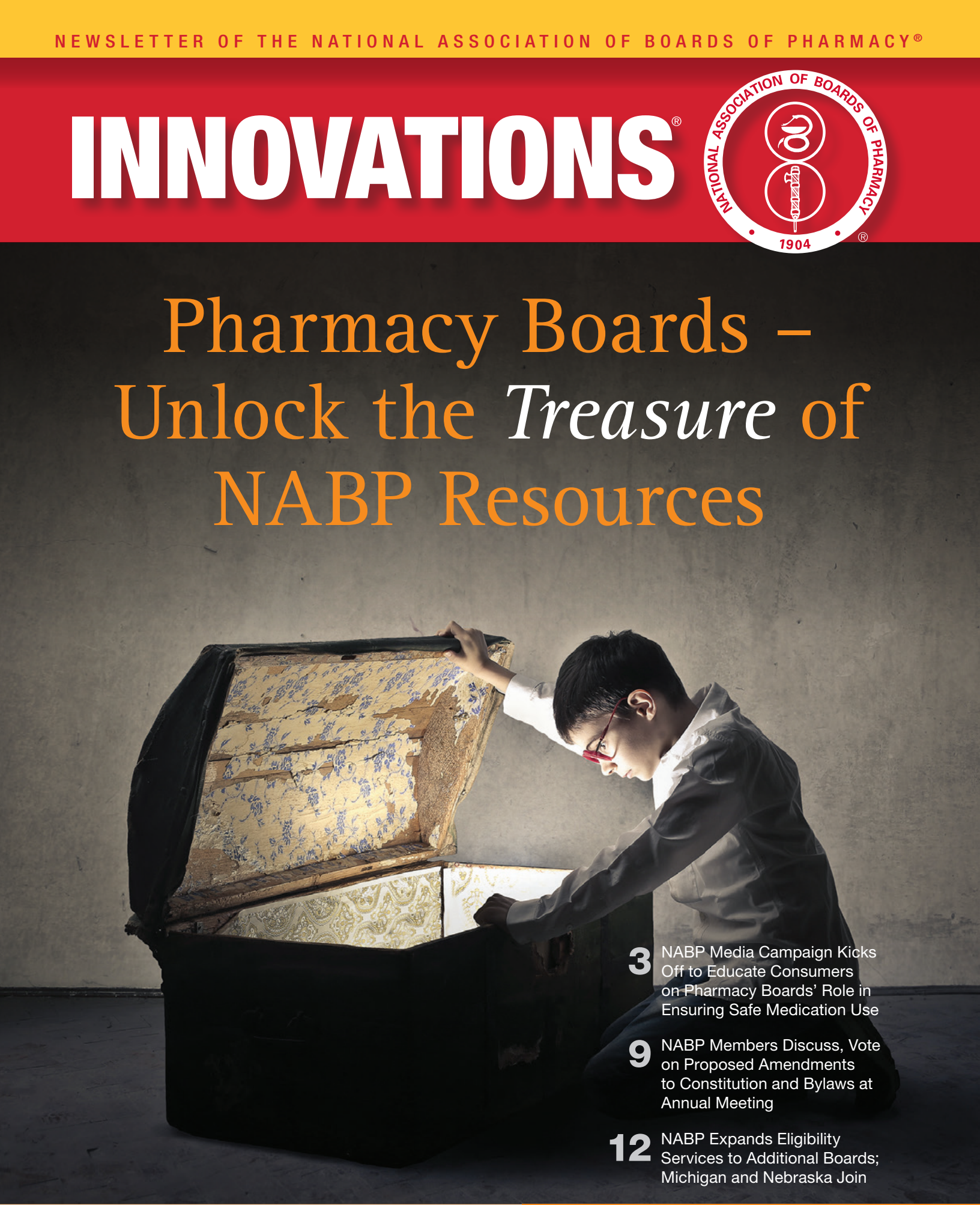
NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS®

Pharmacy Boards – Unlock the *Treasure* of NABP Resources



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

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

NABP Media Campaign Kicks Off to Educate Consumers on Pharmacy Boards' Role in Ensuring Safe Medication Use

In June 2018, NABP launched a campaign to educate consumers on steps the state boards of pharmacy and NABP take to ensure that pharmacies and pharmacists provide safe medicines and patient services to protect the health of consumers. The campaign includes several components that will be rolled out through early 2019 and is an initiative of NABP Chairperson Jeanne D. Waggener, RPh, DPh, from her tenure as 2017-2018 president. Her goal to educate pharmacists, pharmacy technicians, students, consumers, and other stakeholders on the value of pharmacy boards will continue through her term as chairperson.

(Above) NABP Chairperson Jeanne D. Waggener, RPh, DPh, and Joseph L. Adams, RPh, past president of NABP and a former member of the Louisiana Board of Pharmacy, conducted interviews in a Chicago, IL, recording studio with television and radio stations across the country as part of NABP's new consumer awareness campaign.

The campaign began on June 12 with a satellite media tour featuring Waggener and Joseph L. Adams, RPh, past president of NABP and a former member of the Louisiana Board of Pharmacy. From a Chicago, IL, recording studio, Waggener and Adams were interviewed by reporters from 24 television and radio stations across the country, answering questions on the prescription drug abuse issue facing Americans and promoting the boards of pharmacy and NABP as top resources for information. In addition, Adams shared his personal story of losing his son to an opiate overdose and how the loss affected him and his family.

During the interviews – some broadcast live and some recorded for later airing – consumers were encouraged to visit the AWAR$_X$E® Prescription Drug Safety section of NABP's website at *www.nabp.pharmacy/awarxe* for information about using medication safely, identifying prescription drug abuse, finding permanent drug disposal sites in the United States, and more. Pharmacist resources are also available on the site and include a video on identifying the warning signs of prescription drug abuse and Drug Enforcement Administration rules for pharmacies becoming registered as drug disposal sites.

In addition to the satellite media tour, NABP's consumer campaign will feature new television and radio public service announcements; web banner ads tied to keyword or topic searches; video ads on high-profile websites; and advertising on *WebMD.com*.

"In June 2018, NABP launched a campaign to educate consumers on steps the state boards of pharmacy and NABP take to ensure that pharmacies and pharmacists provide safe medicines and patient services to protect the health of consumers."

No Second Bite at the Apple

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

> **"Under procedural due process principles, respondents must be provided with sufficient processes to adequately protect their property interest in a professional license."**

At times, persons subject to administrative actions are also under concurrent criminal investigations or prosecutions. Under these circumstances, the state board may refrain from the administrative proceedings pending the outcome of the criminal prosecution. If so, questions may arise as to whether the respondent may "reargue" the criminal judgment in the ancillary administrative proceeding. Consider the following.

A pharmacist licensed in Nebraska and Pennsylvania was part of a criminal scheme involving prostitution and theft of narcotics. Eventually, the pharmacist was criminally convicted of multiple offenses, sentenced to a prison term and incarcerated at the Federal Correctional Institution in Danbury, CT. The Pennsylvania State Board of Pharmacy revoked her license based upon the criminal convictions. Relying on the same convictions, the Nebraska State Board of Pharmacy also revoked her license as a pharmacist. Representing herself pro se, the pharmacist (hereinafter referred to as Plaintiff) challenged her Nebraska licensure revocation by filing a lawsuit against the Nebraska Board in the United States District Court for the District of Nebraska. Her lawsuit was filed naming the Nebraska Board and the chief medical officer and director of the Division of Public Health, State of Nebraska Department of Health and Human Services as defendants.

The Plaintiff, of Vietnamese descent, alleged that her pharmacist license was revoked based upon her race, national origin, and gender because other white male pharmacists and technicians who testified at the Plaintiff's criminal trial and admitted guilt in the crimes were not punished. Based upon her self-representation, the courts exercised a liberal interpretation of her complaint as alleging claims under federal constitutional principles; specifically, claims that her rights were violated through conduct of a person acting under color of state law. The Plaintiff sought a reversal of the Nebraska Board revocation of her license as well as compensatory and punitive damages.

Nebraska law authorizes the Board of Pharmacy to take adverse action against a licensee based upon numerous grounds, including conviction of a misdemeanor or felony under Nebraska or federal law or conviction of a crime in any jurisdiction which, if committed in Nebraska would have constituted a misdemeanor or felony under Nebraska law and which has a rational connection to the fitness or capacity of the licensee to practice pharmacy. In addition, Nebraska law allows the Board to take adverse action if such licensee has had his or her license subject to discipline by another state based upon acts similar to those described under Nebraska law. Persons subjected to final adverse action by the Nebraska Board are entitled to appeal for judicial review. In this case, the Plaintiff did not seek judicial review of the final action revoking her license. Instead, she initiated litigation.

As part of the discrimination claims, the Plaintiff asked the court for a hearing to allow her to present evidence that she did not commit the crime for which she was convicted in Pennsylvania. Thus, she was attempting to challenge her licensure revocation by showing that her criminal conviction was in error. As noted by the court, pro se plaintiffs must set forth enough factual allegations to "nudge their claims across the line

from conceivable to plausible" or their complaint must be dismissed.

The court first outlined the authority of the Board of Pharmacy to render adverse actions, including revocation of licensure, based upon the legislative enactment of the practice act. Persons aggrieved by a final action of the Board are entitled to judicial review. Turning to the merits of her complaint, the court interpreted the Plaintiff's case to allege violations of equal protection and due process under the law. Under sovereign immunity principles and the Eleventh Amendment of the United States Constitution, the Plaintiff's claims for monetary relief against the Board and director are barred. However, the Plaintiff may sue for prospective declaratory or injunctive relief. Thus, the Plaintiff's claim for reinstatement of her license as a claim for a prospective remedy may be entertained by the court.

In order for her claims for prospective relief to survive, the Plaintiff must substantiate her claims under either substantive due process or equal protection arguments. As held by the court, the Plaintiff's allegations failed to state a plausible claim under either principle. In order to establish a substantive due process claim, the Plaintiff must show that a government official violated one or more fundamental constitutional rights and that such conduct was "shocking to the contemporary conscience." The states' authority under their police powers to regulate the professions and to enforce the practice acts, including revocation of licensure, has been consistently recognized by the courts.

Under procedural due process principles, respondents must be provided with sufficient processes to adequately protect their property interest in a professional license. Such processes include the right to notice and an adequate opportunity to be "heard" and defend accusations of wrongdoing. In this case, the Plaintiff argued that she was denied procedural due process based upon the refusal of the Board to allow her to present evidence challenging her criminal conviction. Thus, the court phrased the issue as to whether the failure to allow the Plaintiff to present evidence at an administrative proceeding challenging her criminal conviction deprived her of procedural right to protect a property interest.

Next, the court addressed whether the Plaintiff must exhaust her state remedies before pursuing claims in federal court. Generally, respondents must exhaust their state remedies before being allowed to pursue federal claims. But, plaintiffs need not exhaust available post-deprivation remedies when claiming entitlement to pre-deprivation process. The court held that the Plaintiff's failure to appeal her administrative revocation of her Nebraska license precludes her from pursuing any procedural due process rights related to her post-deprivation due process. Because the Plaintiff alleged a denial of pre-deprivation process, such allegations are not subject to exhaustion of state remedies and will not be dismissed.

However, because the Plaintiff's claims fail to state a plausible claim of denial of pre-deprivation process, the litigation was dismissed. In substantiating this conclusion, the court noted that the Plaintiff did not claim that she was denied notice or a hearing before her license was revoked. She again argued that her pre-deprivation rights were denied by the failure of the Board to allow her to present evidence of her innocence of the criminal charges. Such an approach undermines the criminal process under which she received sufficient due process rights. Courts have routinely held that plaintiffs may not recover damages under due process claims where any such judgment would necessarily imply the invalidity of a conviction, continued imprisonment, or sentence unless the conviction or sentence is reversed, expunged, or called into question by the issuance of a writ of habeas corpus. Based upon the fact that the Plaintiff had not alleged her conviction was subject to a reversal or expungement, the court held her claims for relief were barred.

Finally, the court held that the Plaintiff's equal protection claims were also subject to dismissal as she failed to allege any facts indicating a plausible claim. The Plaintiff did not allege that the defendants were motivated by discriminatory purpose or that the Plaintiff was treated any differently from any other licensee subject to a criminal conviction. Thus, no facts were alleged indicating discriminatory action or that similarly positioned persons were treated differently.

This case is an example of how a litigant may attempt to collaterally challenge a criminal conviction in a subsequent administrative proceeding. Some boards withhold administrative prosecutions pending the conclusion of the criminal proceeding for a myriad of reasons. If the prosecution results in a criminal conviction, the regulatory board can use the conviction as a basis for administrative action. Challenges to the criminal conviction generally must be argued before the criminal court and any appeals thereof.

Lasher v. Nebraska State Board of Pharmacy, 2018 US Dist LEXIS 71298 ■

Pharmacy Boards – Unlock the *Treasure* of NABP Resources

Are you getting the most out of your NABP membership? As a member of NABP, boards of pharmacy have access to a number of innovative services, programs, and resources that support and strengthen their efforts to protect the public health. While most member boards are familiar with programs required for licensure and other frequently used services, the professional services available as part of your membership may be less familiar. With services offered by a number of NABP departments – Member Relations and Government Affairs, Professional Affairs, and Legal Affairs – member boards are encouraged to look deeper and unlock some hidden treasures that can enhance their processes and provide regulatory and legal guidance and staff training.

> **"As a member of NABP, boards of pharmacy have access to a number of innovative services, programs, and resources that support and strengthen their efforts to protect the public health."**

Providing a Customized Approach

Realizing that no state board of pharmacy is exactly alike, the Member Relations and Government Affairs department, in conjunction with other NABP departments, works toward understanding and meeting the unique needs of each member. Member Relations and Government Affairs works closely with board officers and staff to learn about operational needs and brings that information back to the Association, coordinating with other NABP departments and subject matter experts to develop solutions. Using a customized approach, the department conducts regular outreach to member boards to stay in tune with emerging issues and ensure the Association continues to provide resources that are of value. This outreach effort, along with member discussions at task force and forum meetings, has helped gather the information needed to develop many of the Association's newer programs and services, including the Verified Pharmacy Program® (VPP®) and Multistate Pharmacy Inspection Blueprint.

VPP was developed to provide boards with robust inspection and license verification services, making sure boards have complete and accurate information to make informed licensure decisions. Enhancements to the program continue as Member Relations and Government Affairs aims to understand the member boards' needs that might be served through VPP. VPP currently assists a number of member boards when they lack the resources to complete timely pharmacy inspections. VPP inspections meet national standards for pharmacies that are applying for in-state licensure as well as licensure in other states.

Created by the member boards for their own use is the Multistate Pharmacy Inspection Blueprint program, which aims to provide uniform criteria for state

inspections through training and through the provision of a Universal Inspection Form. Due to each state's unique rules and processes, Member Relations and Government Affairs helps the boards determine the best use of the program and how they can be a Blueprint state. More information about the Blueprint Program can be found in the article "Fifteen Member Boards Deemed Blueprint States" in the June-July 2018 issue of *Innovations*.

Making sure no board is left behind, Member Relations and Government Affairs staff is available to travel to the boards' offices for one-on-one meetings and to attend and present at board meetings. These opportunities are designed to share details about NABP and the programs most relevant to each board as well as to connect the right board staff with the right NABP resources. Member Relations and Government Affairs, in conjunction with other NABP departments such as Accreditation, also helps facilitate webinars to supplement hands-on training sessions. More information about these trainings is available on page 12 of this newsletter.

Member Relations and Government Affairs staff also supports the boards in developing, reviewing, and providing feedback on rules and regulations, as well as board of pharmacy processes.

In sum, Member Relations and Government Affairs help the boards understand the "big picture" and how board operations and patient safety directly benefit from these services.

Educating, Developing Action Items and Protocols

Other resources boards can unlock through their membership are those offered through the support of NABP Professional Affairs staff. Using member input and analysis of issues affecting the practice of pharmacy, Professional Affairs works closely with other NABP departments to develop continuing pharmacy education (CPE) courses and secure speakers for NABP meetings. As a provider of Accreditation Council for Pharmacy Education (ACPE)-accredited CPE, NABP has assisted boards in offering educational opportunities. One example is CPE offerings at the NABP/American Association of Colleges of Pharmacy (AACP) district meetings. NABP has cosponsored CPE activities for the NABP/AACP districts. NABP Professional Affairs staff can also assist the districts with developing the CPE courses as well as ensuring the courses meet ACPE standards.

Beyond educational support, Professional Affairs, in conjunction with Member Relations and Government Affairs, implement NABP policy. Matters brought up at the district level and presented to and approved by the membership as NABP resolutions are acted upon on behalf of the boards to assist them in their efforts to protect the public health. For example, resolutions may result in the development of task forces as well as changes to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. An example of these efforts is the Task Force on Best Practices for Veterinary Compounding, which was established in response to Resolution 113-1-17. Taking action on the proposed resolution, Professional Affairs staff facilitated the review of existing federal and state laws and regulations addressing compounding of medication for animals (non-food-producing), helped task force members determine the applicable role of state boards of pharmacy in regulating the compounding of these products, and assisted in revising *Model Act* language. A summary of this task force was provided in the June-July issue of *Innovations* and a copy of the report is also available in the Publications and Reports section at *www.nabp.pharmacy*, under Research Briefs and Papers.

Further, NABP Member Relations and Government Affairs and Professional Affairs departments have made available educational opportunities to help boards build inspection programs that ensure the highest pharmacy quality standards. Through a partnership with CriticalPoint, LLC, NABP provides a tuition grant for each state to annually send a compliance officer/inspector through a training and certification program on inspecting for compliance with United States Pharmacopeia standards for sterile compounding. NABP also administers a grant from The Pew Charitable Trusts to further assist with funding for additional compliance officers/inspectors to attend the CriticalPoint training, and for a limited number of states to provide in-state field training on conducting inspections of sterile compounding facilities.

Professional Affairs staff also contributes to numerous resources that may assist boards in developing rules and regulations. For example, Professional Affairs staff continuously updates **NABP***LAW*® Online, a comprehensive national database of laws and regulations of all 50 states as well as District of Columbia, Guam, Puerto Rico, the Virgin Islands, and all Canadian provinces and territories. As part of NABP membership, boards of pharmacy receive a special discounted subscription fee for an annual license with unlimited users.

In addition, each year, Professional Affairs, in conjunction with Communications staff, updates the *Survey of Pharmacy Law* to reflect the latest information from the boards. A complimentary copy of the *Survey of Pharmacy Law* is provided to the

Member Relations and Government Affairs
GovernmentAffairs@nabp.pharmacy

Professional Affairs
ProfAffairs@nabp.pharmacy

Legal Affairs
LegalAffairs@nabp.pharmacy

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Collaborate, Network This Fall at the Interactive Forums

Interactive Executive Officer Forum
October 2-3, 2018

Interactive Member Forum*
November 28-29, 2018

- Network with colleagues
- Discuss topics submitted by fellow attendees
- Discover solutions for shared challenges
- No registration fees
- Travel, hotel accommodations, and meals paid by NABP
- Held at NABP Headquarters

Executive officers will receive registration information for the Executive Officer Forum in August and the Member Forum in September. For more information about the forums, contact ExecOffice@nabp.pharmacy. **One member per board may attend at no charge.*

NABP Resources

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executive director of each board for use by staff and board members.

Updated every August, the *Model Act* is another resource supported by Professional Affairs staff. The *Model Act*, which provides model language that may be used when developing state laws or board rules, is updated by Professional Affairs with input from experts, member boards, the Committee on Law Enforcement/Legislation, and the NABP Executive Committee.

Professional Affairs also works side by side with other organizations having common goals and initiatives that support boards of pharmacy. For example, NABP Professional Affairs staff has formed a relationship with the National Association of Pharmacy Regulatory Authorities to develop a statewide protocol on the prescribing and dispensing of naloxone, helping make naloxone more widely available. This protocol can then be used by the boards of pharmacy to implement related laws or regulations.

Legal Guidance

Another hidden treasure to some member boards are the services offered through NABP Legal Affairs. Legal Affairs staff can assist member boards in several ways. The department supports and provides member educational opportunities each year. Held every odd year, the NABP Interactive Compliance Officer and Legal Counsel Forum provides an opportunity for board of pharmacy compliance officers and legal counsel to learn about regulatory trends and recent cases impacting their clients, the boards of pharmacy, and to meet with their peers and discuss challenges. In 2018, the NABP Legal Affairs department will be hosting an educational webinar for board legal counsel. The webinar is exclusive to NABP member boards and is provided at no cost. More information on this event will be provided in future communications.

As an added benefit to members, Legal Affairs staff has partnered with legal counsel and filed several amicus briefs in support of the regulatory and public health protection efforts of the boards. For example, NABP partnered with a board of pharmacy and filed a legal brief in federal court in support of state board regulatory powers and immunity protections that the federal government was seeking to abrogate. NABP has also submitted comments in support of the boards related to regulatory proposals that may threaten the boards' ability to regulate the practice of pharmacy. The NABP Legal Affairs department can also provide member boards with training and guidance on handling and avoiding conflicts of interest.

Further, Legal Affairs staff works closely with NABP outside counsel to provide legal analysis on current cases that relate to the boards of pharmacy.

While each of these NABP departments may focus on specific areas, all NABP staff members work closely with one another to ensure individual board requests are met, pulling in experts from the full Association. Member boards interested in learning about and obtaining any of these professional services may contact NABP staff using the contact information provided on page 7.

NABP Members Discuss, Vote on Proposed Amendments to Constitution and Bylaws at Annual Meeting

During the 114th Annual Meeting in May 2018, NABP members passed an amendment to remove an associate member board from the districts of the Association and presented a technical amendment set to clarify language and eliminate outdated terminology in the NABP Constitution and Bylaws.

The Association's members discussed the proposed amendment "Proposed Removal of New Zealand from District 8" and voted to pass the amendment. The proposal to remove New Zealand from District 8 was submitted to the Committee on Constitution and Bylaws by the NABP Executive Committee after a request by the Pharmacy Council of New Zealand to discontinue its Association membership. New Zealand had been grouped in District 8 as an associate member board of NABP. The Committee on Constitution and Bylaws recommended passage of the proposed amendment to remove New Zealand during its meeting in March 2018. The amendment was passed unanimously during the Final Business Session at the Annual Meeting and has been applied to Article IV of the Bylaws.

The Executive Committee also submitted to the Committee on Constitution and Bylaws a set of proposed technical amendments to provide clarification to the existing language of the NABP Constitution and eliminate outdated terminology. The proposed changes include amending Article II and Article III, Section 1(c) to clarify that licensure transfer is inclusive of jurisdictions within the United States as well as any international jurisdictions that comply with the Constitution and Bylaws. In addition, language regarding Canadian board membership in Article III, Section 1(a) was changed to be consistent with terminology used in Canada. Further, the definition of an affiliated member in Article III, Section 1(e) was revised to remove "an offense involving moral turpitude" and replace this with "a felony" for the purpose of clarification, and the reference in this section to violation of liquor and drug laws was removed since such violations may not affect the pharmacist's license or be enforced by the licensee's board. The Committee on Constitution and Bylaws recommended passage of this proposed amendment at its meeting in March 2018, and the technical amendment set was presented at the Annual Meeting in May during the Second Business Session. Association members will vote on the Proposed Technical Amendment Set in May 2019 at the 115th Annual Meeting in Minneapolis, MN.

The 2018 Report of the Committee on Constitution and Bylaws is available in the Publications and Reports section of the NABP website at *www.nabp.pharmacy.*

Newly Accredited VAWD Facilities

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

Alcon Laboratories, Inc
Fort Worth, TX

AmerisourceBergen Drug Corporation
Buford, GA
Des Moines, WA
Sugar Land, TX
Valencia, CA

Caremark, LLC, dba CVS Specialty Pharmacy
Redlands, CA

Central Admixture Pharmacy Services, Inc (CAPS)
Allentown, PA

Cochran Wholesale Pharmaceutical, Inc
Monroe, GA

Direct Relief
Santa Barbara, CA

Exelixis, Inc
South San Francisco, CA

Fisher Scientific Company, LLC, dba Fisher Scientific and Fisher Healthcare
Florence, KY

Hy-Vee, Inc
Chariton, IA

Integrated Commercialization Solutions, LLC
Lockbourne, OH

Jams Wholesale Distribution Services LLC
Coconut Creek, FL

Kuehne + Nagel Inc
Plainfield, IN (two locations)

McKesson Medical-Surgical Inc
Roseville, CA

Medline Industries, Inc
Aurora, CO

Medline Industries, Inc, dba Medline Industries
Rialto, CA

Merz North America, Inc
Sturtevant, WI

Portola Pharmaceuticals, Inc
South San Francisco, CA

Sarepta Therapeutics, Inc
Cambridge, MA

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

Association Seeks Item Writers for NABP Examinations

NABP seeks volunteers to apply and serve as item writers for the Association's examination programs. Item writers develop test questions for NABP programs, including the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

The opportunity to participate as an item writer is currently available to pharmacists in all areas of practice and to faculty from schools and colleges of pharmacy. Item writers will be selected based on the specific needs of the programs. Those who are selected will be asked to attend an item development workshop and training with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item development process and content-related requirements for their designated examination program. Item writers will then engage in the development of new test items that will be considered for inclusion in NABP licensure, certification, and assessment examination programs.

The NAPLEX focuses on content domains relating to the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The two competency areas of the examination:

- Ensure safe and effective pharmacotherapy and health outcomes, and
- Assess safe and accurate preparation, compounding, dispensing, and administration of medications.

The MPJE combines federal and state-specific questions that test an individual's knowledge in pharmacy jurisprudence and includes the following areas:

- Legal aspects of pharmacy practice,
- Licensure, registration, certification, and operational requirements, and
- Regulatory structure and terms.

Writers for the MPJE are typically assigned by the participating jurisdiction; however, in some cases, individuals may be selected to participate independent of board of pharmacy affiliation.

The FPGEE content domains cover curricula of accredited United States pharmacy programs, including:

- Basic biomedical sciences,
- Pharmaceutical sciences,
- Social, behavioral, and administrative pharmacy sciences, and
- Clinical sciences.

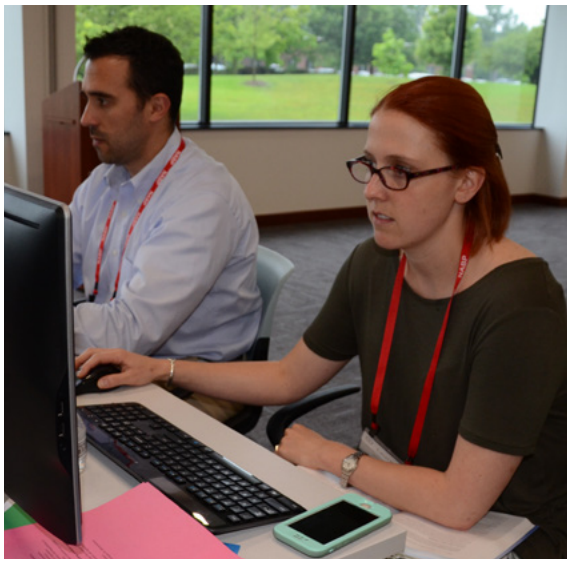
The PCOA is appropriate for administration to pharmacy students in all four professional years. The assessment follows a blueprint that is representative of curricula of accredited US pharmacy programs, including:

- Basic biomedical sciences,
- Pharmaceutical sciences,
- Social, behavioral, and administrative pharmacy sciences, and
- Clinical sciences.

How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form located on the Meetings page of the NABP website at *www.nabp.pharmacy* and upload a current résumé or curriculum vitae.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. ■



(Right) Item writers Thomas Dean Chiampas, PharmD, RPh, BCPS, AAHIVP, University of Illinois at Chicago (left), and Lauren Eichstadt Forsythe, PharmD, RPh, FSVHP, University of California – Davis (right), develop test questions for the North American Pharmacist Licensure Examination® in June 2018 at NABP Headquarters.

NABP Partnerships With FDA and DEA Continue to Advance Common Goals, Initiatives to Protect the Public Health

NABP has a long history of working with state, national, and international agencies with similar objectives and goals to improve standards of pharmacy practice, educate pharmacists, and protect the public health. Two examples are the Association's close partnerships with Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA).

Regulations Impacting Pharmacy Practice

NABP has worked, consulted, and shared information with FDA to develop regulations impacting pharmacists, the pharmacy industry, and consumers. For instance, prior to the establishment of DEA in 1973, FDA began working to stem the growing drug abuse epidemic in 1960, and NABP passed a resolution urging the boards of pharmacy to fully exchange information with FDA, particularly in instances where illegal interstate shipments of drugs are detected or intercepted by the various states. Two years later, NABP member boards passed a resolution to license all outlets from which dangerous drugs are dispensed (pharmacies) as well as all business concerns supplying dangerous drugs to the public (manufacturers and wholesalers). FDA, in turn, asked then NABP President Peter J. Hauper in 1963 to meet with the agency as a consultant regarding state law, policies, facilities, and needs as such matters related to the regulatory aspects of drug control.

More recently, the Association has partnered with FDA to help develop regulations to implement the Drug Quality and Security Act (DQSA) and Drug Supply Chain Security Act (Title II of DQSA), and to enforce provisions of existing laws, such as the Food, Drug, and Cosmetic Act.

NABP also works with the agency to address new challenges. For example, NABP participates in FDA's annual intergovernmental working meeting on pharmacy compounding, which was initiated by FDA after the 2012 fungal meningitis outbreak associated with contaminated compounded drugs at New England Compounding Center. Prior to each meeting, FDA solicits input from NABP on the agenda. During the meetings, attendees – representatives from NABP, boards of pharmacy, health departments, Centers for Disease Control and Prevention, organizations representing state officials, and others – discuss oversight of compounding and identify opportunities to better protect the public health by strengthening oversight of compounders through improved federal-state collaboration. This year's meeting will be held September 25-26 in Silver Spring, MD.

Educational Partnerships

Educational events involving FDA and DEA have also been part of NABP's efforts to help pharmacists and other pharmacy personnel remain up-to-date on federal and state pharmacy regulations and practices. As in past years, FDA and DEA participated this year in NABP's 114th Annual Meeting. FDA and DEA representatives provided information about their agencies and answered attendees' questions during the Educational Table Top Displays.

Prior to the November 2017 NABP Interactive Compliance Officer and Legal Counsel Forum, FDA held an educational session on compounding facility inspections. The sessions provided compliance officers with an overview of federal requirements for compounding activities, FDA oversight of state-licensed pharmacies, outsourcing facility oversight, and more.

From 2011 to 2017, NABP cosponsored DEA's Pharmacy Diversion Awareness Conferences, part of the agency's overall approach to address and respond to potential diversion activity. Held in 48 states, District of Columbia, and Puerto Rico, the conferences were open to pharmacists, pharmacy technicians, loss-prevention personnel employed by pharmacies or hospitals/clinics registered with DEA in the states, and pharmacy students. Attendees were also able to receive Accreditation Council for Pharmacy Education-accredited continuing pharmacy education credit by attending these sessions cosponsored by DEA and NABP.

Sharing FDA and DEA News

The Association continues to share timely information about FDA and DEA through its numerous publication vehicles, including this newsletter, *Innovations; National Pharmacy Compliance News;* and three electronic newsletters – *NABP e-News, AWARxE Prescription Drug Safety News*, and *.Pharmacy News*.

NABP also regularly promotes the DEA National Prescription Drug Take-Back Day, which is held each spring and fall. In addition to promoting DEA's one-day events, NABP encourages consumers to find safe, local, permanent drug disposal sites by using the AWAR$_X$E® Prescription Drug Safety Program's drug disposal locator tool.

In addition to keeping pharmacists and state boards of pharmacy apprised of FDA and DEA activities via its print and electronic newsletters, NABP shares with FDA and DEA information that it gathers and compiles about pharmacy and consumer trends. For example, each spring and fall, NABP publishes the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators*, which provides regulators, including FDA and DEA, and other stakeholders with pertinent details and news related to internet drug outlets.

As the practice and regulation of pharmacy continue to evolve, strong, effective partnerships among NABP, FDA, and DEA will continue to be key to protecting the public health. ■

Sterile Compounding Training Reminder

Apply for Funding Assistance to Send Board Inspectors, Compliance Officers to Participate

NABP and The Pew Charitable Trusts are offering assistance with funding for state board of pharmacy inspectors and compliance officers to attend the NABP/CriticalPoint Certification in Sterile Compounding for Inspectors (CISCI) training. Registration remains open for the on-site training to be held October 8-11, 2018, and November 5-8, 2018.

To earn CISCI, participants must complete the following components of the training:

- preliminary eLearning training modules (must be completed before taking the live training);
- three and one-half days of live, on-site training at a state-of-the-art facility in Totawa, NJ; and
- a post-test.

The on-site training is Accreditation Council for Pharmacy Education-approved for 27.5 hours of continuing pharmacy education. Participants must complete all portions of the training and become certified to receive funding.

NABP will fund the cost of tuition for one person per state, per year, to attend this training. NABP is also administering a grant from Pew to offer additional funding to cover tuition and travel for a second inspector or to assist with travel costs for the first inspector if travel costs are a barrier to participation.

Registration for the CISCI training can be found on the CriticalPoint website at *www.criticalpoint.info/sterile-compounding-inspector-training*. To obtain information about the Pew funding to assist with attending the training, contact NABP at Government Affairs@nabp.pharmacy. ■

Newly Accredited DMEPOS Facilities

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

Arcadia Health Pharmacy
Flushing, NY

King Pharmacy & DME
San Jose, CA

NVR Pharmacy, Inc
Bronx, NY

Prescription Health Resources
Richland Hills, TX

Total Pharmacy Care
Pikeville, KY

A full listing of approximately 300 accredited DMEPOS companies representing almost 26,000 facilities is available on the NABP website at *www.nabp.pharmacy.*

NABP Expands Eligibility Services to Additional Boards; Michigan and Nebraska Join

NABP is expanding its exam eligibility service to include additional state boards of pharmacy. In May 2018, Michigan and Nebraska began participating in this service. With the addition of these two states, NABP now confirms eligibility to take the North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination® for six boards of pharmacy, including Colorado, Maine, Oregon, and Utah. NABP's new online system that launched in April 2018 enables greater automatization of the eligibility review process, such as the elimination of paper applications and the uploading of Americans with Disabilities Act forms during the online application process. This automatization has allowed the Association to expand the service.

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

Around the Association

Board Member Appointments

- **Joseph Leyba, PharmD, RPh,** has been appointed a member of the Arizona State Board of Pharmacy. Leyba's appointment will expire January 16, 2023.
- **Chikita Sanders** has been appointed a public member of the District of Columbia Board of Pharmacy. Sanders' appointment will expire March 12, 2021.
- **Gary Roy, RPh,** has been appointed a member of the Guam Board of Examiners for Pharmacy. Roy's appointment will expire March 15, 2021.
- **Wayne "Mitch" Mitchell, RPh,** has been appointed a member of the Nevada State Board of Pharmacy. Mitchell's appointment will expire October 31, 2018.
- **David A. Rochefort, RPh,** has been appointed a member of the New Hampshire Board of Pharmacy. Rochefort's appointment will expire September 6, 2021.
- **Darryl "Tim" Logan** has been appointed a public member of the Oregon State Board of Pharmacy. Logan's appointment will expire May 31, 2021.
- **Sue Richardson** has been appointed a public member of the Oregon State Board of Pharmacy. Richardson's appointment will expire September 30, 2018. ■

NABP Mourns Passing of Former Outside Legal Counsel John F. "Jack" Atkinson

NABP is sad to announce that John F. "Jack" Atkinson passed away on May 26, 2018. In 2008, Mr Atkinson retired after serving as NABP outside legal Counsel for more than 40 years. Mr Atkinson was a founding partner of Atkinson and Atkinson (A&A), a law firm representing associations of regulatory boards. Mr Atkinson, alongside his son, Dale Atkinson, founded the firm in 1989. Prior to this, Mr Atkinson served as a shareholder of the law firm Hill, Van Santen, Steadman, Chiara & Simpson, and served as a partner of the law firm Witwer, Moran, Burlage & Atkinson, both in Chicago, IL.

In the spirit of Mr Atkinson's commitment to advancing the efforts of NABP and the state boards of pharmacy, the Association established the John F. Atkinson Service Award in his honor at the commencement of NABP's 105th Annual Meeting in 2009. The award recognizes exemplary service in protecting the public health and significant involvement with the Association. This award also recognizes the exceptional accomplishments related to pharmacy law and compliance. Additionally, Mr Atkinson was honored with the Distinguished Service Award (DSA) in 1984, now known as the Lester E. Hosto DSA, for his exceptional contributions to furthering the mission of NABP and protecting the public health.

In addition, Mr Atkinson originally incorporated the Federation of Associations of Regulatory Boards (FARB) in 1974 and was integrally involved in the evolution of the not-for-profit whose mission is to advance excellence in regulation of the professions in the interest of public protection. He was honored with the FARB Lifetime Achievement Award for distinguished service to the regulatory community. The A&A law firm noted that he was a champion for the regulatory community, spending nearly 60 years advising associations.

Mr Atkinson is survived by his three sons, John, Mark, and Dale, one

sister, six grandchildren, and five great grandchildren. NABP is sad to also announce the recent passing of Mr Atkinson's wife of 64 years, Mary. Mary Atkinson passed away on June 11, 2018. ■

Massachusetts Board Requires Licensure for Pharmacy Technicians

As of April 6, 2018, all pharmacy technician trainees in Massachusetts must be licensed by the Massachusetts Board of Registration in Pharmacy. Under the revised regulation (247 Code of Massachusetts Regulation 8.03), no individual may work as a technician trainee without holding a valid pharmacy technician trainee license. Pharmacy technician trainees – who were employed when the rule took effect – were required to receive a Board-approved license by July 6, 2018, to continue work in this capacity. Pharmacy technician trainees hired on or after April 6, 2018, must obtain a pharmacy technician training license before beginning work in a pharmacy.

Ohio Upgrades OARRS Patient Reports for MME, Buprenorphine Calculations

As of April 2018, the Ohio Automated Rx Reporting System (OARRS) calculates and displays a patient's narcotic (opioids) and buprenorphine equivalences separately. This change is due to a guidance released by the Centers for Disease Control and Prevention that excludes buprenorphine from the narcotic morphine milligram equivalent (MME)/day calculation.

For most of 2017, a typical dose of buprenorphine was 16 mg when prescribed for medication-assisted treatment. This would result in a patient report of 480 MME value.

The OARRS system includes the following upgrades to the MME column in the patient reports:

- Buprenorphine excluded from displayed MME calculations.
- Summary section of patient report no longer only displays active daily MMEs.
- Prescriptions section of patient report updated to reflect mg/day for buprenorphine.

Additional information can be found at *www.pharmacy.ohio.gov/OARRSenhancements*.

South Carolina Approves Expungement Policy

In March 2018, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy approved an expungement policy and established a procedure to allow a licensee/permittee who has been issued a reprimand to petition the Board for expungement of the reprimand from the licensee/permittee's record.

Pursuant to South Carolina Code Annotated §40-1-120(E), if the Board grants a licensee/permittee's petition, the relevant records relating to the reprimand previously issued by the Board shall be sealed, subject only to production in response to lawful requests for the same by state or federal agencies, or appropriate third parties. Aside from the limited exceptions previously mentioned, the records will not be available to the public and will be removed from the Board's website. Further, the proceedings and resulting reprimand shall be deemed by the Board to have not occurred.

The Board will not consider a petition for expungement until a minimum of one year has passed after the licensee/permittee's satisfactory completion of any conditions imposed by the Board relating to the reprimand sought to be expunged.

Reprimands resulting from the following conduct by individual licensees shall not be eligible for expungement:

- Offenses involving controlled substance (CS) diversion and abuse or misuse;
- Offenses in which drugs, including non-controlled and/or CS, were diverted and distributed to a third party;
- Unlicensed practice; and
- Practicing while impaired.

Reprimands resulting from the following conduct by permittees shall not be eligible for expungement:

- Shipping into South Carolina without a permit (nonresident facilities);
- Permit holders with nonreciprocal and nonrelated offenses; and
- Offenses involving distribution of misbranded and/or adulterated drugs.

A licensee/permittee must file a petition for expungement with the Board administrator, and the Board will consider the petition at a meeting.

Utah Passes Bills on Pharmacist Dispensing, Medical Cannabis, CS, and Opiate Abuse

During the 2018 General Session, the Utah Legislature passed several pharmacy-related bills, which are noted below.

- Senate Bill 184 2 Sub: Pharmacist Dispensing Authority Amendments permits a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription drug order established under a licensed physician.
- House Bill (HB) 195 3 Sub: Medical Cannabis is a "right to try" bill that allows cannabis-based treatment for terminally ill patients.
- HB 127 2 Sub: Controlled Substance Database Act Amendments changes the requirements for checking the Utah Controlled Substance Database.
- HB 399 3 Sub: Opioid Abuse Prevention and Treatment Amendments requires pharmacists to affix a warning label to certain opiate prescriptions and commissions and requires the Utah Department of Health to develop a pamphlet with information about opiates.

More details can be found in the Utah Board of Pharmacy's May 2018 *Newsletter*.

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, United States Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids*, with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, Food and Drug Administration (FDA) issued a new policy that is designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear, and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm607339.htm*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services*, describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm*.

Pharmacists Are Critical to Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability*, FIP provides a global picture of the role of the pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- consider how to most effectively use the skills of the staff and personnel available;
- provide and seek training where needed; and
- keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be found at *www.fip.org/news_publications*. ■

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UPCOMING EVENTS

NABP/AACP Districts 1 and 2 Meeting
September 20-22, 2018
Washington, DC

FPGEE Administration
October 2, 2018

NABP Interactive Executive Officer Forum
October 2-3, 2018
NABP Headquarters

NABP/AACP Districts 6, 7, and 8 Meeting
October 14-17, 2018
Kansas City, MO

NABP/AACP District 4 Meeting
November 7-9, 2018
Grand Rapids, MI

NABP Interactive Member Forum
November 28-29, 2018
NABP Headquarters

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