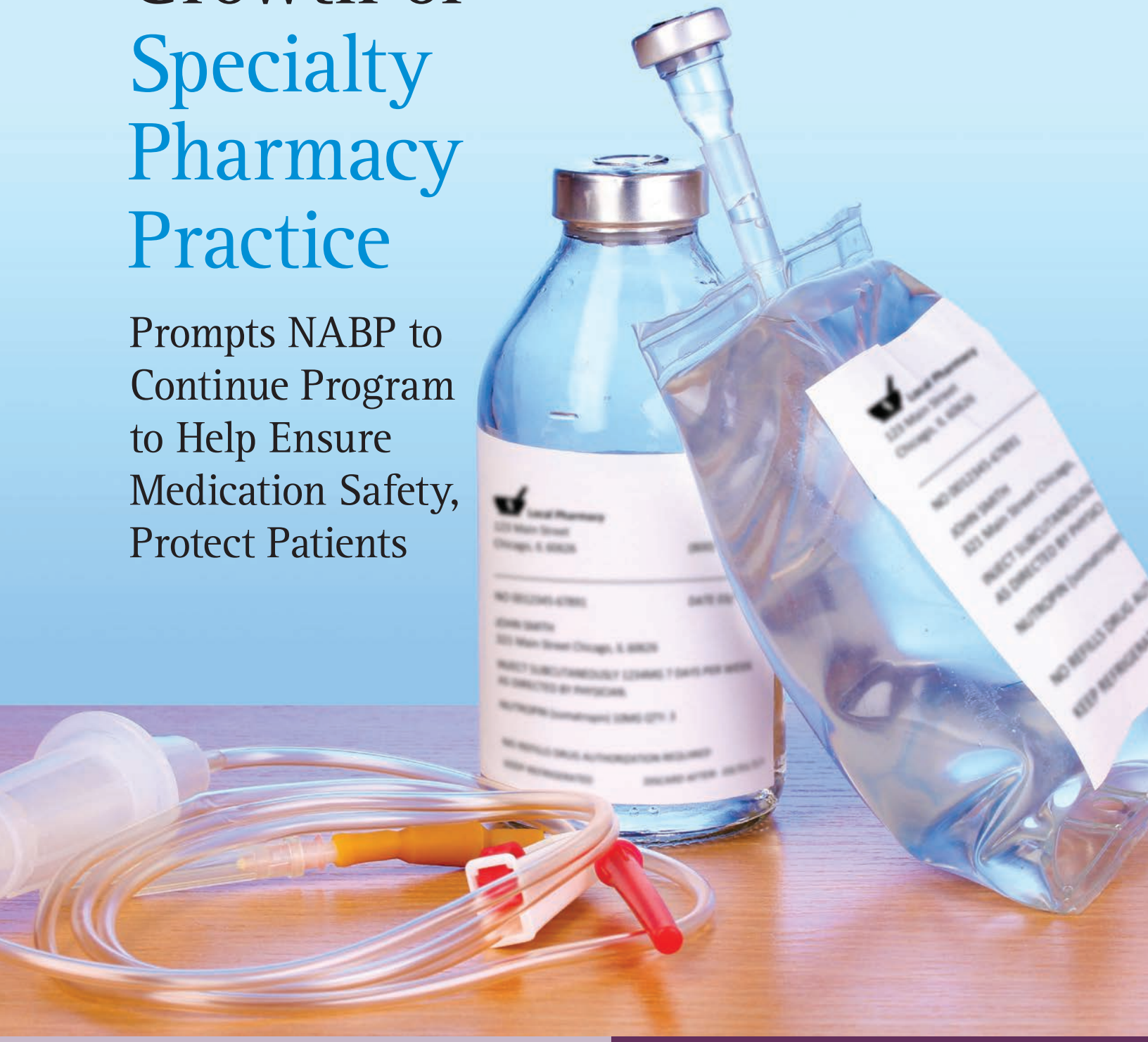
NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS

Growth of Specialty Pharmacy Practice

Prompts NABP to Continue Program to Help Ensure Medication Safety, Protect Patients



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INNOVATIONS
table of contents

Innovations
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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.

4 Legal Briefs
47: A Safe Prime, a Supersingular Prime, and an Eisenstein Prime

9 Association News
NABP Partners With Website Template Provider to Help .Pharmacy Registrants Promote Public Health

11 2017-2018 FPGEE/PCOA Review Committee Members

14 113th Annual Meeting
Still Time to Request a Travel Grant

18 State Board News
Maryland Issues Reminder Related to State PDMP Requirements

19 Professional Affairs Update
FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

6

Feature News
Growth of Specialty Pharmacy Practice Prompts NABP to Continue Program to Help Ensure Medication Safety, Protect Patients

12

113th Annual Meeting
NABP to Honor Leaders at the Forefront of Public Health Protection During Annual Meeting Awards Dinner

Interview With a Board Executive Director

Alexandra Blasi, JD, MBA
Executive Secretary,
Kansas State Board of Pharmacy

Alexandra Blasi, JD, MBA

Executive Secretary, Kansas State Board of Pharmacy

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

I joined the Board of Pharmacy as executive secretary in November 2015, but have been working for the state of Kansas for over five years. I've served as in-house disciplinary counsel at other regulatory agencies and most recently left the Kansas Department of Commerce, where I served as an attorney for workforce services. As a juris doctor and master of business administration graduate of Washburn University, I've always had a passion for health care, and I love this job!

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

We had a very outdated licensing system with limited connectivity to inspections, case management, document storage, and disciplinary actions. It was breaking down and wasn't web-enabled. Though it may seem trivial, it's one of the most critical pieces of the puzzle for regulating, notifying, and providing good customer service to our licensees/registrants and even other states. The threat of failed data linkages or system functionality was a strong motivator to explore vendor options and request permission to use state pharmacy dollars to pursue alternatives, something staff had made significant progress on before I took the position.

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

The Board set aside funding and identified several potential software vendors. In addition, the Board allowed staff to ask questions and see demonstrations before finalizing a plan. After careful consideration and some collaborative discussions with the Mississippi Board of Pharmacy, the Board partnered with a Mississippi-based business software company to expand the company's pharmacy board licensing software to include custom inspection and disciplinary components, linked documents and storage, reports and dashboards, and the ability to further integrate with NABP's systems for exchange of information. The system is also real-time and web-enabled, making it accessible for field staff to complete electronic inspection reports during the inspection and allowing consumers to verify licenses anytime, anywhere, with accuracy. Development is ongoing, but we use and appreciate the system every day. Recent milestones include completion of our first full year of online renewals in the new system, allowing remote printing of licenses/registrations, launching online applications for facilities, and integrating our user data with K-TRACS – the Kansas prescription drug monitoring program (PDMP).

What other key issues has the Board been focusing on?

It's been a busy year in Kansas, chock-full of new regulations for collaborative practice, automation, and continuing education. We've also seen staffing additions and shifts to accommodate workload changes. We now have a

continued on page 8

Kansas State Board of Pharmacy

Number of Board Members: 6 pharmacist members and 1 public member
Number of Compliance Officers/Inspectors: 5
Rules and Regulators Established by: State Board of Pharmacy
Number of Pharmacist Licensees: 5,595
Number of Pharmacies: 1,825 (in-state)
Number of Wholesale Distributors: 1,075

47: A Safe Prime, a Supersingular Prime, and an Eisenstein Prime

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

> **"As technology evolves and allows for interstate and international practice without physical presence of the practitioner, the regulatory systems are challenged to maintain relevance and enforceability."**

Persons and entities engaging in the practice of pharmacy in multiple jurisdictions must become licensed in each such jurisdiction in order to lawfully practice. Under the United States Constitution, the right to local regulation is vested in the states, which have the latitude to establish and enforce licensure systems for the benefit of their consumers.

As technology evolves and allows for interstate and international practice without the physical presence of the practitioner, the regulatory systems are challenged to maintain relevance and enforceability. In pharmacy, perhaps like few other professions, the regulatory systems are a combination of state and federal laws that can be confusing and lead to inconsistent application. With that said, the states have the right to enforce their regulatory laws as authorized through relevant state statutes and rules/regulations.

Pharmacists and pharmacies licensed in multiple states face the potential for multiple adverse actions against their licenses in the event of one state's disciplinary determinations. Each state should have the right in statute to administer sanctions based upon a final disciplinary action of another state. Must the reciprocal disciplinary sanctions from each state be consistent? Consider the following.

A pharmacy and prescription drug outlet has its primary facility located in Colorado Springs, CO. Including Colorado, the pharmacy (referred to as Respondent) is licensed in 47 states. In 2007, Food and Drug Administration (FDA) brought charges against the Respondent for illegally compounding human growth hormone (HGH). Specifically, the owner (TB) was charged with purchasing HGH from a wholesaler that had purchased the unregistered, unapproved drug from a Chinese manufacturer.

While the FDA matter was pending, the Colorado State Board of Pharmacy initiated an administrative action against the Respondent. The Board matter was settled in 2007 through consent, and the Respondent agreed to pay a $250,000 fine, and to probation for a seven-year period, and TB agreed to step down from his position and relinquish all ownership of the company. Quarterly affidavits were to be filed with the Board attesting to the fact that HGH was not being compounded, but the Respondent was allowed to sell HGH purchased from FDA-approved and Colorado-registered suppliers. A pharmacist-in-charge was appointed (JG), who later became the chief executive officer of the Respondent in 2009.

In 2008, during a routine audit, the Colorado Board discovered that the Respondent had purchased HGH from a wholesaler that was not licensed in Colorado. Further, a veterinarian in Illinois had ordered HGH from the Respondent and listed herself as both the prescribing physician and the patient, a practice not allowed under Colorado law. JG testified that these events occurred before he took over and that new measures were implemented to verify conditions before dispensing. Based upon these events, the Colorado Board entered into a new settlement with the Respondent in 2009. The new consent agreement extended the probationary period to seven years from the 2009 entry date. Further, the Board prohibited the Respondent from procuring, purchasing, selling,

distributing, dispensing, transferring, or handling HGH.

Finally, in 2013 the Colorado Board issued a letter of admonishment to the Respondent for placing "seven months beyond use dates on an injectable medication drug that in fact had a one year 'beyond use date.'" The Respondent self-reported the letter of admonishment to all 47 of the states where it was licensed, including Michigan.

In 2014, the Michigan Board of Pharmacy filed an administrative complaint against the Respondent. The complaint cited the 2007, 2009, and 2013 administrative penalties as the bases for its actions. The Board alleged that it is able to render disciplinary action(s) under a Michigan statute that authorizes action where a pharmacy, manufacturer, or wholesale distributor has been denied a license or federal registration, has had its license or federal registration limited, suspended, or revoked, or has been subject to any other criminal, civil, or administrative penalty.

Following a hearing, the administrative law judge (ALJ) issued a proposal for decision (PFD). The ALJ found that the Respondent's conduct in 2007 and 2009 occurred under the previous owner and that, since the new owner took over, Respondent had complied with all imposed reporting requirements. The ALJ also concluded that the Michigan Board had the authority to impose sanctions against the Respondent under Michigan law as administrative penalties had been rendered against the Colorado licenses in 2007, 2009, and 2013. The Michigan Board of Pharmacy Disciplinary Subcommittee accepted the findings of fact and conclusions of law in the PFD and revoked the Respondent's license to practice as a pharmacy in Michigan. The Respondent appealed to the Court of Appeals.

The court reviewed the standard of review and noted that, as the Respondent only challenged the sanctions and not the authority of the Disciplinary Subcommittee, the court need only address whether the decision is supported by competent, material, and substantial evidence on the record as a whole.

The Respondent argued that the Michigan Board erred by revoking its pharmacy license instead of imposing a lesser sanction and that the Disciplinary Subcommittee failed to consider mitigating circumstances. The Respondent did not contest that the Board has the authority to revoke its license when such has been the subject of an administrative penalty in another state. The Respondent conceded that the 2007 and 2009 orders were administrative penalties, but challenged whether the 2013 letter of admonishment was a penalty. The mitigating circumstances cited by the Respondent included the fact that systems were implemented by JG to track wholesaler licensing, that Respondent no longer did bulk distribution, and that no product safety allegations had been filed since the 2009 order.

However, the focus of the appeal was on procedural grounds. The Respondent argued that the final order failed to comply with administrative rules regarding the adoption, modification, or rejection of the PFD. Specifically, the Respondent argued that the Michigan Board "modified or rejected" the mitigating circumstances identified by the ALJ by not noting in the record the bases for rejecting such mitigating circumstances. The court concluded that the final order issued by the Board did **not** modify or reject the PFD. The final order clearly stated that it was accepting the findings of fact and conclusions of law found in the PFD. The PFD contained the findings of fact and conclusions of law and offered that the Michigan Board "may" consider the mitigation of such findings. As noted by the court, "may" is discretionary, not mandatory. The Board was therefore free to not consider the mitigating factors. Further, the court emphasized that the PFD did not "indicate that consideration of the mitigating factors it identified should lead to the result hoped by [R]espondent—a lesser sanction."

As a result, the court found that the decision was supported by competent, material, and substantial evidence and the Michigan Board had acted within its authority in revoking the license of the Respondent. The authority of a board of pharmacy to render reciprocal discipline is an important component of public protection. The authority of a state board of pharmacy to determine the necessary sanction(s) under reciprocal disciplinary circumstances, while potentially argued as unfair, recognizes a respect for states' rights as guaranteed by the US Constitution. Under the current set of facts and the requirement for persons and entities to be licensed in each state where they practice, are there 45 additional proceedings involving the Respondent that will take place?

In re College Pharmacy, 2017 Mich App LEXIS 195 (App Ct MI 2017 UNPUB) ■

Growth of Specialty Pharmacy Practice Prompts NABP to Continue Program to Help Ensure Medication Safety, Protect Patients

Specialty drugs make up a large and increasing percentage of the pharmaceutical marketplace, and pharmacies that can provide the specialized medication handling and intensive patient care that go along with these drugs – and the disease states they treat – have likewise gained prominence.

To help ensure that specialty pharmacies have the necessary elements to maximize patient safety, optimize therapeutic outcomes, and manage costs, stakeholders ranging from third-party payers and pharmacy benefit managers (PBMs) to pharmacy-related associations, including NABP, have looked to accreditation as a tool. As part of this effort, NABP will continue the program developed by the Center for Pharmacy Practice Accreditation (CPPA) as well as include a specialty pharmacy module for its Verified Pharmacy Program® (VPP®). These efforts will assist patients, providers, and payers in identifying those specialty pharmacies that have met the standards necessary to provide services in this area of practice.

> **"NABP brings to the specialty pharmacy arena the Association's many years of evaluation, inspection, and accreditation experience and expertise, joining programs such as VPP, the Verified-Accredited Wholesale Distributors® (VAWD®) program, and the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program."**

Working with the American Pharmacists Association (APhA) to continue CPPA's accreditation efforts, NABP brings to the specialty pharmacy arena the Association's many years of evaluation, inspection, and accreditation experience and expertise, joining programs such as VPP, the Verified-Accredited Wholesale Distributors® (VAWD®) program, and the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program. Because of this background, NABP can emphasize not only the patient management services that are important in supplying specialty pharmacy services, but also the safety of the medications being dispensed.

Specialty Drugs

Specialty products may be oral, injectable, infusible, or inhaled. Specialty drugs also tend to have a high monthly cost, often more than $750 per month. While historically, specialty drugs may have been limited to very few and comparatively rare conditions such as hemophilia, the field has expanded markedly in the last couple of decades. Specialty medications are now commonly used to treat many conditions, including rheumatoid arthritis, multiple sclerosis, gastroenterological issues, hepatitis B and C, HIV, solid organ and bone marrow transplantation, growth disorders, cancer, bleeding disorders, renal failure, and pulmonary disorders. Specialty drugs are being developed even for such common conditions as high cholesterol.

One of the challenges directly impacting specialty pharmacy practice is the myriad of definitions directing practice. Definitions of specialty drugs and what constitutes specialty pharmacy practice seem to be dependent more on economic issues, exclusivity, and pricing considerations than on patient-centered practice. To address this concern, the NABP Committee on Law Enforcement/Legislation developed a definition of specialty pharmacy practice and specialty drugs for inclusion in the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act).* The committee's recommendation will be presented to the NABP Executive Committee for approval when they meet prior to the NABP 113th Annual Meeting this May 2017. The definition of specialty pharmacy practice that the committee will be recommending for adoption and uniformity across the states is as follows:

> "Specialty Pharmacy Practice" means the provision of Pharmacist Care Services, which involves Drugs used to treat chronic or specific diseases and conditions that require frequent communication with other health care providers, extensive patient monitoring and case

management, and comprehensive counseling with the patient and/or caregiver. Drugs Dispensed by a Specialty Pharmacy may also require instruction and training on complex administration processes and/or handling and storage considerations.

The definition of a specialty drug that the committee will be recommending for adoption and uniformity across the states is as follows:

> "Specialty Drug" means a Drug used to treat a chronic or specific disease or condition that requires frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver.

The Committee on Law Enforcement/Legislation will also be recommending a definition be added to the *Model Act* on what constitutes a specialty pharmacy.

Specialty drugs made up roughly half of all new drugs and biologics approved by the Food and Drug Administration in 2015. According to some estimates, pharmacies dispensed about $115 billion in specialty drugs in 2016, accounting for 28% of the industry's prescription dispensing revenues. The numbers are expected to continue growing.

Specialty Pharmacies

Because of the attributes of specialty drugs and the attributes of the patients who take them, specialty pharmacies cannot operate like a typical retail pharmacy. They must be able to deal with the often stringent handling, storage, and shipping requirements of the medications, both to protect the medications' integrity and to minimize waste. The pharmacies also must be able to provide the ongoing clinical and operational services needed by patients. On the clinical side, these services range from providing intensive patient education and training to working with physicians to address issues such as side effects or adverse drug reactions. Some medications may also require continual access to pharmacists and other health care providers to provide support. On the operational side, services include managing drug supply chains, coordinating patient care among different providers, and assisting patients with medication access by working with insurers or facilitating enrollment in patient assistance programs.

Paramount in providing these ongoing services is patient safety and trying to ensure that the patient has the optimal response to his or her medication therapy. Activities like helping patients to comply with their treatment regimens, helping them to mitigate and manage side effects, and monitoring their response to treatment all further the goals of medication safety and effectiveness. These activities also address a secondary goal, particularly for third-party payers and PBMs paying for what are often highly expensive drugs: cost-effectiveness. For payers, activities such as proper storage and shipping, monitoring for patient adherence, and measuring a patient's responsiveness to therapy help to control costs while simultaneously facilitating better therapeutic outcomes.

Because specialty drugs have taken such a prominent place in the pharmaceutical marketplace, many pharmacies have entered into specialty pharmacy practice. While some specialty pharmacies are independent, others are owned by retail chains, PBMs, health plans, wholesalers, hospital systems, and physician practices. Nonetheless, just a few companies dominate the sector. In 2016, for example, just five companies accounted for about two-thirds of prescription revenues from pharmacy-dispensed specialty medications. This dynamic is intensified both by manufacturers, which frequently limit distribution of recently launched specialty drugs to a select few pharmacies in order to better control such factors as quality issues and monitoring, and by payers. Often, PBMs and health plans require patients to use a specialty pharmacy owned and operated by that company or to use a network of pharmacies with which they have contracted. Most specialty drugs – about 70% – are also dispensed through mail or central-fill pharmacies.

Accreditation

With the sector's high costs and intensive patient-care requirements, accreditation is a way for specialty pharmacies to demonstrate to health plans and PBMs their qualifications to be included in a payer's or manufacturer's network. As noted earlier, NABP's experience with accreditation and its national perspective on (and expertise in) safeguarding the supply chain makes the Association uniquely qualified to manage the complex and multifaceted requirements of a specialty pharmacy accreditation program.

As noted earlier, the specialty pharmacy accreditation program originated through CPPA, an organization established by NABP in partnership with the APhA and the American Society of Health-System Pharmacists (ASHP). To better service the pharmacies seeking accreditation by CPPA and help ensure protection of public health, the partner organizations determined that a reorganization was in order. Thus, NABP and APhA will continue the accreditation program for non-health-system specialty pharmacies, and ASHP will develop a program for hospital-based specialty pharmacies.

Because of the unique nature of specialty pharmacy, a pharmacy's processes – its policies and procedures – are crucial to its ability to adequately handle specialty drugs and provide patient care. Both the accreditation standards and the program's application process reflect this importance.

Once a pharmacy submits its application to NABP, the Association will use policy and procedure assessment tools to verify that the pharmacy understands the necessary processes and verify that they are in place, and that the pharmacy meets the accreditation standards. Once a thorough assessment has been completed, NABP will conduct an on-site visit to evaluate compliance with the pharmacy's policies and procedures, as well as general compliance with relevant pharmacy law.

NABP is anticipated to begin accepting applications to the specialty pharmacy accreditation program early fourth quarter 2017. The Association will provide updates about the program on its website and in future issues of *Innovations*. ■

2016-2017 ACE Members Convened in March 2017

In March 2017, members of the 2016-2017 Advisory Committee on Examinations (ACE) convened in Rosemont, IL, to oversee development and administration of the Association's examination and certification programs. Pictured are (front row, left to right) Gary W. Dewhirst, RPh, DPh, NABP Executive Committee liaison; Anita Young, EdD, RPh, Northeastern University Bouvé College of Health Sciences; David C. Young, PharmD, RPh, Salt Lake City, UT; (back row, left to right) Holly L. Mason, PhD, Purdue University College of Pharmacy (ex officio member); Theresa M. Talbott, RPh, member, Pennsylvania State Board of Pharmacy; Michael A. Burleson, RPh, former executive director, Kentucky Board of Pharmacy; Debra Glass, BPharm, RPh, member, Florida Board of Pharmacy; and Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences (ex officio member). Amy Mattila, PharmD, RPh, Wal-Mart (ex officio member) is not pictured. During the meeting, Mason and Decerbo also were presented certificates of recognition for their dedication and contributions as ACE members.

Alexandra Blasi

continued from page 3

fifth inspector and a full-time, dedicated program manager for the PDMP. The Board also participated in a multistep strategic planning process to better focus and direct the agency. We are currently pursuing legislation to update the Kansas Pharmacy Practice Act, with necessary changes related to the federal Drug Supply Chain Security Act, increased authority to regulate compounding and automation, and certification requirements for pharmacy technicians. We're also working to expand the Board's authority to schedule controlled substances on an emergency basis, after several Kansans were victims of the drug U-47700. As federal grant dollars for ongoing PDMPs subside, Kansas is seeking a long-term funding solution for software, staff, and maintenance costs associated with program continuation and is attempting to rebrand and increase use of our PDMP.

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

I think it's a daily challenge, but remaining focused on the Board's core mission and strategic objectives is essential to moving forward. Distractions and deterrents continuously attempt to steal resources and attention from actual progress. Staff strives to take on tasks we're capable of achieving that coincide with the Board's direction and not overloading the priority list. In fact, we keep running notes and "wish lists" of things we hope to change or achieve down the road and then gradually work to fit them into our strategic plan. There are always items you can't plan for and have to incorporate, but sometimes you just have to be willing to say "no" or "not right now."

Next PARE Testing Window Is June 5-16, 2017

More information about the Pharmacist Assessment for Remediation Evaluation® (PARE®), including registration details and future testing windows, is available in the Programs section of the NABP website at *www.nabp.pharmacy*.

NABP Partners With Website Template Provider to Help .Pharmacy Registrants Promote Public Health

.pharmacy

To support the initiatives of the .Pharmacy Verified Websites Program by further increasing the number of easy-to-identify, safe pharmacy websites for consumers who are buying medicine online, NABP is partnering with RefillRx Connect, a company that provides pharmacies with website solutions. RefillRx Connect offers its customers templated sites that adhere to the .Pharmacy Program's core safety standards.

Online pharmacies that use the template and successfully complete the NABP application process will be granted approval to use the .pharmacy domain for their website. A .pharmacy domain is part of a website's address like ".com" or ".biz": (*www.safe.pharmacy*). It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before being able to register the domain.

As part of its service, RefillRx Connect submits its customers' websites to multiple search engines, including Google, Yahoo!, MSN, and Bing, thereby helping to ensure they appear to consumers in search results. As more verified .pharmacy websites appear in search results, it increases the likelihood that consumers will find legitimate online pharmacies from which to purchase instead of rogue internet drug outlets.

In addition, NABP continues to educate consumers on the risks of purchasing medications from unknown and unapproved sources online and how they can stay safe by using websites with the .pharmacy domain. The Association's newest television public service announcement (PSA) campaign will be released in May 2017.

RefillRx Connect customers can find out more information about special .pharmacy application pricing by emailing info@safe.pharmacy. The new television PSAs will be available at *www.safe.pharmacy*.

"As more verified .pharmacy websites appear in search results, it increases the likelihood that consumers will find legitimate online pharmacies from which to purchase instead of rogue internet drug outlets."

Newly Accredited DMEPOS Facilities

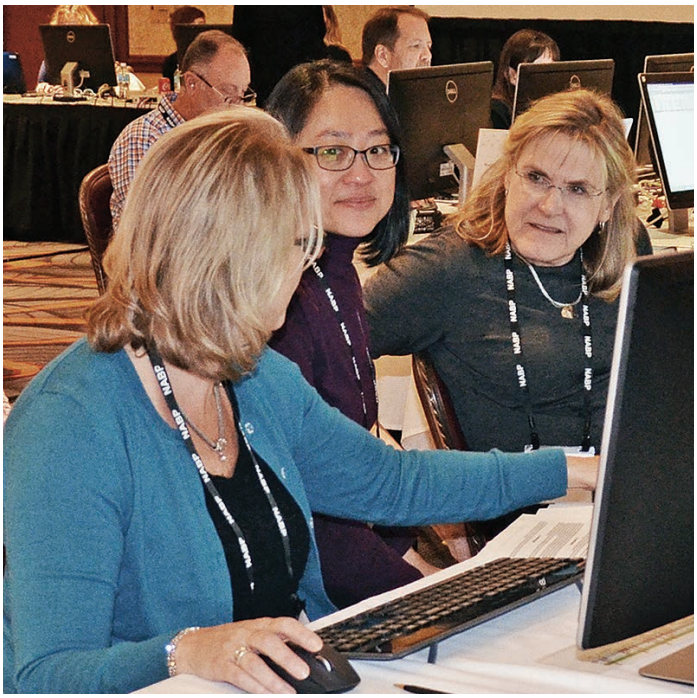
The following facilities were accredited through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) program:

B&T Marlboro Pharmacy
Brooklyn, NY

Sun Pharmacy
San Jose, CA

A full listing of nearly 350 accredited DMEPOS companies representing almost 26,000 facilities is available on the NABP website at *www.nabp.pharmacy.*

Volunteers Convene to Write and Review Exam Items



(Pictured above) In March 2017, 42 item writers gathered in Northbrook, IL, to review items for the Multistate Pharmacy Jurisprudence Examination® (MPJE®) during an item-development workshop. Pictured from left to right are Michele L. Mattila, RPh, pharmacy surveyor, Minnesota Board of Pharmacy; Grace Cheung, RPh, Kenmore, WA; and Candice Fleming, RPh, pharmacy surveyor and associate director of compliance, Minnesota Board of Pharmacy.

(Pictured below) In February 2017, volunteer item writers met in Northbrook, IL, to evaluate and develop new test questions for the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and Pharmacy Curriculum Outcomes Assessment® (PCOA®). Clockwise from left are Kyle Parker, MBA, RPh, Ohio Northern University; Kem P. Krueger, PharmD, PhD, University of Wyoming College of Health Sciences School of Pharmacy; Cortney Mospan, PharmD, Wingate University School of Pharmacy; and Sarah Raake, PharmD, BCACP, LDE, Sullivan University College of Pharmacy.

AWAR$_x$E Content Moved to the NABP Website

The AWAR$_x$E® Prescription Drug Safety Program has moved to the Initiatives section of the NABP website at *www.nabp.pharmacy*. There, you can find valuable offerings like the drug disposal locator tool, tips to prevent medication misuse and abuse, and resources for pharmacists. Flyers are also available to download and print.

NABP will continue to operate the *www.AWARErx.pharmacy* web address. Since the AWAR$_x$E website content moved to the NABP website, the web address will redirect to the new pages to ensure that any organization that links to the address as a resource will not have a broken link on its website.

Now that the AWAR$_x$E program information is on NABP's main website, consumers and pharmacists will be able to more easily access information about NABP's other consumer protection initiatives. In the Initiatives section of *www.nabp.pharmacy*, consumers and pharmacists will also be able to learn about the .Pharmacy Verified Websites Program, to find safe online pharmacy sites, and NABP PMP InterConnect.®

2017-2018 FPGEE/PCOA Review Committee Members

NABP is pleased to announce 23 returning members and two new members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®)/Pharmacy Curriculum Outcomes Assessment® (PCOA®) Review Committee for 2017-2018. This group of dedicated volunteers contributes its time and expertise to review and verify the examination questions and forms and assists with the development of new test questions for the FPGEE and PCOA programs. The FPGEE/PCOA Review Committee ensures the integrity and validity of the examination programs and acts under the policy and planning guidance of the NABP Advisory Committee on Examinations and the NABP Executive Committee. The FPGEE/PCOA Review Committee is composed of pharmacists and academicians who are representative of the diversity of pharmacy education and are specialists in the areas of clinical sciences, pharmaceutical sciences, and basic biomedical sciences, as well as social, behavioral, and administrative pharmacy sciences. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency statements. The FPGEE/PCOA Review Committee members are appointed to a three-year term.

Members

Sally A. Arif, PharmD, RPh, BCPS • Midwestern University Chicago College of Pharmacy

Melissa Badowski, PharmD, RPh, BCPS • University of Illinois at Chicago College of Pharmacy

Kimberly Burns, JD, RPh • Lake Erie College of Osteopathic Medicine School of Pharmacy

Jean Carter, PharmD, PhD, RPh • University of Montana Skaggs School of Pharmacy

Carolyn Friel, PhD, RPh • Massachusetts College of Pharmacy and Health Sciences

Brian Hemstreet, PharmD, RPh, FCCP, BCPS • Regis University School of Pharmacy

Brian M. Hodges, PharmD, RPh, BCPS, BCNSP • West Virginia University School of Pharmacy

Sheldon G. Holstad, PharmD • American College of Clinical Pharmacy

Lynn Kassel, PharmD, RPh • Drake University College of Pharmacy & Health Sciences

William Kolling, PhD, RPh • Southern Illinois University Edwardsville School of Pharmacy

Karen Kopacek, RPh • University of Wisconsin School of Pharmacy

Kem P. Krueger, PharmD, PhD • University of Wyoming College of Health Sciences

Matthias Lu, PhD • Professor Emeritus, University of Illinois at Chicago College of Pharmacy

Holly L. Mason, PhD • Purdue University College of Pharmacy

Jennifer Mathews, PhD • St John Fisher College Wegmans School of Pharmacy

David "Dave" McCaffrey, PhD, RPh • St John Fisher College Wegmans School of Pharmacy

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Philip Proteau, PhD • Oregon State University College of Pharmacy

Ana Quiñones-Boex, PhD • Midwestern University Chicago College of Pharmacy

Ralph Raasch, PharmD, RPh, FCCP, BCPS • Professor Emeritus, University of North Carolina at Chapel Hill Eshelman School of Pharmacy

Kevin Rynn, PharmD, RPh, FCCP, DABAT • University of Illinois at Chicago College of Pharmacy

Kelly M. Shields, PharmD, RPh • Ohio Northern University Raabe College of Pharmacy

Bruce Waldrop, PhD • Samford University McWhorter School of Pharmacy

Ronald Worthington, PhD • Southern Illinois University Edwardsville School of Pharmacy

Dale Eric Wurster, Jr, PhD • University of Iowa College of Pharmacy ■

Orange color denotes new member

> "This group of dedicated volunteers contributes its time and expertise to review and verify the examination questions and forms and assists with the development of new test questions for the FPGEE and PCOA programs."

NABP to Honor Leaders at the Forefront of Public Health Protection During Annual Meeting Awards Dinner

Leaders in the practice of pharmacy whose support and initiatives have furthered the Association's mission of protecting the public health will be honored during the NABP 113th Annual Meeting Awards Dinner on Tuesday, May 23, 2017. The 2017 awards will include the NABP Lester E. Hosto Distinguished Service Award, the Honorary President Award, the Fred T. Mahaffey Award, the Henry Cade Memorial Award, and the John F. Atkinson Service Award.

Lester E. Hosto Distinguished Service Award

The Lester E. Hosto Distinguished Service Award, which was named in honor of the late 1990-1991 NABP President Lester E. Hosto, is the highest honor bestowed by NABP. **John A. Foust, PharmD, DPh**, is receiving the 2017 award posthumously for his strong commitment to protecting the public health and his involvement with NABP. Foust was serving the second year of a three-year member term, representing District 6, on the Executive Committee before resigning in the summer of 2016 due to health reasons. He passed away on February 16, 2017.

Foust demonstrated ongoing dedication to NABP by serving as the chair of the NABP Task Force on Prescription Drug Abuse in 2014, and under his leadership in 2012, the Oklahoma State Board of Pharmacy received NABP's Fred T. Mahaffey Award for contributions to the protection of the public health and welfare.

Prior to becoming executive director of the Oklahoma Board in 2008, Foust practiced pharmacy for over 30 years and was the director of pharmacy at multiple hospitals and medical facilities. Foust received the Bowl of Hygeia Award for the state of Oklahoma in 2012 and was also selected as "Pharmacist of the Year" by the Oklahoma Society of Health-System Pharmacists in 2014.

Foust earned his doctor of pharmacy degree from the University of Oklahoma and his bachelor of science degrees in chemistry and pharmacy from Southwestern Oklahoma State University. Accepting the award on his behalf is his daughter, Caroline Foust-Wright.

Honorary President

Michael A. Moné, BSPharm, JD, FAPhA, has been named 2017 Honorary President for his commitment to protecting the public health and his involvement with NABP. Moreover, Moné is a member of the State of Ohio Board of Pharmacy and is currently vice president associate general counsel – regulatory for Cardinal Health. Moné was the executive director of the Kentucky Board of Pharmacy from 1996 to 2004 and was a member of the NABP Executive Committee from 2002 to 2005. In addition to serving on the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee since 1998, Moné has served as chair of both the Committee on Constitution and Bylaws and the Committee on Law Enforcement/Legislation and was also a member of other multiple NABP committees and task forces.

In addition, Moné is currently serving his sixth year of a second six-year term on the Accreditation Council for Pharmacy Education Board of Directors. His other affiliations include the American Society for Pharmacy Law, the American

"Leaders in the practice of pharmacy whose support and initiatives have furthered the Association's mission of protecting public health will be honored during the NABP 113th Annual Meeting Awards Dinner on Tuesday, May 23, 2017."

Pharmacists Association, and the Florida Pharmacy Association.

Prior to his current position, Moné was the director of regulatory compliance at Medicine Shoppe International, served as assistant attorney general at the Florida Office of the Attorney General, and was a staff attorney with United States Pharmacopeial Convention.

Moné received his bachelor of science degree in pharmacy from the University of Florida College of Pharmacy and his juris doctor degree from the University of Florida College of Law.

Fred T. Mahaffey Award

For their contributions to the regulation of the practice of pharmacy and their efforts to develop standard procedures for licensed Oregon pharmacists to prescribe hormonal contraceptives, the members of the **Oregon State Board of Pharmacy** will receive the 2017 Fred T. Mahaffey Award.

In 2015, House Bill 2879 was signed into law and the Oregon Board led a collaboration of several organizations, such as physician and nursing groups, to develop Oregon Administrative Rule 855-019-0400 through 855-019-0435, guide the creation of a training program, and develop educational materials for pharmacists to safely prescribe contraceptives. To date, over 1,000 Oregon pharmacists are certified to prescribe contraceptives, more than 3,000 prescriptions for contraceptives have been written by pharmacists, and numerous women have been referred to a primary care provider for a more complex contraceptive evaluation.

Accepting the award on the Board's behalf is Penny Reher, RPh, vice president of the Oregon Board.

Henry Cade Memorial Award

Receiving the 2017 Henry Cade Memorial Award is **Luc Besançon, MS, PharmD**, for his dedication to supporting NABP's mission to protect the public health by certifying online pharmacy. Most notably, Besançon serves on NABP's .Pharmacy Executive Board and .Pharmacy Regulator Advisory Committee, where he provides insight on international perspectives for the .Pharmacy Verified Websites Program and promotes the interests of the global public health.

Besançon is chief executive officer of International Pharmaceutical Federation (FIP), the global federation that represents 3 million pharmacists and pharmaceutical scientists worldwide. Prior to that, Besançon was the acting general secretary for professional, scientific, and external affairs of FIP.

Besançon earned his doctor of pharmacy degree from the Université de Bourgogne and his master's degree in public affairs from Université Paris-Sorbonne (Paris IV).

John F. Atkinson Service Award

Katie Busroe, RPh, will be receiving the 2017 John F. Atkinson Service Award for her dedication to protecting the public health through her work in pharmacy inspections and investigations, as well as sterile and nonsterile compounding training. Busroe serves as an NABP surveyor and inspects pharmacies for compliance with United States Pharmacopeia Chapter <795> and <797> standards. Since 2016, Busroe has served on the MPJE Review Committee. She also served as an MPJE item writer for the Kentucky Board of Pharmacy.

Busroe is currently the pharmacy inspections and investigations supervisor for the Kentucky Board of Pharmacy. She has been instrumental in training Kentucky Board staff and licensees on safe sterile and nonsterile compounding practices. Busroe is commended for her role in leading inspectors to adopt more efficient methods to conduct routine inspections and complex investigations. In addition, she contributes her expertise in monitoring prescription drug use to other health professional licensing boards, state police, Drug Enforcement Administration, Food and Drug Administration, and the Attorney General's office. She is active in the Bluegrass Pharmacists Association and speaks to other associations across Kentucky. Busroe received the 2014 NADDI Investigator of the Year award from the National Association of Drug Diversion Investigators.

Busroe received her bachelor of science degree in pharmacy from the University of Kentucky College of Pharmacy. ■

Award Winners to Be Honored at NABP 113th Annual Meeting

Lester E. Hosto Distinguished Service Award
John A. Foust, PharmD, DPh

Honorary President
Michael A. Moné, BSPharm, JD, FAPhA

Fred T. Mahaffey Award
Oregon State Board of Pharmacy

Henry Cade Memorial Award
Luc Besançon, MS, PharmD

John F. Atkinson Service Award
Katie Busroe, RPh

Helpful Tips as You Prepare for the Meeting

- NABP encourages attendees to **bring mobile devices** (ie, tablets, laptops) that can accommodate pdf documents.

- **Wi-Fi** will be available for all attendees in the general business session rooms. Please plan accordingly.

- Professional or **business casual** attire is appropriate for most of the meeting functions, with the exception of the Annual Awards Dinner, which is semiformal.

- Temperatures in meeting rooms may vary, so **dressing in layers** is recommended.

- **Orlando temperatures** in May range from average daytime highs of 88° F to evening lows of 68° F.

A reminder on these important details will be emailed to all attendees prior to the Annual Meeting. ■

NABP 2017-2018 Executive Committee Elections

Information about the nominees for the open officer and member positions is available on the Executive Committee page in the About section of the NABP website at *www.nabp.pharmacy*.

Voting will take place Tuesday, May 23, during the Final Business Session of the 113th Annual Meeting. ■

Still Time to Request a Travel Grant

Are you an active board of pharmacy member or administrative officer who is attending the NABP 113th Annual Meeting?

NABP has travel grant opportunities available for qualified individuals to cover costs for needed expenses. 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. ■

Annual Meeting
Online Registration
Is Available at
www.NABPAnnualMeeting.pharmacy

On-site registration is also available!

EXPLORE, DISCOVER, ACT
Imagineering the Future of Pharmacy Regulation

NABP 113th Annual Meeting
May 20 - 23, 2017
Orlando, FL

Schedule of Events

Saturday, May 20, 2017

10 AM - 5 PM
Registration/Information Desk Open

1:30 - 3:30 PM
Pre-Meeting CPE
Expanded Scopes of Practice — No More Mickey Mousing
ACPE UANs: 0205-0000-17-001-L03-P/T
(0.2 CEUs — 2 contact hours)

4 - 5 PM
From District Meeting to Annual Meeting — Learning About NABP

6 - 9 PM
President's Welcome Reception Honoring NABP President Hal Wand, MBA, RPh
Dinner will be served.
Dress: Business casual

Sunday, May 21, 2017

7:30 AM - 4:45 PM
Registration/Information Desk Open

7:30 - 8:30 AM
NABP AWAR$_x$E Fun Run/Walk

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

8:30 - 11:30 AM
Joint CPE
Educational Poster Session: Imagineering for the Protection of Public Health
ACPE UANs: 0205-0000-17-002-L04-P/T
(0.1 CEU — 1 contact hour)

Noon - 3:15 PM
First Business Session
Presiding: Hal Wand, MBA, RPh, NABP President

- Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
- Presentation of Colors
- National Anthem
- Keynote Address, Howard Fineman, Global Editorial Director, Huffington Post Media Group
- Call to Order
- Greetings From the Host State Florida Board of Pharmacy
- Report of the Executive Committee
  Edward G. McGinley, MBA, RPh, DPh, Chairperson, NABP Executive Committee
- President's Address
  Hal Wand, MBA, RPh, NABP President
- Report of the Treasurer
  Susan Ksiazek, RPh, NABP Treasurer
- Announcement of Candidates for Open Executive Committee and Member Positions
- Open Microphone Session (Time permitting)

3:45 - 4:45 PM
Joint CPE
Specialty Pharmacy — The Future of Pharmacist Care?
ACPE UANs: 0205-0000-17-003-L03-P/T
(0.1 CEU — 1 contact hour)

Monday, May 22, 2017

7:30 AM - 12:30 PM
Registration/Information Desk Open

7:30 - 9 AM
USP Update and Breakfast
Plated breakfast served from 7:30 - 8 AM

9:15 - 10:15 AM
Joint CPE
Telehealth — Another Epcot Experiment?
ACPE UANs: 0205-0000-17-004-L03-P/T
(0.1 CEU — 1 contact hour)

10:30 AM - Noon
Second Business Session
Presiding: Hal Wand, MBA, RPh, NABP President

- Report of the Executive Director/Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
- First Report of the Committee on Resolutions
  Jeanne D. Waggener, RPh, DPh, NABP President-Elect and Chairperson, Committee on Resolutions
  – Presentation of Resolutions
- First Report of the Committee on Constitution and Bylaws
  Laura Forbes, RPh, Member, Committee on Constitution and Bylaws
  – Presentation of Proposed Amendments to the Constitution and Bylaws

continued on page 16

EXPLORE, DISCOVER, ACT
Imagineering the Future of Pharmacy Regulation

NABP 113th Annual Meeting
May 20 - 23, 2017
Orlando, FL

Schedule of Events

continued from page 15

- Candidate Speeches for Open Executive Committee Officer and Member Positions

Noon - 12:30 PM
Informal Member/Candidate Discussion

Free Afternoon: No programming

Tuesday, May 23, 2017

7:30 AM - 4:15 PM
Registration/Information Desk Open

7:30 - 8:30 AM
NABP Breakfast

8:30 - 10 AM
Executive Officer and Board Member CPE
Naloxone and Beyond: Can Expanded Scopes Impact the Opioid Epidemic?
ACPE UANs: 0205-0000-17-005-L03-P/T
(0.15 CEUs — 1.5 contact hours)

8:30 - 10 AM
Compliance Officer CPE
USP <800> Hazardous Drugs: It's a Small, Dangerous World
ACPE UANs: 0205-0000-17-006-L03-P/T
(0.15 CEUs — 1.5 contact hours)

10:30 AM - Noon
Expanding on Forum Discussions — The Magic of Networking on Shared Topics

Noon - 1:30 PM
Lunch Break
(On your own)

1:30 - 4:15 PM
Final Business Session
Presiding: Hal Wand, MBA, RPh, NABP President

- Election of the 2017-2018 Executive Committee Officers and Members
- Remarks of the Incoming President Jeanne D. Waggener, RPh, DPh, NABP President-Elect
- Installation of 2017-2018 Executive Committee Officers and Members
- Final Report of the Committee on Constitution and Bylaws
  Laura Forbes, RPh, Member, Committee on Constitution and Bylaws
  - Discuss and Vote on Amendments to the Constitution and Bylaws
- Final Report of the Committee on Resolutions
  Jeanne D. Waggener, RPh, DPh, 2017-2018 NABP President and Chairperson, Committee on Resolutions
  - Discuss and Vote on Resolutions
- Invitation to the 2018 Annual Meeting in Denver, CO

6 - 6:45 PM
Awards Dinner Reception

7 - 9 PM
Annual Awards Dinner
Dress: Semiformal

Presiding: Jeanne D. Waggener, RPh, DPh, 2017-2018 NABP President

- Presentation to 2017 Honorary President
- Presentation to Hal Wand, MBA, RPh, 2017-2018 Chairperson, NABP Executive Committee
- Presentation of the 2017 Fred T. Mahaffey Award
- Presentation of the 2017 Henry Cade Memorial Award
- Presentation of the 2017 John F. Atkinson Award
- Presentation of the 2017 Lester E. Hosto Distinguished Service Award

Note: The 113th Annual Meeting program is subject to change. The final schedule will be posted just prior to the meeting at *www.NABPAnnualMeeting.pharmacy.*

The 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, descriptions, and speaker information for each CPE session are available on the CPE page at www.NABPAnnualMeeting.pharmacy. *Instructions for claiming CPE credits, including continuing legal education credits, are also provided.*

NABP Chairperson Edward G. McGinley Receives the 2017 Joseph B. Sprowls Lecture Award From Temple University

Edward G. McGinley, MBA, RPh, DPh, NABP chairperson and member of the New Jersey State Board of Pharmacy, is the recipient of the 2017 Joseph B. Sprowls Lecture Award from Temple University. The Pharmacy Alumni Association in conjunction with the School of Pharmacy annually present the Sprowls Lecture Award to an outstanding individual who has achieved recognition within the profession of pharmacy. McGinley presented the 2017 Sprowls Lecture, titled "Batch Preparation to Individualized Formulation— A Pharmacy Career Journey," on April 5, 2017, at Temple University's School of Pharmacy.

Temple also recognized McGinley's leadership with NABP, including his efforts in fighting prescription drug abuse and his support of the Association's efforts to educate consumers about rogue internet drug outlets and the significance of the .pharmacy domain.

McGinley earned his bachelor of science degree in pharmacy from Temple University College of Pharmacy, earned a master of business administration from Temple University Fox School of Business and received an honorary doctor of pharmacy license from the Oklahoma State Board of Pharmacy. More information is available on Temple University's School of Pharmacy website at *https://pharmacy.temple.edu/node/791*.

Edward G. McGinley, MBA, RPh, DPh (pictured left), receives the 2017 Joseph B. Sprowls Lecture Award from Temple University School of Pharmacy. Photo courtesy of Temple University School of Pharmacy.

Around the Association

Board Member Appointments

- **Gayle MacAfee, MS,** has been appointed a public member of the Delaware State Board of Pharmacy. MacAfee's appointment will expire December 20, 2019.
- **Jason Tremblay, RPh,** has been appointed a member of the Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy. Tremblay's appointment will expire November 30, 2019.
- **Linda Varrell** has been appointed a public member of the Maine Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation – Board of Pharmacy. Varrell's appointment will expire November 30, 2017.
- **Dayna Quiñones-Burgos, PharmD,** has been appointed a member of the Puerto Rico Board of Pharmacy. Quiñones-Burgos' appointment will expire November 15, 2020.
- **Norma Rivera, RPh,** has been appointed a member of the Puerto Rico Board of Pharmacy. Rivera's appointment will expire November 19, 2018.
- **Noel Santiago-Torres, RPh,** has been appointed a member of the Puerto Rico Board of Pharmacy. Santiago-Torres' appointment will expire March 8, 2020.
- **Ana Vázquez-Maldonado, BS, PharmD,** has been appointed a member of the Puerto Rico Board of Pharmacy. Vázquez-Maldonado's appointment will expire November 15, 2020.

Board Member Reappointments

- **María Carrasquillo-Dávila, RPh,** has been reappointed a member of the Puerto Rico Board of Pharmacy. Carrasquillo-Dávila's appointment will expire November 19, 2018.
- **María Dueño-Palmer, PharmD,** has been reappointed a member of the Puerto Rico Board of Pharmacy. Dueño-Palmer's appointment will expire July 4, 2020.
- **Suzette Montalvo-Ruiz, PhT, HO,** has been reappointed a member of the Puerto Rico Board of Pharmacy. Montalvo-Ruiz's appointment will expire August 23, 2020.

Maryland Issues Reminder Related to State PDMP Requirements

On April 26, 2016, Maryland Governor Larry Hogan signed into law House Bill 437, which includes the following legal changes related to the prescription drug monitoring program (PDMP):

- Beginning July 1, 2017, prescribers and dispensers licensed to prescribe and/or dispense Controlled Drug Substances (CDS) in Maryland must be registered with the PDMP through the Chesapeake Regional Information System for our Patients (CRISP).
- Beginning July 1, 2018, prescribers must, with some exceptions, query and review their patients' PDMP data prior to initially prescribing an opioid or benzodiazepine and at least every 90 days thereafter as long as the course of treatment continues to include prescribing an opioid or benzodiazepine. Prescribers must also document PDMP data query and review in patients' medical records.

  Pharmacists must query and review patient PDMP data prior to dispensing any CDS if they have a reasonable belief that a patient is seeking the drug for any purpose other than the treatment of an existing medical condition. Information regarding mandatory use is available on the Maryland Department of Health and Mental Hygiene (DHMH) PDMP website.
- Prescribers and pharmacists may delegate health care staff to obtain CRISP user accounts and query PDMP data on their behalf. Delegates may include both licensed practitioners without prescriptive authority and non-licensed clinical staff who are employed by, or under contract with, the same professional practice or facility where the prescriber or pharmacist practices.

For updated information, visit the DHMH PDMP website at *http://bha.dhmh.maryland.gov/PDMP.* For more information about the opioid addiction and overdose epidemic in Maryland and what health care providers can do to help, visit *http://bha.dhmh.maryland.gov/OVERDOSE_PREVENTION.*

Virginia Board Addresses USP Chapter <800> Implementation, Opioid Crisis, and Inspection Reports for Nonresident Pharmacies

Virginia Board Plans for Implementation of USP Chapter <800>

The Virginia Board of Pharmacy is forming a workgroup to develop guidance for its licensees on how to comply with United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings.

Additionally, the Board determined that inspectors should begin inspecting for compliance in 2017 in an effort to assist pharmacists in identifying areas that do not comply with the new standards. No sanctions will be imposed prior to the effective date of the chapter, which is July 1, 2018.

Virginia Board Requires Pharmacists to Earn CE Related to the State's Opioid Crisis

Pursuant to §54.1-3314.1(J) of the Code of Virginia and to address Virginia's opioid abuse crisis, which the state health commissioner recently declared a public health emergency, the Board determined at its December 2016 full Board meeting that all pharmacists must obtain at least one hour of continuing education (CE) in 2017 in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2017 and is not in addition to the required 15 hours. This is a one-time requirement that applies only to pharmacists, not pharmacy technicians.

The requirement is intended to be general to allow each pharmacist the flexibility in choosing an appropriate CE program that focuses on the proper use of opioids, opioid overdose prevention, or naloxone administration. The CE must be obtained between January 1 and December 31, 2017. Additional information was provided in the Virginia Board's February 2017 newsletter, which is available in the Boards of Pharmacy section on NABP's website at *www.nabp.pharmacy.*

Virginia Board Amends Guidance Document Requiring Nonresident Pharmacies to Submit Current Inspection Report

At its December 2016 full Board meeting, the Virginia Board of Pharmacy amended Guidance Document 110-38: Requirement for Non-resident Pharmacies to Submit Current Inspection Report. Pursuant to §54.1-3434.1 of the Code of Virginia, as a prerequisite to obtaining an initial nonresident pharmacy registration or renewing such registration, the nonresident pharmacy must submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with Virginia law, including United States Pharmacopeia and the National Formulary (USP-NF) standards for performing compounding. Because an "opening" inspection of a new pharmacy is generally performed prior to the pharmacy beginning operations, the inspection does not indicate if the pharmacy performs compounding in compliance with USP-NF standards. Thus, the Board voted to amend the guidance document. Amendments to the guidance document are highlighted in the Board's February 2017 Newsletter.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at *www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.*

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at *www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm*.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act"
- "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act"

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a "bulk drug substance" and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at *www.fda.gov/Drugs/DrugSafety/ucm502075.htm,* FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf* and *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.*

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services*. "[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation," indicates the APhA guide. For more information, visit the APhA Immunization Center at *www.pharmacist.com/immunization-center.* ■

Health care providers and patients are encouraged to report adverse events or quality problems to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

INNOVATIONS

National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

UPCOMING EVENTS

NABP 113th Annual Meeting
May 20-23, 2017
Orlando, FL

PARE Administration
June 5-16, 2017

NABP Program Review and Training
June 27-28, 2017
NABP Headquarters

PMP InterConnect Steering Committee Meeting
July 19-20, 2017
NABP Headquarters

2017 Tri-Regulator Symposium
July 25-26, 2017
Chicago, IL

NABP/AACP District 5 Meeting
August 3-5, 2017
West Des Moines, IA

NABP/AACP District 3 Meeting
August 6-9, 2017
Louisville, KY