newsletter

National Association of Boards of Pharmacy®

AWARxE GET INFORMED.™

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aid to government
the profession
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1904 to 2016

Upcoming Events

January 20-21, 2016
Committee on Law Enforcement/Legislation Meeting
Rosemont, IL

February 9-20, 2016
PARE Administration

April 1, 2016
FPGEE Administration

April 6, 2016
Committee on Constitution and Bylaws Meeting

May 14-17, 2016
NABP 112th Annual Meeting
San Diego, CA

June 28-29, 2016
NABP Program Review and Training
NABP Headquarters

Executive Officers Reconnect to Collaborate, Create Solutions at NABP Interactive Forum

Thirty-one board of pharmacy executive officers gathered on October 13-14, 2015, in Northbrook, IL, for the NABP Interactive Executive Officer Forum, the annual networking event that offers an opportunity to collaborate and discuss common challenges faced by the state boards. The forum, themed "Reconnect, Recharge, Revitalize – Strengthening Board of Pharmacy Collaboration," reinforced the partnership between the boards of pharmacy and NABP and the shared mission to protect the public health.

The format of the meeting was divided into two days of sessions with topics chosen for their high relevance to board of pharmacy executive officers. In addition, to ensure that the forum focused on issues of special interest, a survey was sent to invitees prior to the meeting asking them what current topics they would like to discuss. These topics were incorporated into the shared discussion portions of the meeting. Throughout the forum, attendees posed challenging questions and offered a variety of relevant experiences, perspectives, and information. Panelists on each topic included board of pharmacy executive officers and NABP staff. Each panelist provided a brief overview of the topic and then time was provided for discussion among all attendees.

Also taking place the first day of the forum was the New Executive Officer Orientation Program, which was held the morning of October 13 before the events of the forum began. A record number of nine new executive officers attended this orientation program, which allows attendees to get acquainted with NABP membership and governance.

Forum Overview

Day one of the Interactive Forum kicked off with NABP Chairperson Joseph L. Adams, RPh, welcoming all executive officers to the event. Adams emphasized the importance that interaction and discussion have in the success of the meeting. He encouraged all board of pharmacy executive officers to discuss issues freely and honestly with their colleagues to help better understand and create solutions to

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In This Issue . . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 66 member boards of pharmacy to the profession and the public.

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Interactive Forum

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the challenges faced by the boards.

The first collaboration topic of the forum, "DQSA Revamped," discussed both Title I and Title II of the Drug Quality and Security Act (DQSA) of 2013. During this session, panelists led a discussion on the challenges in regulating sterile compounding under DQSA. In addition, a discussion was led on how limited federal preemption currently affects state laws and regulations and how they may be affected by future federal regulation.

The second collaboration topic, "Pharmacist Care Reviewed," covered a variety of topics including pharmacist prescriptive authority, regulation of pharmacist care services, and team-based care. During this session, three executive officers served as panelists. Topics were compiled from the findings of two recent task force meetings – the Task Force on Pharmacist Prescriptive Authority and the Task Force on the Regulation of Pharmacist Care Services. In addition, one of the panelists had attended the Tri-Regulator Symposium in Arlington, VA, on October 6-7, 2015, and discussed the outcomes from that meeting as they related to team-based care.

The first day of the forum ended with a group dinner, which provided an opportunity for additional networking. NABP President Edward G. McGinley, MBA, RPh, greeted and thanked attendees for their participation in the day's discussions. Prior to dinner being served, the discussion topics session was held. Each table was given a topic that had been suggested through the pre-meeting survey. Topics addressed included opioid misuse and abuse, opioid disposal, naloxone distribution, pharmacy benefit manager oversight, the Verified Pharmacy Program® process, licensing of hospital systems versus facilities, United States Pharmacopeia Chapter <800>, biosimilars, over-the-counter insulin, medical marijuana, and formatting, storage, and maintenance of electronic licensure records.

Day two of the meeting began with a recap from the shared discussion topics that were addressed during the dinner. Representatives who were designated by each group shared findings from the discussion with all attendees.

Following the shared discussion topic recap was the session "Connecting the Dots: Board Duties and State Resources – Help!" During this session, two executive officers discussed best practices when operating with limited resources, as well as NABP programs that can provide assistance. Also, two other executive officers discussed how they are using or plan to use the Multistate Pharmacy Inspection Blueprint in their states.

The final session of the Interactive Forum was "Reconsidering Technological Advances." This session examined how technology is affecting pharmacy practice, both in the US and in other countries. During this session, two executive officers and an NABP staff person served as panelists. An overview on the International Pharmaceutical Federation's October 2015 meeting was provided. In addition, a discussion was led on the boards' experiences with telemedicine and how it relates to telepharmacy. Specifically, they discussed the issues surrounding whether to fill a prescription that resulted from a telemedicine consult. An update on the .Pharmacy Top-Level Domain Program was also provided.

Closing the meeting, NABP President-elect Hal Wand, MBA, RPh, reminded attendees of the number of resources that are available to members, including NABP programs and services and NABP activities. For example, attendees were encouraged to volunteer to be a member of a committee or task force, as well as encouraged to submit nominations for the awards to be presented at the NABP 112th Annual Meeting. Attendees were also informed about the new Qualified Persons Credentialing Program offered by CriticalPoint, LLC.

Future Collaboration

Continuing the theme, "Reconnect, Recharge, Revitalize – Strengthening Board of Pharmacy Col-

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Open Positions Announced for the 2016-2017 NABP Executive Committee; Elections to Take Place During 112th Annual Meeting in San Diego, CA

Officers and members of the 2016-2017 NABP Executive Committee will be elected in May 2016 during the 112th Annual Meeting in San Diego, CA. Open officer positions include president-elect and treasurer. The open member positions are for Districts 1, 2, and 5.

The treasurer serves a one-year term, while the individual selected as president-elect makes a three-year commitment to the Association. Following one year as president-elect, he or she serves one year as the NABP president before assuming the responsibilities of chairperson of the Executive Committee for the final year.

Officer Nominations

Individuals interested in running for an open officer position must submit written notification including a letter of intent, the expiration date for their term on the active member board, and a résumé or curriculum vitae to the NABP executive director/secretary at least 45 days prior (**by March 31, 2016**) to the Annual Meeting's First Business Session.

As of press time, NABP has received the following nominations for the open officer positions.

President-elect (one-year term)
- Jeanne D. Waggener, RPh, Texas

Treasurer (one-year term)
- Susan Ksiazek, RPh, New York

Member Nominations

Each district has the opportunity to nominate up to two candidates at the respective district meetings.

As of press time, the following nominations have been accepted for the Executive Committee member positions from the districts:

District 1 (three-year term)
- Timothy Fensky, RPh, FACA, Massachusetts

District 2 (three-year term)
- Caroline Juran, RPh, Virginia

District 5 (three-year term)
- Gary Dewhirst, RPh, North Dakota
- Stuart Williams, JD, Minnesota

In addition to the nominations made by the districts for the open district member positions, individuals may seek to become a candidate by providing written notice to the NABP executive director/secretary. The written notice must include a letter of intent, the expiration date for their term on the active member board, and a résumé or curriculum vitae, and must be submitted after the relevant district meeting, but received no later than 45 days prior (**by March 31, 2016**) to the Annual Meeting's First Business Session, as stated in Article IV, Section 3(c)(ii) of the NABP Constitution and Bylaws. Only those individuals who have been determined by NABP to meet all qualifications for the open member positions will be placed on the ballot.

Qualifications and Voting Procedures

District member and officer nominees must meet the following criteria:
- The individual must be an affiliated member (administrative officer or board member) of the Association currently serving on a board of pharmacy of an active member state at the time of nomination and election.
- The individual must not, in addition to his or her board of pharmacy activities, currently serve as an officer, official, or board or staff member for any national or state pharmacy organization.
- The individual must not have a conflict of interest with the purpose, mission statement, and operation of NABP.

During the First Business Session of the Annual Meeting on Sunday, May 15, NABP President

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Executive Committee

Joseph L. Adams
Chairperson
One-year term

Edward G. McGinley
President
One-year term

Hal Wand
President-elect
One-year term

Jeanne D. Waggener
Treasurer
One-year term

James T. DeVita
Member, District 1
Serving third year of a second three-year term

Susan Ksiazek
Member, District 2
Serving third year of a three-year term

Jack W. "Jay" Campbell
Member, District 3
Serving second year of a three-year term

Philip P. Burgess
Member, District 4
Serving second year of a three-year term

Gary Dewhirst
Member, District 5
Serving third year of a three-year term

John A. Foust
Member, District 6
Serving first year of a three-year term

Mark D. Johnston
Member, District 7
Serving first year of a second three-year term

Richard B. Mazzoni
Member, District 8
Serving second year of a three-year term

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

Fourth Amendment and Ten Yards to Go

By Dale J. Atkinson, JD

The regulatory community, which includes boards of pharmacy, has enforcement authority intended to allow for the administrative prosecution of persons or entities that offend the relevant practice act or rules/regulations. This authority empowers the board or department to investigate complaints and, where deemed appropriate, administratively prosecute respondents. In order to adequately investigate alleged wrongdoing, the boards are generally provided with subpoena powers. A duly served subpoena requires the recipient to appear before the administrative tribunal to testify as to relevant matters, produce relevant documents, or both. Without grounds to object, failure to comply with a subpoena subjects the recipient to motions to compel compliance and, potentially, to contempt charges.

The United States Drug Enforcement Administration (DEA) is a federal agency akin to a state board of pharmacy that is statutorily created and empowered under applicable federal laws. DEA also has subpoena power, the breadth of which has been under recent challenge. Consider the following two judicial opinions that arrived at opposite conclusions.

In *United States v. Zadeh*, the district court for the Northern District of Texas addressed the issue of the scope of an administrative subpoena issued by DEA. DEA was conducting an investigation of possible violations of the Controlled Substances Act (CSA) by a licensed physician. The physician was a DEA registrant permitted to prescribe CSA-defined controlled substances in Schedules II through V. As part of its investigation, DEA issued an administrative subpoena to the physician seeking production of 35 specific patient files. The physician did not respond to the subpoena and the US sought judicial intervention to compel compliance.

A US magistrate issued findings of fact and conclusions of law, and recommended that the Petition to Enforce the Subpoena be granted. The physician filed his objections to this recommendation and the US District Court reviewed the matter. The court addressed the legal standard, the Fourth Amendment of the US Constitution and patient records, the Texas Medical Practice Act, and federal preemption.

In enforcing a subpoena, the court examines whether such was issued for a lawful purpose, whether the subpoena is relevant in its scope, and whether the requests are reasonable and not unduly burdensome. Finding that the CSA empowers DEA to investigate matters and issue subpoenas in order to do so, the court upheld the lawful purpose argued by the government.

Next, the court reviewed the physician's argument that a subpoena requesting private medical records violates the Fourth Amendment rights against unlawful search and seizure. The court held that administrative subpoenas must meet a relatively low threshold to be enforceable. Based on the authority of DEA granted through the CSA, the court quickly found the subpoena to be authorized and not in violation of the Fourth Amendment.

The physician next argued that complying with the subpoena puts him at risk under Texas law for potential civil liability thus justifying his refusal to comply. The court found that because the subpoena was "authorized" under federal law, the physician's argument of privilege was subject to an exception and thus the subpoena was enforceable.

The court also upheld the scope of the subpoena as within matters relevant to the investigation thereby rejecting the arguments of the physician. Finally, the court rejected the physician's argument that the issuance of the subpoena was an abuse of process. The burden is on the physician to establish that the subpoena was intended to harass or was issued in bad faith. These arguments were easily rejected by the court which upheld the issuance of the subpoena and accepted the recommendations of the magistrate to compel compliance.

In *Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration,* the US District Court for the District of Oregon also addressed the issue of the enforceability of a DEA-issued administrative subpoena. In the Oregon case, the Oregon Prescription Drug Monitoring Program (PDMP), a legislatively created electronic databank maintained by the Oregon Health Authority, sought declaratory relief related to compliance with DEA-issued subpoenas. Approximately 7 million prescription records are uploaded into the PDMP annually and, pursuant to Oregon statutes, are not subject to disclosure except under limited circumstances.

In this case, DEA issued subpoenas to the PDMP for individual records of select patients and all prescription drugs prescribed by two physicians. The PDMP objected to the subpoenas, arguing that disclosure of the requested information would violate Oregon law. Shortly thereafter, the PDMP initiated a declaratory action asking the court to determine whether the Supremacy Clause of the US Constitution and the relevant sections of the CSA preempt Oregon law related to confidentiality. Certain parties were allowed to intervene.

Under a Fourth Amendment challenge, the court noted that such protection does not prohibit all searches and seizures, but rather "guards against searches and seizures of items or places in which a person has a reasonable expectation of privacy." Finding that patients and physicians both have reasonable expectations of privacy regarding prescription records, the court recognized the existence of certain privacy rights. The next issue is whether the law enforcement agencies maintain rights to access such records as part of administrative investigations. Distinguishing previous cases where electric usage records and banking information were subject to disclosure, the court noted the heightened expectations of privacy related to medical records and the diagnosed conditions drawn from prescription data. The court also noted that prescription data are not voluntarily submitted to the PDMP, but are provided under a statutory mandate. Indeed, the physician and patient are not in a position to agree to disclose such data to the databank, but are compelled to produce and the only way to avoid submission is to forgo medical treatment.

Based on the foregoing, the court held that the use of administrative subpoenas to obtain prescription records from the PDMP violates the Fourth Amendment. Based upon its findings that the administrative subpoenas violate the Fourth Amendment and the protections against unreasonable searches and seizures, the court did not address the preemption argument of whether the federal law authorizing administrative subpoenas supersedes the Oregon law prohibiting disclosure.

These two cases represent differing approaches to the scope of administrative subpoenas and the authority of DEA to investigate alleged wrongdoing by prescribers. It appears that where information is housed may affect the reach of an administrative subpoena. A similar question can be asked regarding the scope of administrative subpoenas issued by state boards of pharmacy conducting investigations.

United States v. Zadeh, 2015 US Dist. LEXIS 11538; Oregon Prescription Drug Monitoring Program v. United States Drug Enforcement Administration, 2014, 998 F. Sup. 2d 957.

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

Interactive Forum

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laboration," the second forum held in 2015 was the NABP Interactive Compliance Officer and Legal Counsel Forum, which took place on December 1-2, 2015. This interactive, two-day event provided an opportunity for dialogue, presentations, and networking among board of pharmacy compliance officers and legal counsel. In addition, NABP surveyors were invited to participate. More information about this forum will be provided in future NABP communications. A forum for board of pharmacy members will be held in 2016, as well as another forum for board executive officers.

For more information about the NABP Interactive Forums and future meetings, visit the Meetings section on the NABP website at *www.nabp.net.*

Executive Committee Open Positions

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Edward G. McGinley, MBA, RPh, will announce the open Executive Committee officer and member positions. The president will also announce any additional nominations of those candidates who have submitted the required materials to run for office by the specified deadlines and have been qualified by NABP. The final ballot for the Executive Committee will include those individuals nominated at the district meetings, as well as those candidates announced during the First Business Session.

During the Annual Meeting's Second Business Session, time will be designated for candidate speeches and/or speeches given on the candidates' behalf for open Executive Committee officer and member positions. Individuals giving candidate speeches must be affiliated members of NABP, and a maximum of two speeches may be given for each candidate, including the candidate's own speech. Individuals giving speeches must limit their remarks to two minutes.

Voting will take place during the Final Business Session on Tuesday, May 17. Candidates, whether running opposed or unopposed, must receive a majority of the delegate votes present in order to be elected to office. If more than two candidates are slated for office, the candidate(s) receiving the fewest votes will be eliminated from subsequent ballots. The results of the election will be announced immediately and an installation ceremony will be conducted for the new officers and members of the 2016-2017 Executive Committee. Terms commence immediately following the Annual Meeting.

More information about the procedures for nominating and electing Executive Committee officers and members is available in Article IV, Sections 3(b) and 3(c) of the NABP Constitution and Bylaws.

Updates to the list of nominations will be posted in the Meetings section of the NABP website at *www.nabp.net.*

More information on the 112th Annual Meeting is available on pages 16-21.

Newly Approved e-Advertisers

The following entities were granted approved e-Advertiser status through the NABP e-Advertiser Approval℠ Program:

Kelley-Ross and Assoc, Inc
www.krrph.com

Little Acorn Pharmacy, LLC, dba Little Acorn Pharmacy
www.littleacornpharmacy.com

Low T Centers, Inc, dba Low T Center
www.lowtcenter.com

W-S Associates, Inc, dba Apple Discount Drugs
appledrugs.com

Since 2010, NABP has offered the e-Advertiser Approval Program for Internet advertisers that offer only limited pharmacy services or other prescription drug-related services online. A full listing of NABP-approved e-Advertisers is available on the NABP website at *www.nabp.net.*

.Pharmacy TLD Initiative Reaches United States and International Pharmacy Communities Through Educational Visits

With the .pharmacy Top-Level Domain (TLD) now available to legitimate Internet pharmacies and other pharmacy-related information and service providers around the world, NABP has focused on educating and raising awareness among pharmacy stakeholders about the importance of the .pharmacy TLD. As part of these efforts, NABP attended several meetings – both in the United States and abroad – to present information about the .pharmacy TLD initiative to key stakeholders in the pharmacy community.

Security of US Drugs

NABP took part in the CardinalHealth Risk Mitigation Seminar, a meeting focused on the security of the US drug supply chain, on October 27-28, 2015, in Powell, OH. NABP presented information on drug diversion, primarily at the wholesale level, and how to help maintain the security of the US drug supply chain. In addition, NABP presented on Internet fraud and explained how the .Pharmacy TLD Program helps to keep consumers safe.

Attendees of the meeting included CardinalHealth's security branch and other representatives who oversee the security of distribution and manufacturing warehouses, including those on the medical side (eg, manufacturers of medical devices and hospital supplies) and on the pharmaceutical side (eg, manufacturers of over-the-counter medications, prescription medications, and controlled substances). Representatives who handle the security of nuclear pharmacies, those that make radioactive doses for diagnostic and treatment purposes, were also in attendance.

International Outreach

NABP continues to observe developments in the European Union's (EU) implementation of the "common logo" and to explore potential relationships with regulators in the EU member states. Association staff attended a meeting, hosted by the Alliance for Safe Online Pharmacies (ASOP), in collaboration with the Italian Medicines Agency, in Rome, Italy, on October 15, 2015. The meeting gathered the EU member states to further discuss the common logo – an image that will be posted on all websites selling medicine online in EU member states to show they are appropriately licensed to operate.

NABP staff also presented during a session at the 54th international public meeting of the Internet Corporation for Assigned Names and Numbers (ICANN) on October 18-22, 2015, in Dublin, Ireland. The session, titled "Illicit Internet Pharmacies: A Growing Threat to Online Security and Consumer Safety," covered three key objectives:

1. Acknowledge that voluntary policies and procedures by registrars and registries are playing a critical role in reducing the proliferation of online sellers of fake medicines that put patient safety at risk;
2. Demonstrate the support that organizations are providing to enhance patient safety on the Internet; and
3. Raise awareness of the issue and seek ideas to support further engagement from the registrar and registry community.

NABP staff explained the Association's role in Internet pharmacy and how it addresses and combats illegal online drug sellers through its accreditation programs and the .Pharmacy TLD Program. Other presenters during this session included ASOP, the Center for Safe Internet Pharmacies (CSIP), LegitScript, and the registrar BlackKnight Solutions. About 95 individuals representing registrars and registry operators attended the session.

NABP also attended the 75th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences held September 29-October 3, 2015, in Düsseldorf, Germany. This meeting joined practitioners, researchers, and academics worldwide to help shape modern pharmacy practice. During the meeting,

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VPP Supports Boards With Verified Pharmacy Inspection Data

Important pharmacy data, including licensure, inspection, and disciplinary action information, continues to be made available through the Verified Pharmacy Program® (VPP™) and the secure information sharing network to authorized individuals at the state boards of pharmacy. This verified data is provided to the member boards in an effort to support the boards in making informed licensure decisions for their nonresident pharmacies.

The VPP inspection examines a pharmacy's full operations, including general retail and any compounding activities. The verified data is then provided to the individual states to use in determining compliance. Information and observations obtained in the general inspection module are based on a minimum set of criteria developed through the Multistate Pharmacy Inspection Blueprint.

The nonsterile compounding and sterile compounding inspection components are focused on patient-specific activities and based on compliance with United States Pharmacopeia Chapters <795> and <797>, respectively. Although some pharmacies are also registered with Food and Drug Administration as outsourcing facilities, NABP does not currently examine compliance with current Good Manufacturing Practices (cGMPs).

By keeping a current inspection report on file with NABP, the pharmacy is allowing the state boards of pharmacy to have access to not only verified licensure and disciplinary data, but a complete observation of the pharmacy's operations and activities to further assist the boards when making their licensure decisions.

At press time, at least 376 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies. Of the 376 VPP facilities:

- 162 pharmacies engage in nonsterile compounding;
- 49 pharmacies engage in sterile compounding;
- 118 pharmacies engage in both sterile and nonsterile compounding;
- 44 pharmacies are general retail or mail-order pharmacies with no compounding;
- 2 pharmacies are nuclear pharmacies; and
- 1 pharmacy is an outsourcing facility.

For more information about VPP, contact the NABP Accreditation department at vpp@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.*

.Pharmacy Educational Visits

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NABP staff presented information about the global risk of rogue Internet drug outlets that distribute dangerous drug products and how the .pharmacy TLD is helping to combat this epidemic.

NABP joined stakeholders and regulators from several other countries at a meeting of the Asia-Pacific Economic Cooperation on August 26-27, 2015, in Cebu, Philippines. During the meeting, NABP staff presented on the dangers of illegal online drug sales, the .pharmacy TLD, and the importance of cross-industry partnerships to shut down illegal sellers. Other speakers included regulators from Canada, Peru, Italy, Singapore, Malaysia, Nigeria, and Philippines, representatives of the US Food and Drug Administration and the Office of the US Intellectual Property Enforcement Coordinator, as well as representatives of ASOP, CSIP, the Pharmaceutical Security Institute, and Microsoft.

At the direction of the .Pharmacy Supporter Advisory Committee – which is now divided into two groups, one composed of regulators and one of registrants/supporters – NABP will continue to look for opportunities to raise awareness among pharmacy stakeholders, both in the US and abroad, about the importance of the .pharmacy TLD.

Additional details about the .Pharmacy TLD Program, including a list of approved .pharmacy sites, are available at *www.safe.pharmacy.*

State Boards Report 1,516 Disciplinary Actions in Third Quarter 2015

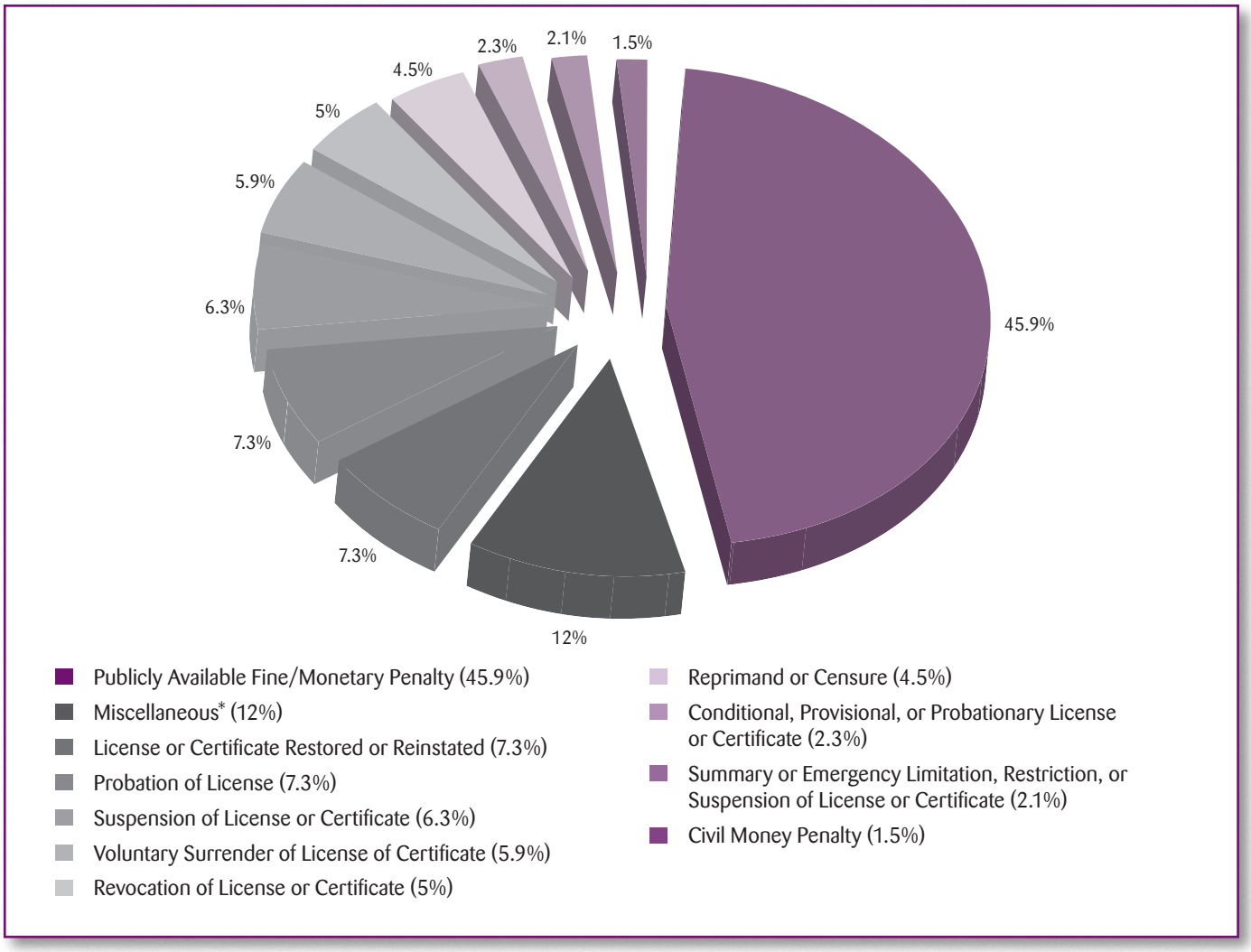
During the third quarter of 2015, the state boards of pharmacy reported a total of 1,516 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacy technicians, pharmacy interns, pharmacies, wholesalers, and other licensees.

Of the 1,516 actions:

- 627 actions (41.8%) were taken on pharmacies;
- 507 actions (33.8%) were taken on pharmacists;
- 326 actions (21.7%) were taken on pharmacy technicians;
- 21 actions (1.4%) were taken on pharmacy interns;
- 14 actions (0.9%) were taken on wholesalers;
- 5 actions (0.3%) were taken on other licensees; and
- 1 action (0.07%) was taken on mail-order pharmacies.

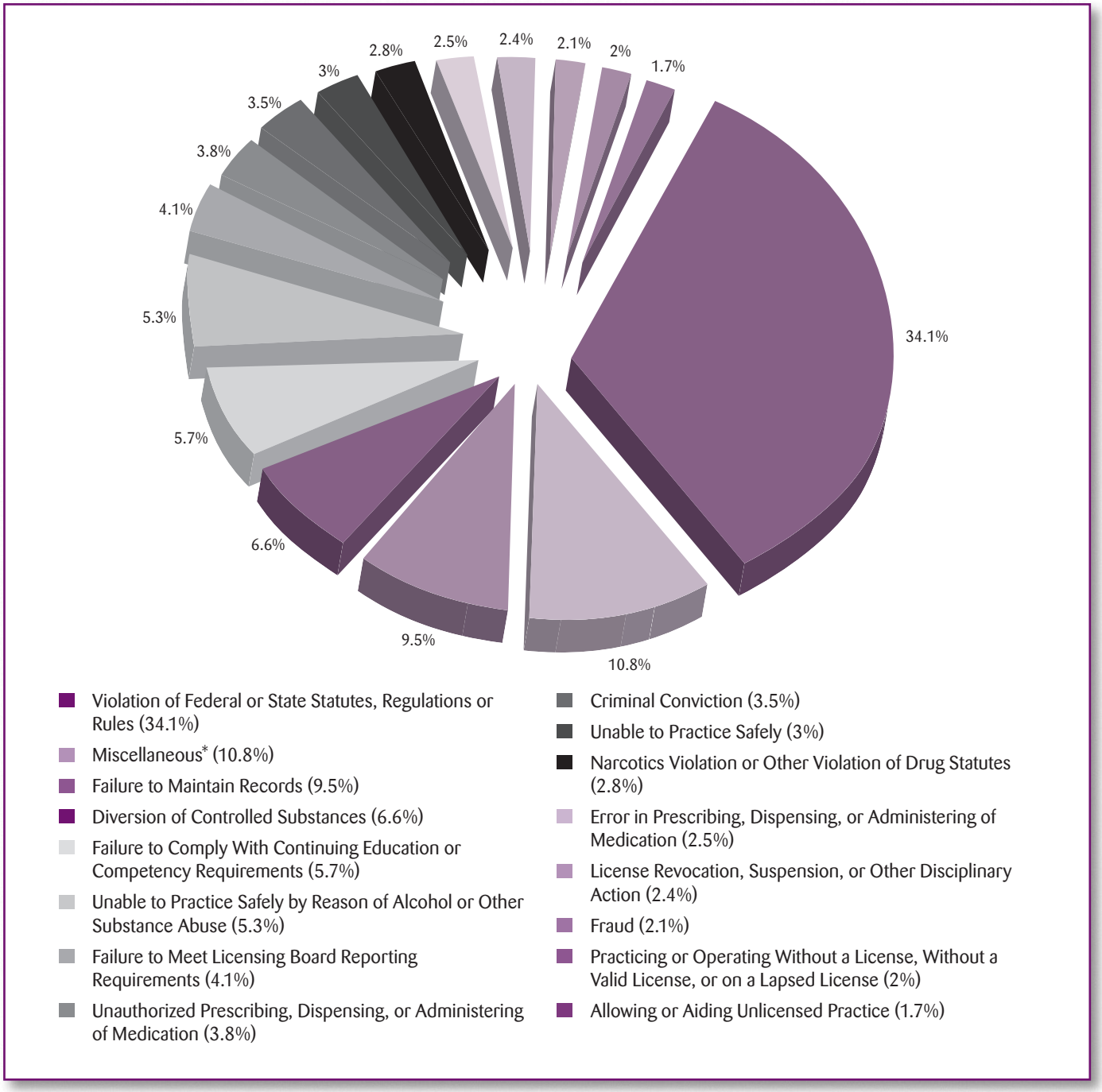
For a full breakdown of the actions taken and the bases for actions taken during third quarter 2015, see Figure A below and Figure B on page 10. Additional information about the NABP Clearinghouse is available under Member Services in the Programs section of the NABP website at *www.nabp.net.*

Figure A: Disciplinary Actions Reported During Third Quarter 2015



*The miscellaneous category includes cease and desist; denial of initial license; denial of license renewal; directed in-service training; directed plan of correction; extension of previous licensure action; interim action – agreement to refrain from practice during investigation; limitation or restriction on license; modification of previous licensure action; other licensure action – not classified; publicly available negative action or finding; reduction of previous licensure action; summary or emergency action; and voluntary limitation or restriction on license.

Figure B: Bases for Disciplinary Actions Reported During Third Quarter 2015



*The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; conduct evidencing moral unfitness; deferred adjudication; drug screening violation; expired drugs in inventory; failure to comply with patient consultation requirements; failure to cooperate with board investigation; failure to disclose; failure to maintain equipment/missing or inadequate equipment; failure to take corrective action; immediate threat to health or safety; improper or abusive billing practices; improper or inadequate supervision or delegation; inadequate security for controlled substances; incompetence; lack of appropriately qualified professionals; misappropriation of patient property or other property; misbranding drug labels/lack of required labeling on drugs; negligence; nolo contendere plea; operating beyond scope of license; other disciplinary action – not classified; other unprofessional conduct; practicing beyond the scope of practice; sexual misconduct; substandard or inadequate care; unable to practice safely by reason of physical illness or impairment; and violation of or failure to comply with licensing board order.

States Continue Working Toward Connection to PMP InterConnect; New Software Enhancements Under Way for Participants

Several state prescription monitoring programs (PMPs) continue to work toward a connection to the NABP PMP InterConnect® program with five additional states having signed a memorandum of understanding (MOU) to participate and four states/jurisdictions reviewing an MOU. These states plan to join the following 30 state PMPs that are already connected to PMP InterConnect: Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin.

Software Upgrade

As a benefit to the 30 connected state PMPs participating in PMP InterConnect, NABP, in conjunction with its technology provider Appriss, Inc, is continuing to roll out the newly upgraded software version to further streamline access to prescription drug data. The new software version – application programming interface (API) Version 4 – further supports the data exchanges between PMP InterConnect participants with its new, expanded role-based permission categories and response codes. The majority of state PMPs have already transitioned to the new software. Other states are working with their vendors to make the full transition.

Additional details on the software enhancements were provided in the November-December 2015 *NABP Newsletter.*

Meetings Unite State PMPs

NABP and the state PMPs remained committed to addressing and combating prescription drug abuse by participating in several meetings over the past few months. In October 2015, NABP and several state PMPs attended the 2015 National Association of State Controlled Substance Authorities (NASCSA) Conference in Scottsdale, AZ. NASCSA's 31st annual conference gathered a number of organizations, state and federal government agencies, state PMPs, and other key stakeholders to address prescription drug abuse and misuse and other substance issues. During the meeting, NABP was invited to attend a roundtable meeting, hosted by the Pew Charitable Trusts, to discuss PMP data quality.

In addition to the NASCSA conference, the NABP Steering Committee convened by teleconference in November 2015. Composed of representatives of PMPs that participate in the PMP InterConnect program, the Steering Committee serves as the governing body of the program. During its teleconference, the committee discussed potential educational efforts and other issues related to the administration and function of the program. The Steering Committee's next in-person meeting is scheduled for July 20-21, 2016.

More information about PMP InterConnect, including the most up-to-date information on state participation, is available in the Programs section of the NABP website at *www.nabp.net.*

Newly Accredited VAWD Facilities

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

American Pharmaceutical Ingredients, LLC
Waterford, MI

CareFusion 2200, Inc
Tucker, GA

Kenco Group, Inc, dba Kenco Bracco
Southaven, MS

McKession Medical-Surgical, Inc
Sacramento, CA

Neovia Logistics Distribution, LLC
Ontario, CA

TOLMAR Pharmaceuticals, Inc
Fort Collins, CO

TOLMAR Pharmaceuticals, Inc
Windsor, CO

UPS Supply Chain Solutions, Inc
Logan Township, NJ

A full listing of more than 550 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*

Upcoming 2016 PARE Testing Windows Announced; Opportunity for Secure, Remote Proctoring Available in February

The 2016 testing windows for the Pharmacist Assessment for Remediation Evaluation® (PARE®) will be as follows:

- February 9-20, 2016
- June 7-18, 2016
- September 13-24, 2016
- November 29-December 10, 2016

The next available PARE testing window is scheduled during the two-week time period of February 9-20, 2016.

Member boards of pharmacy are encouraged to take advantage of this web-based assessment that was created to assist the boards as part of their decision-making process when considering cases of remediation or brief departures from practice. Beginning with the February testing window, boards of pharmacy will have the option to administer the examination remotely. NABP has contracted with a remote proctoring service that will facilitate a secure, proctored remote test session for the PARE. To pre-register an individual for any of the above-mentioned PARE testing windows, boards of pharmacy may use the NABP Clearinghouse via NABP e-Profile Connect, or they may contact the NABP Competency Assessment department via email at NABP_Comp_Assess@nabp.net.

More information about PARE may be found in the Programs section of the NABP website at *www.nabp.net.*

2015-2016 Advisory Committee on Examinations Meets at NABP Headquarters

In August 2015, members of the 2015-2016 Advisory Committee on Examinations convened at NABP Headquarters to oversee the development and administration of all of the Association's examination and certification programs. Pictured from left to right: Amy Mattila, PharmD, RPh, Wal-Mart (ex officio member); Holly L. Mason, PhD, Purdue University College of Pharmacy (ex officio member); Anita Young, EdD, RPh, Northeastern University Bouvé College of Health Sciences; Michael A. Burleson, RPh, Kentucky; Neal F. Walker, RPh, Fairview Range; Debra Glass, BPharm, Florida Board of Pharmacy; and Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences (ex officio member). Members not pictured: Carl W. Aron, RPh, Louisiana Board of Pharmacy and David C. Young, PharmD, RPh, Utah Board of Pharmacy.

FPGEE Undergoes Evaluation and Expert Review to Ensure Passing Standard Represents Acceptable Mastery of US PharmD Curricula

The Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) is a means of assessing a level of mastery of the content covered in United States doctor of pharmacy curricula for foreign pharmacy graduates. The FPGEE is offered twice each year, and passing is a requirement for the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification process. Periodically, the FPGEE competency statements that comprise the blueprint of the examination are reviewed and revised by a panel of experts and then validated by a survey to ensure that the content remains consistent with entry-level PharmD programs in the US. Beginning with the April 1, 2016 administration, updated FPGEE competency statements will go into effect.

Revisions to the FPGEE competency statements were made as a result of responses received from a 2015 College of Pharmacy Curricula Survey, which was developed using input from NABP examination review committee members and US pharmacy program academics.

As part of this process, an FPGEE standard setting study was conducted to evaluate the current FPGEE passing standard. Outcomes from the two-day study, held at NABP Headquarters in Mount Prospect, IL, on October 23-24, 2015, will help to ensure that the passing standard represents the expectations for an acceptable level of mastery in coursework taught in US pharmacy programs. Educators representing 24 US pharmacy programs and the eight NABP districts participated in the meeting. The standard setting raters, or panel, consisted of 27 academicians from PharmD programs across the US. Of those 27 raters, 18 are also licensed pharmacists. The outcome of the standard setting produced a recommendation that takes into consideration all of the expert participants' contributions to the process.

Standard Setting Process

Upon convening for a two-day study at NABP Headquarters, the panelists received training consisting of an overview of the FPGEE and discussion of test development and standard setting. Practice examples and opportunities for discussion were also part of the training process.

Throughout the meeting, panelists actively participated in discussions framed by the test blueprint or competency statements, which describe the level of knowledge expected for the entry-level PharmD programs in the US.

The panel members then provided ratings on the standard setting form items. The ratings were estimates of the percentage of examinees with an acceptable (but minimal) level of mastery in the PharmD didactic curriculum who, in their opinion, would answer the item correctly. After the panel members finished rating each test question, ratings were collected and analyzed. The outcome of the ratings was applied to historical score data to estimate the impact on pass rates for the FPGEE.

On the second day of the study, following a discussion of first ratings and outcomes, the participants were instructed to rate each item on the standard setting form for a second time. These second ratings were subsequently analyzed and the data was presented back to the group. Predictions of the impact to the pass rate based upon the average ratings were provided to the group. The panel members engaged in further discussion to address their impressions of the outcomes prior to making its recommendation.

The committee's recommendation were reviewed by the FPGEE/Pharmacy Curriculum Outcomes Assessment® Review Committee, the NABP Advisory Committee on Examinations, and the NABP Executive Committee. Prior to implementing the recommended passing standard, NABP will provide notice to the boards of pharmacy. NABP plans to implement the approved recommendation in 2016.

More information about the FPGEE is available in the Programs section of the NABP website at *www.nabp.net.*

Item Writers Develop FPGEE and PCOA Test Questions
In October 2015, volunteer item writers convened for a Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and Pharmacy Curriculum Outcomes Assessment® (PCOA®) item development workshop at NABP Headquarters. Pictured: Dee Fanning, PharmD, Philadelphia College of Osteopathic Medicine School of Pharmacy (left) and Jean Carter, PharmD, PhD, RPh, University of Montana Skaggs School of Pharmacy (right) discuss examination questions.

Panelists Share Experiences, Lead Discussions on Current Board of Pharmacy Challenges During 2015 Interactive Executive Officer Forum

Board of pharmacy executive officers convened for the NABP Interactive Executive Officer Forum themed "Reconnect, Recharge, Revitalize – Strengthening Board of Pharmacy Collaboration," on October 13-14, 2015, in Northbrook, IL. The two-day interactive forum provided an opportunity for attendees to share and collaborate with peers on timely and relevant topics facing the boards of pharmacy. Discussions were led by expert panels composed of board executive officers and NABP staff. More information is available in the cover story of this *Newsletter*.

Panelists Lead Discussion on the Challenges of Regulating as it Relates to the DQSA

Panelists began the forum with a discussion on both Title I and Title II of the Drug Quality and Security Act (DQSA) of 2013 during the session "DQSA Revamped." The discussion included a focus on the challenges in regulating for sterile compounding under DQSA and how limited federal preemption currently affects state laws and regulations and the impact of potential future federal regulation. Pictured from left to right: Gregg Goneconto, supply chain security consultant, NABP; Caroline Juran, RPh, executive director, Virginia Board of Pharmacy; Gregg Jones, RPh, CPh, compliance senior manager, NABP; and session moderator Mark D. Johnston, RPh, member, NABP Executive Committee.

Boards Explore Strategies for Working With Limited Resources and How NABP Programs Can Help

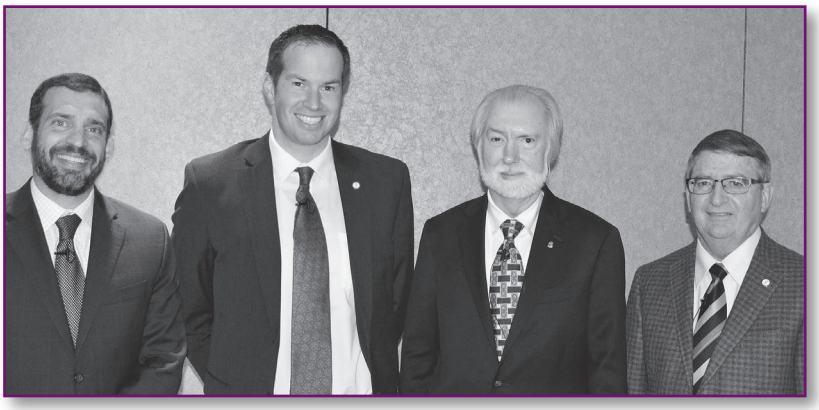
Day two of the forum began with a recap from the shared discussion topics that were addressed during the group dinner on Tuesday, October 13. Following this portion was the session "Connecting the Dots: Board Duties and State Resources – Help!" During this session, panelists discussed best practices when operating with limited resources and how NABP programs can provide assistance. Panelists also shared how their boards are using or plan to use the Multistate Pharmacy Inspection Blueprint. Pictured from left to right: John A. Foust, PharmD, DPh, member, NABP Executive Committee; Larry L. Pinson, PharmD, RPh, executive secretary, Nevada State Board of Pharmacy; Gay Dodson, RPh, executive director/secretary, Texas State Board of Pharmacy; session moderator (shared discussion topics) Edward G. McGinley, MBA, RPh, NABP President; David Sencabaugh, RPh, executive director, Massachusetts Board of Registration in Pharmacy; and session moderator Jack W. "Jay" Campbell IV, JD, RPh, member, NABP Executive Committee.

Experts Discuss Pharmacist Prescriptive Authority, Regulation of Pharmacist Care Services, and Team-Based Care

Sharing the outcomes from two recent NABP task force meetings and the 2015 Tri-Regulator Symposium in Arlington, VA, panelists led a discussion on pharmacist prescriptive authority, the regulation of pharmacist care services, and team-based care during the session "Pharmacist Care Reviewed." Pictured from left to right: Steve Hart, RPh, executive director, Kentucky Board of Pharmacy; Virginia Herold, MS, executive officer, California State Board of Pharmacy; Kamlesh Gandhi, PharmD, RPh, executive director, Arizona State Board of Pharmacy; and session moderator James T. DeVita, RPh, member, NABP Executive Committee.

Panelists Examine How Technological Advances Are Affecting Pharmacy Practice

The final session of the forum, "Reconsidering Technological Advances," sought to examine how technology is affecting pharmacy practice. Panelists provided an update on the International Pharmaceutical Federation World Congress practice, the .Pharmacy Top-Level Domain Program, and telemedicine, and how it relates to telepharmacy. Pictured from left to right: Marty Allain, JD, .Pharmacy Senior Manager, NABP; Mark Hardy, PharmD, RPh, executive director, North Dakota State Board of Pharmacy; Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy; and session moderator Gary Dewhirst, RPh, member, NABP Executive Committee.



Nine New Board Executive Officers Attend Orientation

The New Executive Officer Orientation Program was held the morning of October 13, 2015, prior to the day's events of the Interactive Executive Officer Forum. The orientation provided the newly appointed executive officers the opportunity to get acquainted with NABP membership and governance.

Back row pictured from left to right: Michael R. Dupuis, MHA, RPh, executive director, New Hampshire Board of Pharmacy; Steven Schierholt, Esq, executive director, State of Ohio Board of Pharmacy; Alex Adams, MPH, PharmD, RPh, executive director, Idaho State Board of Pharmacy; Andrew Funk, PharmD, RPh, executive director, Iowa Board of Pharmacy; and Steve Hart, RPh, executive director, Kentucky Board of Pharmacy. Front row pictured from left to right: Kari Shanard-Koenders, RPh, executive director and interim prescription drug monitoring program director, South Dakota State Board of Pharmacy; Shauna White, PharmD, RPh, executive director, District of Columbia Board of Pharmacy; Hal Wand, MBA, RPh, NABP president-elect; Kamlesh Gandhi, PharmD, RPh, executive director, Arizona State Board of Pharmacy; and Ted Cotterill, JD, director, Indiana Board of Pharmacy.

'America's Finest City' Welcomes Boards of Pharmacy for NABP 112th Annual Meeting

NABP invites its members and other pharmacy stakeholders to explore "America's Finest City" during the NABP 112th Annual Meeting in San Diego, CA. Famous for its sunny weather and white sand beaches along the Pacific coastline, San Diego is the perfect backdrop for this year's Annual Meeting, "All Hands on Deck – Forging Ahead to a New Regulatory World." After participating in important business sessions and timely continuing education sessions, attendees will have the opportunity to experience the rich history and vast regions San Diego has to offer. The Annual Meeting will be held May 14-17, 2016, at the Hilton San Diego Bayfront Hotel.

San Diego has a long history dating back to approximately 9,000 years ago when the earliest cultural group, now known as the San Dieguito people, lived there. Several other groups later settled in the region, including the La Jollan, Yuman, Shoshonean, and Diegueño cultural groups. In 1542, Juan Rodríguez Cabrillo sailed his ship into the region from Mexico, named the area San Miguel, and declared it a possession of the King of Spain. Sixty years later, Sebastian Vizaíno arrived and renamed the region after the Spanish Catholic saint, San Diego de Alcalá. The first permanent Spanish colonies in the region were established in 1769 in the area now known as Old Town San Diego. The same year, Father Junípero Serra established the first mission of a chain of 21 missions that would become the cornerstone of California's colonization. Therefore, Old Town San Diego is referred to as the "birthplace of California." In 1848, Mexico ceded California to the United States in the Treaty of Guadalupe Hidalgo, which ended the US-Mexican War and set the boundary line between the US and Mexico. In 1850, six months before California was granted statehood, San Diego was officially incorporated as a city.

San Diego continued to grow, and is currently California's second largest city and the eighth largest city in the US. San Diego is known for its military presence, with an US Marine Corps air station, base camp, and recruit depot, as well as three US Naval Bases, which host the largest naval fleet in the world. The San Diego region is growing into a health care and life sciences hub, and is considered a leader in health innovation due in part to the University of California, San Diego and major pharmaceutical and research institutions in the area. The city's world-famous tourist attractions, international culture, and picturesque coastline make San Diego a remarkable place to visit.

Local Sites and Attractions

San Diego is divided into many unique neighborhoods and communities across 4,200 square miles, and San Diego County is composed of 18 incorporated cities and towns. The region offers a variety of attractions, museums, and gardens that range from leisurely beach activities to adventurous mountain hiking. With a vast variety of things to do in the area, Annual Meeting attendees will have the opportunity to take in the sights of their choice during a free afternoon on Monday, May 16. In addition to the sites mentioned here, attendees may contact the hotel concierge for suggestions of attractions to visit and things to do while in San Diego.

Downtown San Diego consists of six districts

that are within walking distance of the hotel. The most famous are Little Italy and the Gaslamp Quarter. The Gaslamp Quarter is home to Horton Plaza, a multilevel outdoor mall, and a variety of shops, art galleries, historic buildings, and museums. The Gaslamp Quarter is famous for its vibrant nightlife with rooftop bars, nightclubs, and fine dining. Little Italy is well known for its award-winning restaurants and its emerging art district. On the harbor side of Little Italy, there is a vibrant boardwalk with historic ships and submarines.

History buffs will enjoy exploring the USS Midway Museum, which honors the legacy of those who have served aboard the USS Midway, as well as all those who serve in uniform. The USS Midway is the most visited floating ship museum in the world, and is also the longest-serving Navy aircraft carrier of the 20th century.

Balboa Park, the nation's largest urban cultural park, is located minutes from downtown San Diego. The park contains 15 major museums, including the San Diego Air & Space Museum, an affiliate of the Smithsonian Institution; the San Diego Natural History Museum; the San Diego Hall of Champions Sports Museum, the nation's largest multi-sport museum; and the Veterans Museum at Balboa Park. Balboa Park's most famous attraction, however, is the San Diego Zoo. The zoo sits on 100 acres and is known for offering a unique experience by exhibiting animals in habitats that mimic natural environments. It hosts more than 3,700 rare and endangered animals, and has a botanical collection with more than 700,000 plants.

Located within walking distance from the Hilton San Diego Bayfront Hotel is the historic Gaslamp Quarter. This downtown San Diego district is famous for its shopping, dining, and active nightlife. Photo courtesy of Joanne DiBona and SanDiego.org.

La Jolla is a coastal village that offers plenty of coastline for swimming, snorkeling, and surfing. One of its cove beaches is home to a colony of harbor seals, which often sun on the shore and play in the waves. La Jolla also offers designer boutiques and upscale art galleries. Also offering plentiful sandy beaches, Coronado is located across the bay from downtown San Diego on the other side of the San Diego-Coronado Bridge. Flecks of the mineral mica are present in the sand, which makes Coronado beaches glitter in the sunlight. Coronado is most famous for the historic Hotel del Coronado, which is rumored to have been the inspiration for the Emerald City in *The Wizard of Oz*.

San Diego's most southern community is South Bay, and it is located adjacent to the Mexican border. With a passport and safety precautions, it is easy to walk across the border to visit Baja California, Mexico. On the US side, attendees may dine at restaurants with authentic Mexican cuisine, and visit South Bay's nature centers that feature a turtle lagoon, and a shark and stingray exhibit, and offer plenty of space for hiking and viewing endangered birds and wildlife species. South Bay also features outlet shopping and golf courses, and it is home to the US Olympic Training Center and a portion of Naval Base San Diego.

Getting Around

The Hilton San Diego Bayfront Hotel is located in downtown San Diego, approximately four miles from the San Diego International Airport. Individuals arriving from the airport may take a shuttle service, available at the Transportation Plazas located across from Terminals 1 and 2, for approximately $9 per person one way. A transportation coordinator will place individuals with the first available shuttle unless a particular shuttle company is specified. A list of shuttle companies is available at *www.san.org/Parking-Transportation/Shuttles*. Taxis can be ar-

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Additional San Diego Links

Balboa Park
www.balboapark.org

Belmont Park
www.belmontpark.com

Coronado Visitor Center
www.coronadovisitorcenter.com

SanDiego.com
www.sandiego.com

San Diego Tourism Authority
www.sandiego.org

San Diego Zoo
www.sandiegozoo.org

SeaWorld San Diego
www.seaworldparks.com/en/seaworld-sandiego

NABP Seeking Poster Session Participants for 112th Annual Meeting; Event to Feature New Contest on .Pharmacy TLD

NABP is currently seeking Poster Session participants for its Annual Educational Poster Session. The Poster Session will be held Sunday, May 15, from 8:30 to 11:30 AM, during the NABP 112th Annual Meeting, at the Hilton San Diego Bayfront Hotel in San Diego, CA.

Posters must reflect the overall theme of patient safety.

New this year, the Poster Session will feature a contest inviting participants to create online content that will encourage patient safety by educating consumers about the .Pharmacy Top-Level Domain (TLD) Program. State board of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to participate, and boards are encouraged to partner with the schools on posters as well. To qualify for the contest, those displaying posters must create or plan a web page, website, or other online content that focuses on educating patients about the dangers of purchasing medications online from unknown sources, and how to look for a safe, trusted pharmacy-related website via the .Pharmacy TLD Program. The Poster Session presenter(s) that best demonstrates the .pharmacy patient safety initiative will win the contest and be awarded a $100 American Express gift card.

For all Poster Session participants, one contact hour (0.1 CEU) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit may be earned for their attendance and participation. Presenters are not automatically qualified for CPE. To earn CPE, both presenters and participants must spend at least one hour interacting with other Poster Session presenters and complete a post-session test.

Guidelines for Submitting a Poster

For those interested in participating, the following is a list of suggestions on preparing a poster:

- Powsters must reflect the overall theme of patient safety.
- Keep the poster title short, highlighting the topic.
- Make the font size at least 14 point, and double-space paragraph lines to ensure readability from a distance of two to four feet.
- Prepare handouts to provide an overview of the poster and/or additional information, including contact names, should attendees have questions.

The display should be staffed by a qualified representative, such as a registered pharmacist, throughout the duration of the session. Student presenters must be accompanied by a licensed pharmacist.

Participating boards and schools and colleges of pharmacy will be provided with one four-foot by six-foot bulletin board, which should be staffed by a qualified representative, such as a registered pharmacist, during display times. Assembly time will be available on Sunday, May 15, from 7:30 to 8:15 AM. Student presenters are welcome and must be accompanied by a licensed pharmacist.

All participating pharmacy school students will receive a free voucher valued at $65 to take the Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination® (NAPLEX®).

Those interested in participating should contact the NABP Professional Affairs manager via email at Prof-Affairs@nabp.net by **Friday, March 4, 2016.**

Annual Meeting Location

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ranged from the designated taxi zones located at the transit islands on the arrivals/baggage claim level adjacent to each terminal. Taxis are approximately $23 to the hotel, depending on traffic.

Guests choosing to rent a vehicle can select one of several agencies located at the airport's consolidated rental car center. Car rental shuttles regularly operate at the Terminal 1 center traffic aisle and at the traffic island at the far west end of Terminal 2.

Once in San Diego, local transportation is available by MTS buses, light rail, and trolleys. The MTS offers an all-day regional, unlimited transportation pass that is valid on most MTS bus and trolley routes. The day passes start at $5, and there is a one-time $2 fee for the first-time purchase of a Compass Card. Compass Cards may be reloaded at trolley ticket machines and on most MTS buses. Visit *www.sdmts.com/fares.asp* for additional information.

Transportation to local sites may also be available via taxi, Uber, pedicabs, horse-drawn carriages, ferries, and water taxies.

Additional information about the 112th Annual Meeting is available in the Meetings section of the NABP website at *www.nabp.net.*

NABP Encourages Boards to Apply for Annual Meeting Travel Grant

The NABP Foundation™ is once again offering active member state boards of pharmacy travel grant opportunities to attend the NABP 112th Annual Meeting, to be held May 14-17, 2016, at the Hilton San Diego Bayfront Hotel in San Diego, CA. 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.

In order to receive reimbursement, active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions.

The grant was established to assist boards in sending voting delegates to the Annual Meeting so they may participate in important business, including discussing and voting upon resolutions and amendments to the NABP Constitution and Bylaws, electing NABP Executive Committee officers and members, and attending educational sessions regarding current issues facing pharmacy regulators.

The NABP Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for travel expenses, including travel, hotel rooms, meals, taxis, parking, and tips. Eligible individuals can receive up to $1,500 in grant monies to attend the NABP 112th Annual Meeting. The grant does not include Annual Meeting registration fees.

Grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. Applications can be submitted by mail to NABP Headquarters or via email at exec-office@nabp.net. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether they have qualified for the grant. Last year, 40 state boards of pharmacy applied and were approved for the NABP 111th Annual Meeting Travel Grant.

For more information on the Annual Meeting Travel Grant, contact the NABP Executive Office at exec-office@nabp.net.

Available in February: 112th Annual Meeting Online Registration

NABP Launching New, Improved Registration System to Streamline Process

Online registration will be available in February 2016 for the NABP 112th Annual Meeting, which will be held May 14-17, 2016, at the Hilton San Diego Bayfront Hotel in San Diego, CA.

New this year, NABP will launch an improved online registration system in an effort to simplify and streamline the registration process for attendees.

Once available, registration may be accessed via the Meetings section of the NABP website. Attendees are encouraged to register early to receive reduced meeting registration and hotel reservation rates. In order to receive the early registration rate, attendees must register on or before April 8, 2016. NABP offers attendees three payment options:

- Using a credit card (American Express, MasterCard, or Visa)
- Mailing in the payment
- Paying on site in San Diego

The deadline to receive the early hotel reservation rate is April 21, 2016.

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More information about the 112th Annual Meeting is also available in the Meetings section of the NABP website at *www.nabp.net.*

Meeting Program

May 14-17, 2016 Hilton San Diego Bayfront Hotel San Diego, CA

Saturday, May 14, 2016

10 AM - 6 PM
Registration/Information Desk Open

1:30 - 3:30 PM
Pre-Meeting CPE

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

6 - 9 PM
President's Welcome Reception Honoring NABP President Edward G. McGinley, MBA, RPh
Dinner will be served.
Dress: business casual

Sunday, May 15, 2016

7 AM - 4:30 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

Noon - 3:15 PM
First Business Session

12:30 - 1:30 PM
Keynote Address
Boris Brott
Motivational Speaker and Symphony Conductor

3:30 - 4:30 PM
Joint CPE

Monday, May 16, 2016

7:30 AM - 1 PM
Registration/Information Desk Open

7:30 - 9 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention
(Breakfast served from 7:30 - 8 AM)

9:15 - 10:15 AM
Joint CPE

10:30 AM - Noon
Second Business Session

Noon - 12:30 PM
Informal Member/Candidate Discussion

Free Afternoon
(No programming)

Tuesday, May 17, 2016

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

7:45 - 8:45 AM
NABP Breakfast

8:45 - 10:15 AM
Executive Officer and Board Member CPE

8:45 - 10:15 AM
Compliance Officer CPE

10:30 AM - Noon
Joint CPE

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

1:30 - 4 PM
Final Business Session

5:45 - 6:45 PM
Awards Dinner Reception

7 - 10 PM
Annual Awards Dinner
Dress: semiformal

Note: The 112th Annual Meeting schedule is subject to change.

NABP and the NABP Foundation™ are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of continuing pharmacy education (CPE). ACPE Provider Number: 0205. Participants may earn ACPE-accredited CPE credit by completing a Statement of Continuing Pharmacy Education Participation online and submitting it electronically to NABP. Full attendance and completion of the program evaluation and learning assessment for each session are required to receive CPE credit and for the credit to be recorded in the CPE Monitor® system. If you do not submit your CPE claim within 60 days of the date you completed the CPE activity, you will be unable to receive credit, as this is the maximum amount of time allowed for providers to transmit CPE claims to ACPE for credit. Please submit your claim as soon as possible to ensure that you receive credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

Proposed Resolutions Will Be Distributed to Boards in March 2016

Proposed resolutions received at NABP Headquarters by Friday, March 4, 2016, will be distributed electronically to state boards of pharmacy on the following Thursday, March 10, 2016, for review prior to the NABP 112th Annual Meeting, where the resolutions will be presented and voted upon. This mailing will constitute the only preconference distribution of proposed resolutions. All resolutions – those distributed for early review as well as those received after March 4 – will be presented to the voting delegates during the Annual Meeting on Monday, May 16, 2016, by the chair of the Committee on Resolutions.

To be considered during the Annual Meeting, resolutions must adhere to the requirement of Article IV, Section 6, Part (d) of the NABP Constitution and Bylaws, which states the following:

"(d) Any active member board, District, or committee of the Association may submit resolutions to the Association. Except as otherwise provided in subparagraph (c) of this section, all resolutions submitted in writing to the Association at least twenty (20) days prior to the date of the Annual Meeting shall be presented at the Annual Meeting for consideration. Resolutions not submitted within such time limitations, but which are submitted within a time frame set by the Executive Committee, may be presented during the Annual Meeting (pursuant to Section 6 (c)) and will be considered for adoption by the Association upon the affirmative vote of three-fourths (3/4) of those active member boards presented and constituting a quorum."

Questions regarding resolution procedures should be directed to the NABP Executive Office via email at exec-office@nabp.net.

Sponsorship and Educational Grant Opportunities Available for the Association's 112th Annual Meeting in San Diego, CA

NABP is offering numerous sponsorship and educational grant opportunities for organizations seeking to support public protection efforts during the NABP 112th Annual Meeting, to be held May 14-17, 2016, at the Hilton San Diego Bayfront Hotel in San Diego, CA.

Contributing organizations help NABP provide quality programs designed to assist board of pharmacy members, executive officers, and compliance staff to meet their responsibilities for safeguarding the public health, while creating visibility for the sponsoring organization.

Annual Meeting sponsors will be recognized appropriately in various materials and aspects of the Annual Meeting. In addition, sponsoring organizations contributing $5,000 or more to the meeting are entitled to two complimentary meeting registrations valued at $575 each. Contributions of $1,000 to $4,999 entitle the donors to one complimentary meeting registration.

For more details on sponsorship and grant opportunities, organizations may contact NABP via email at Prof-Affairs@nabp.net or via phone at 847/391-4406.

Newly Accredited DMEPOS Facilities

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

Naugatuck Pharmacy
Naugatuck, CT

Prescription Pharmacy
Two facilities in Santa Barbara, CA

Woodmark Pharmacy of Massachusetts, LLC
Waltham, MA

A full listing of over 500 accredited DMEPOS companies representing nearly 28,000 facilities is available on the NABP website at *www.nabp.net.*

Task Force on Pharmacist Prescriptive Authority Convenes

On September 1-2, 2015, the Task Force on Pharmacist Prescriptive Authority met at NABP Headquarters to explore the need for and feasibility of all states granting limited prescriptive authority in order to meet existing and future patient health care needs. The task force was established in response to Resolution 111-4-15, passed at the 111th Annual Meeting.

Front row pictured from left to right: Kerstin Arnold, JD, Texas State Board of Pharmacy; Joyce Tipton, MBA, RPh, FASHP, Texas State Board of Pharmacy; Cathryn J. Lew, RPh, Sacred Heart Home Infusion; Virginia Herold, MS, California State Board of Pharmacy; and Cynthia "Cindy" Warriner, RPh, Virginia Board of Pharmacy. Back row pictured from left to right: Krystalyn Weaver, PharmD, RPh, National Alliance of State Pharmacy Associations (guest); Robert Braylock, PharmD/MBA Candidate, The University of Findlay (guest); Cathy Hanna, PharmD, RPh, Kentucky Board of Pharmacy; Timothy Fensky, RPh, FACA, Massachusetts Board of Registration in Pharmacy; Leo Lariviere, RPh, Rhode Island Board of Pharmacy; Dennis Wiesner, RPh, Texas State Board of Pharmacy; Michael A. Podgurski, RPh, Rite Aid; James T. DeVita, RPh, NABP Executive Committee liaison; and Thomas F.X. Bender, Jr, RPh, New Jersey State Board of Pharmacy.

Volunteers Attend MPJE State-Specific Review Meeting

In September 2015, volunteer item reviewers attended the Multistate Pharmacy Jurisprudence Examination® (MPJE®) State-Specific Review Meeting at NABP Headquarters. Out of the 48 jurisdictions that participated in the MPJE program during that time, state board of pharmacy representatives from 14 jurisdictions convened to determine the appropriateness of current examination items for candidates seeking licensure in their state and reviewed new items according to changes in state and federal pharmacy law. Pictured from left to right: Anna Jeffers, Esq, legislative and regulations manager, Maryland Board of Pharmacy and Sajal Roy, PharmD, RPh, CGP, CPSO, member, Maryland Board of Pharmacy.

Pre-NAPLEX Updated to Correspond to the Revised NAPLEX Competency Statements

The Pre-NAPLEX® content has been updated as of October 12, 2015, to correspond to the North American Pharmacist Licensure Examination® (NAPLEX®) Competency Statements that went into effect on November 1, 2015. The Pre-NAPLEX is the only NAPLEX practice examination written and developed by NABP to familiarize students with the NAPLEX testing experience. The items on the Pre-NAPLEX are actual items that have previously appeared on the NAPLEX. The Pre-NAPLEX score is intended to provide candidates with information on their performance under pre-testing conditions when answering a subset of test questions similar to those that may be included on the NAPLEX. NABP does not claim that a strong performance on the Pre-NAPLEX indicates a likelihood of passing the NAPLEX. For more information about the Pre-NAPLEX and the new Competency Statements, visit the Programs section of the NABP website at *www.nabp.net.*

NAPLEX Item Writers Gather for Workshop to Develop Exam Questions

Volunteer item writers convened in October 2015 to develop examination questions that will be considered for the North American Pharmacist Licensure Examination® (NAPLEX®). Pictured right: Winter Smith, PharmD, DPh, BCPS, University of Oklahoma College of Pharmacy (left) and Felix Yam, PharmD, RPh, MAS, BCPS, University of California San Diego Skaggs School of Pharmacy and Pharmaceutical Sciences (right). Pictured below: Marlon Honeywell, PharmD, RPh, Florida A&M University College of Pharmacy and Pharmaceutical Sciences (left); Mikel Bofenkamp, PharmD, BCPS, Methodist Hospital in St Louis Park, MN (right).

NABP Seeks Members for 2016-2017 Committees and Task Forces

NABP is seeking volunteers from its active member boards of pharmacy to serve on the 2016-2017 committees and task forces. Executive officers and board members interested in serving on a committee or task force are encouraged to submit an application and a current résumé or curriculum vitae. Board of pharmacy staff interested in volunteering for NABP task forces are also encouraged to apply.

All submissions must be sent to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters or execoffice@nabp.net by **Friday, June 3, 2016**. All materials will be forwarded to NABP President-elect Hal Wand, MBA, RPh, who will make the appointments when he becomes NABP president following the Association's 112th Annual Meeting in San Diego, CA.

A link to the application form is available for download in the Members section under Committee & Task Force Reports on the NABP website at *www.nabp.net.*

Task Force Meets to Review State Laws/Regulations and *Model Act* on Pharmacist Care Services Outside Traditional Pharmacy Setting

On September 9-10, 2015, the Task Force on the Regulation of Pharmacist Care Services met in Rosemont, IL, to assist the boards of pharmacy in oversight and regulation of pharmacist care outside the traditional pharmacy setting by recommending amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. The task force was established in response to Resolution 111-6-15, passed at the 111th Annual Meeting.

Back row pictured from left to right: John Marraffa, Jr, RPh, New York State Board of Pharmacy; Dennis K. McAllister, RPh, FASHP, Arizona State Board of Pharmacy; Joel Thornbury, RPh, Kentucky Board of Pharmacy (chairperson); Reginald B. "Reggie" Dilliard, DPh, Tennessee Board of Pharmacy; Barbara Ellen Vick, PharmD, JD, RPh, North Carolina Board of Pharmacy; and Allison Benz, MS, RPh, Texas State Board of Pharmacy. Front row pictured from left to right: Kamlesh Gandhi, PharmD, RPh, Arizona State Board of Pharmacy; Phyllis Stine, BS, Texas State Board of Pharmacy; Hal Wand, MBA, RPh, NABP Executive Committee liaison; and Lenora Newsome, PD, Arkansas State Board of Pharmacy.

Louisiana Law Directs Officials to Develop Rules for Medical Cannabis

Effective June 29, 2015, Louisiana Act 261 amended the state's existing controlled substance (CS) law that permits the prescribing of marijuana for therapeutic purposes by directing the Louisiana Department of Agriculture & Forestry to develop rules for the growth and harvesting of the plant, as well as the production of pharmaceutical-grade products. Further, the law directs the Louisiana Board of Medical Examiners to develop rules for the prescribing of marijuana by physicians, as well as the production of an annual report to the legislature recommending additional medical conditions for which marijuana may be prescribed. The law also directs the Louisiana Board of Pharmacy to develop rules for the licensing of special pharmacies for the dispensing of marijuana products produced in the state.

The Board of Pharmacy provides additional information in Bulletin No. 15-02, which can be accessed in the Public Library section of the Board's website.

California Legislation Permits Substitution With Interchangeable Biological Products

In California, a bill (SB 671) authorizing pharmacists filling a prescription for a biological medication to select an interchangeable biological product was signed into law by Governor Jerry Brown. A substitution cannot be made if the prescriber indicates "do not substitute," or words of similar meaning. The law requires the California State Board of Pharmacy to maintain a link on its website to Food and Drug Administration's (FDA's) current list of interchangeable biological products. Further, the law requires a pharmacist or a designee to enter the biological product that was dispensed in an electronic system within five days; the system must be one that the prescriber can access. If the pharmacy does not have access to such a system, another approved method of communication must be used to inform the prescriber. The law also requires that the substitution of a biological product be communicated to the patient.

Text of the law is available on the California Legislature website at *http://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=201520160SB671*.

Oklahoma Provides Regulation Updates

According to Oklahoma regulation 535:15-3-9(h), all pharmacies licensed by the Oklahoma State Board of Pharmacy are required to have a written drug diversion detection and prevention plan, which should be a part of the pharmacy's policies and procedures. This requirement for the diversion detection and prevention plan applies to all drugs, not just CS. Many non-controlled drugs are often targeted for diversion, and it is the pharmacy's responsibility to have and follow a policy and procedure to detect and prevent diversion. The Board notes that oftentimes, diversion has occurred because the pharmacy and pharmacist-in-charge (PIC) did not follow their own policy and procedure.

According to Oklahoma regulation 535:15-7-3, retail pharmacies are not allowed to resell drugs to wholesalers. They may return drugs to the wholesaler from which the drugs were purchased. In addition, wholesalers are not allowed to purchase drugs from a pharmacy. They are allowed to accept returns of drugs purchased from them.

Oklahoma regulation 535:25-9-13 indicates that a pharmacy may not place a prescription on automatic refill without the express request from the patient or the patient's agent. A pharmacy should have a method of documentation of the patient's request for automatic refills. Such documentation might include the date of the request and at least the initials of the person who took the request from the patient.

South Dakota Tech-to-Pharmacist Ratio Rules Finalized

Technician-to-pharmacist ratio rules have changed in South Dakota. Effective August 19, 2015, ARSD 20:51:29:19 – 20:51:29:19.02 increased the technician-to-pharmacist ratio from 2:1 to 3:1 in all pharmacies. Further, there is an exception to the ratio for mail-order, long-term care, and hospital pharmacies. This exception allows the PIC to determine the ratio only if the following are employed by the pharmacy in filling prescriptions: technology (scanning) to ensure accuracy in the filling process; role-based software platform with stop points where a pharmacist must intervene; software with drug utilization review checks for allergies, interactions, and age-appropriate dosage ranges; clinically significant computer warnings that require pharmacist review; electronic surveillance technology to control access and to provide continuous monitoring of all areas where drugs are stored or dispensed or both; a quality assurance program to identify and evaluate dispensing errors, including continuous quality improvement programs; appropriate training programs for all pharmacy functions; and strict monitoring to prevent diversion of CS. The South Dakota State Board of Pharmacy notes that, as with all PIC accountabilities, it is the PIC's responsibility to design all processes to ensure that the health and safety of patients is top priority. Text of the rule is available on the South Dakota Legislature website at *http://legis.sd.gov/rules/DisplayRule.aspx?Rule=20:51:29:19* and *http://legis.sd.gov/rules/DisplayRule.aspx?Rule=20:51:29:19.02*.

Executive Officer Changes

- **Shauna White, PharmD, RPh**, is serving as the executive director of the District of Columbia Board of Pharmacy. Prior to this position, she served as pharmacist inspector for the Board while also serving as interim executive director. Dr White received her bachelor of science degree in biology from Xavier University of Louisiana and her doctor of pharmacy degree from the University of Maryland School of Pharmacy, Baltimore.

Board Member Appointments

- **Vickilee Einhellig, RPh**, has been appointed a member of the Colorado State Board of Pharmacy. Einhellig's appointment will expire July 1, 2019.
- **Radhika Nath, PhD,** has been appointed a member of the Colorado State Board of Pharmacy. Nath's appointment will expire July 1, 2019.
- **Vicki Pyne** has been appointed a public member of the Colorado State Board of Pharmacy. Pyne's appointment will expire July 1, 2019.
- **Laura Rang, PharmD, RPh**, has been appointed a member of the Colorado State Board of Pharmacy. Rang's appointment will expire July 1, 2019.
- **David Bisaillon** has been appointed a public member of the Florida Board of Pharmacy. Bisaillon's appointment will expire October 31, 2017.
- **Efstratios Bouyoukas, PharmD, RPh**, has been appointed a member of the Maryland Board of Pharmacy. Bouyoukas's appointment will expire April 30, 2019.
- **Ellen Yankellow, PharmD, RPh**, has been appointed a member of the Maryland Board of Pharmacy. Yankellow's appointment will expire April 30, 2019.
- **Douglas Lang, RPh**, has been appointed a member of the Missouri Board of Pharmacy. Lang's appointment will expire July 20, 2020.
- **Candace Bouchard** has been appointed a public member of the New Hampshire Board of Pharmacy. Bouchard's appointment will expire October 22, 2016.
- **Tanya Schmidt, PharmD, RPh**, has been appointed a member of the North Dakota State Board of Pharmacy. Schmidt's appointment will expire May 8, 2020.

Board Member Reappointments

- **Joseph "Steve" Bryant, PD**, has been reappointed a member of the Arkansas State Board of Pharmacy. Bryant's appointment will expire June 30, 2020.
- **Allen Schaad, RPh**, has been reappointed a member of the California State Board of Pharmacy. Schaad's appointment will expire June 1, 2019.
- **Stanley Weisser, RPh**, has been reappointed a member of the California State Board of Pharmacy. Weisser's appointment will expire June 1, 2019.
- **Armand Potestio, RPh**, has been reappointed a member of the Colorado State Board of Pharmacy. Potestio's appointment will expire July 1, 2019.
- **Jay Galloway** has been reappointed a public member of the Delaware State Board of Pharmacy. Galloway's appointment will expire August 20, 2017.
- **Holly Henggeler, PharmD, RPh**, has been reappointed a member of the Idaho State Board of Pharmacy. Henggeler's appointment will expire June 30, 2020.
- **Del Fanning, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. Fanning's appointment will expire August 31, 2019.
- **Daniel Ashby, MS, RPh**, has been reappointed a member of the Maryland Board of Pharmacy. Ashby's appointment will expire April 30, 2019.
- **Mitra Gavgani, PharmD, RPh**, has been reappointed a member of the Maryland Board of Pharmacy. Gavgani's appointment will expire April 30, 2018.
- **Zeno St Cyr III, MPH**, has been reappointed a public member of the Maryland Board of Pharmacy. St Cyr's appointment will expire June 30, 2018.
- **Suit Hing "Mary" Moy-Sandusky, RPh**, has been reappointed a member of the Michigan Board of Pharmacy. Moy-Sandusky's appointment will expire June 30, 2019.

Awards and Honors

- **Edward G. McGinley, MBA, RPh,** NABP President, was awarded the Bowl of Hygeia from the New Jersey Pharmacists Association during its 145th Annual Meeting and Convention in October 2015. The award is presented to New Jersey licensed pharmacists who have compiled an outstanding record of community service that, apart from the practice of pharmacy, reflects well on the profession.

Avoid Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following a recent FDA inspection during which investigators observed insanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products.

However, the company refused to recall its products, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm*.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

Risk of Dose Confusion With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm*.

Since Avycaz's approval in February 2015, FDA has received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. To date, no adverse events were reported.

US Compounding Recalls Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm*.

The company issued this recall out of an abundance of caution. A list of all sterile compounded products that have been recalled is provided on FDA's website available at *www.fda.gov/Safety/Recalls/ucm464072.htm*. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall.

FDA Investigates Risks of Using Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm*.

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.accessdata.fda.gov/scripts/medwatch*.

nabp newsletter

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