



# newsletter

National Association of Boards of Pharmacy®



November-December 2013 / Volume 42 Number 10

aid to government  
the profession  
the public  
1904 to 2013

## Bill Aimed to Ensure Safety of Compounded Drugs and Protect the Integrity of the Nation's Drug Supply Chain Passes US House and Senate

*Season's Greetings*  
from  
**NABP**

### Upcoming Events

January 20-31, 2014  
PARE Administration

January 21-22, 2014  
Committee on Law Enforcement/Legislation  
NABP Headquarters

February 27, 2014  
ACE Meeting  
NABP Headquarters

April 1-12, 2014  
PARE Administration

April 24, 2014  
PCOA Forum  
NABP Headquarters

New legislation aimed to ensure the safety of compounded medications distributed across state lines has passed in the United States House of Representatives and the Senate. The bill (HR 3204) was intended to address the fall 2012 multistate outbreak of fungal meningitis linked to contaminated compounded medications, and also includes provisions intended to protect the nation's drug supply chain from counterfeit and substandard drugs. The bill does not incorporate significant changes requested by the state boards of pharmacy and NABP. Provisions of the bill require enhanced communications about compounding pharmacies between the state boards of pharmacy and Secretary of Health and Human Ser-

vices (HHS) and create a new voluntary category for facilities that produce non-patient-specific drugs.

The "Drug Quality and Security Act" (HR 3204), introduced by Representative Fred Upton, chairman of the House Committee on Energy and Commerce, is a compromise compounding bill, which also includes "track and trace" supply chain integrity provisions.

The bill's provisions, related to compounding, would amend Section 503A Pharmacy Compounding of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a) that was enacted by the Food and Drug Administration Modernization Act of 1997. As referenced in congressional committee hearings that followed the meningitis outbreak,



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Section 503A has not been fully enforced by Food and Drug Administration (FDA) since a provision of the act prohibiting the advertising and promotion of compounded preparations was ruled unconstitutional by the Supreme Court. HR 3204 reaffirms the "old" 503A by amending it to remove the prohibition against advertising,

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**Compounding**

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and leaving the remainder mostly intact.

Under new Section 503B, facilities that want to produce and distribute non-patient-specific compounded sterile products would be able to register with FDA as “outsourcing facilities” and will be inspected and regulated by the agency under new standards.

Under the proposed law, such facilities are not required to be licensed as a pharmacy, but must be under the supervision of a licensed pharmacist. These facilities would be required

to follow specific labeling requirements to include “not for resale” and “for office use.”

The bill would also establish new penalties for violations of the act, including penalties for the intentional falsification of prescriptions under either 503A or 503B.

State boards of pharmacy would need to determine whether they will require state licensure for outsourcing facilities, and if so, they will need to determine the appropriate category of licensure. As such, new state legislation and/or board rules may be needed to accommodate the outsourcing facility category.

The bill also adds a new section, “Enhanced Communications,” that requires the HHS secretary to establish, in consultation with NABP, a reporting system for state boards of pharmacy to report the following activities:

- suspensions, revocations, disciplinary actions, sanctions, warning letters taken against pharmacies for compounding violations;
- recall activities by a pharmacy for issues related to the purity or quality of a compounded product; and

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**NABP White Paper Stresses Need to Address Prescription Drug Supply Chain Vulnerabilities, Regulatory Gaps**

*Role of VAWD Accreditation Program in Ensuring Supply Chain Integrity Highlighted*

NABP stressed, in a white paper released on October 9, 2013, that closing vulnerable regulatory gaps is paramount in preventing counterfeit or diverted drugs from infiltrating the United States prescription drug supply chain. In “Wholesale Drug Distribution: Protecting the Integrity of the Nation’s Prescription Drug Supply,” NABP points to the roles of unscrupulous wholesalers in distributing counterfeit drugs

and unapproved foreign-sourced drugs that have endangered patients across the country. To help safeguard the distribution chain, NABP has implemented updated criteria for the Association’s Verified-Accredited Wholesale Distributors® (VAWD®) accreditation program, including revised criteria allowing virtual wholesale distributors to qualify for VAWD. Further, as noted in the white paper, the Association supports state efforts to strengthen and work toward uniformity

in prescription drug distribution laws in order to eliminate the regulatory gaps that leave the supply chain susceptible to suspect wholesalers.

The white paper is available for download in the Members section of the NABP Web site at [https://www.nabp.net/system/rich/rich\\_files/rich\\_files/000/000/064/original/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf](https://www.nabp.net/system/rich/rich_files/rich_files/000/000/064/original/wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf). ©

## Twenty-One States Now Sharing Data Via PMP InterConnect; Testing of PMP Software Continues

Five additional states – Arkansas, Delaware, Minnesota, Mississippi, and Wisconsin – have now implemented NABP PMP InterConnect®, making interstate prescription monitoring program (PMP) data accessible to authorized users in these states. In addition, North Dakota will be the fifth state to assist NABP with piloting the new PMP AWA<sub>R</sub>X<sub>E</sub>™ software.

### NABP InterConnect Participation Expands

NABP InterConnect participation has seen continued growth in the last quarter of 2013. Authorized users in 21 states are now sharing data through the NABP InterConnect, with recent deployment by the following state PMPs: the Arkansas Prescription Monitoring Program, Delaware Prescription Monitoring Program, Minnesota Prescription Monitoring Program, Mississippi Prescription Monitoring Program, and Wisconsin Prescription Drug Monitoring Program. These five states join participants in the states of Arizona, Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, and Virginia.

It is expected that a total of 25 states will be connected by the end of 2013 as four additional states work to implement NABP InterConnect. In addition, four states are reviewing memorandums of understanding (MOUs) to participate in NABP InterConnect. Four states have MOUs under review.



It is expected that a total of 25 states will be connected by the end of 2013 as four additional states work to implement NABP InterConnect.

### State Joins PMP Software Pilot

In first quarter 2013, NABP began to develop and test a new, comprehensive PMP software system, called PMP AWA<sub>R</sub>X<sub>E</sub>, to provide greater flexibility and more services for PMP administrators. To ensure the software meets the needs of state PMPs, a number of states have agreed to assist NABP in testing the software. North Dakota plans to participate as the fifth state to pilot the software joining Idaho, Kansas, Mississippi, and Nevada.

In addition to offering several other benefits, the

new PMP software is designed to work seamlessly with NABP InterConnect.

Kansas and Mississippi are among the states that have already piloted the new software, with launch dates of July 2013 and October 2013, respectively. The next state to launch the new software will be Nevada with an anticipated launch date of December 2013. Following Nevada's launch will be Idaho, which is expected to launch in January 2014. As with the previous pilots, NABP is working to apply additional improvements to the software for the upcoming pilot states.

NABP is currently providing the new software free of charge to the aforementioned five states, and it is the ultimate goal to make this software available to all states at no cost in the future.

More information about PMP AWA<sub>R</sub>X<sub>E</sub> may be found in the October 2013 *NABP Newsletter*. Additional information about NABP InterConnect, including the most up-to-date information about state participation, is available on the NABP Web site at [www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect](http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect). ©

### Executive Committee

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One-year term

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*President*  
One-year term

**Joseph L. Adams**  
*President-elect*  
One-year term

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Serving first year of a second three-year term

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

**Mark T. Conrad**  
*Member, District 3*  
Serving third year of a three-year term

**William John Cover**  
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**Gary Dewhirst**  
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*Member, District 7*  
Serving second year of a three-year term

**Hal Wand**  
*Member, District 8*  
Serving third year of a second three-year term

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

## No Backsies

By Dale J. Atkinson, JD

A vast majority of complaints filed against licensees are resolved without the need for a formal administrative hearing. Both the regulatory board and respondent have various incentives to settle a matter short of a hearing. Resolution eliminates the uncertainty of an outcome and adds an element of control over the terms and conditions of the consent order. Settlement also provides a basis for both parties to negotiate a definitive sanction(s), as well as craft language agreed upon by both sides. Of course, agreed language does not necessarily mean either side is or must be happy with the selected verbiage. As the saying goes, if both sides are unhappy, it likely is a good resolution.

Many important elements are included in a consent order including recitals, jurisdiction, stipulated facts, acknowledgement and waiver of procedural rights, agreed upon sanctions/penalties and reinstatement (if allowed), consequences for violations of the consent order, presentation to and ultimate approval by the board, and publication of the order. In addition, terms and conditions related to admissions of wrongdoing by the respondent and finality and prohibition of modifications to the order are worthy of discussion.

Final administrative actions always have the potential to trigger ancillary consequences and respon-

dents should seek legal advice in anticipation thereof. Consider the following.

A physician (Licensee) practicing in two distinct areas (pain management and anesthesiology) had been licensed since 1973. In 2009, the Maryland Board of Physicians (Board) received a report that the Licensee had been sending through the mail prescriptions for painkillers to patients without conducting an appropriate examination. After an investigation, the Board charged the Licensee with violations of the practice act with allegations of prescribing potent painkillers (OxyContin®, Percocet®, and other opioid medications) from her

home, without justification, without monitoring patients, and without examining or seeing such patients. The allegations spanned a period of time extending over eight years.

In January 2011, the Board issued an order summarily suspending the Licensee's license to practice medicine. At the rule to show cause hearing later that month, the Board declined to reinstate her license. A case resolution conference was held and the matter was scheduled for administrative hearing. Before the hearing, the parties agreed to settle the matter and entered into a consent order. The May 2011 consent order was comprehensive and included numerous provisions including findings of fact and conclusions of law relative to the accusations and violations of the practice act. Pursuant to the order, the Licensee also agreed to not practice algology or pain management and agreed to forfeit her federal Drug Enforcement Administration (DEA) registration number and Maryland controlled dangerous substance (CDS) number.

The order placed her on probation but allowed for a petition after two years for full reinstatement. The Licensee also acknowledged her opportunity to consult with counsel and agreement that she would be bound by the conditions and restrictions of the consent order,

as well as waive her right to contest the findings of fact and conclusions of law. Finally, the Licensee acknowledged the validity of the consent order as if it were entered after a formal evidentiary hearing in which she would have had the right to counsel, confront witnesses, give testimony, call witnesses, and all other substantive and procedural protections provided by law. The Licensee signed the agreement acknowledging that she had an opportunity to consult with counsel, signed without reservation, and understood and comprehended the language, meaning, and terms of the consent order. The order was also signed by her attorney.

In July 2011, counsel for the Licensee sent a letter to the executive director of the Board asking that the consent order be revised or interpreted to allow her the right to have a DEA or CDS registration for the sole purpose of writing orders for anesthesia drugs for hospital patients. The Licensee alleged that she did not realize that forfeiting her DEA and CDS numbers would preclude her from anesthesiology practice at the hospital. Apparently her hospital privileges were also dependent upon such current registration numbers.

After receiving advice from counsel, the Board denied her request for modification of the order

and disagreed with the Licensee's characterization that the order was entered by mistake or misunderstanding. In fact, the Board noted the representation by the Licensee that she fully comprehended the meaning and terms of the order. The Licensee filed for relief in the circuit court seeking judicial review, declaratory relief, and/or an administrative mandamus arguing that the parties entered into the order with an understanding that the Licensee would be able to return to work as an anesthesiologist.

The Board filed a motion to dismiss that was granted by the court. The Licensee appealed the matter to the Court of Special Appeals.

The appellate court first noted that the case was not about an order entered through fraud, duress, misrepresentation, mistake, mutual mistake, or anything else that could cast doubt on its formation. As noted by the court, had such allegations existed, the Licensee may have had legal rights to challenge the order under principles of contract. In reality, the case addressed post-agreement rights of a party to an agreement seeking to revise or modify such already agreed upon terms and conditions. The Licensee argued that the circuit court erred in refusing to compel the Board to modify the order.

The court emphasized that the Licensee knowingly

and voluntarily and with full disclosure and advice of counsel waived her right to challenge the order. It dissected the language of the order underscoring the acknowledgements of the Licensee, including the recognition that the order was valid. In rejecting the right of the Licensee to challenge the terms of the consent order, the court cited authority holding that consent orders from administrative proceedings are treated the same as consent orders issued by the courts. Consent orders in both settings serve a common function of resolving disputes, ending litigation, and avoiding appeals. There is no need to distinguish between administrative consent orders and judicial consent orders. Thus, the court found that the refusal by the Board to consider or grant a revision was not an error of law.

Next, the court reviewed the practice act and applicable administrative procedures and found that the law did not require the Board to review, much less revise, a final administrative order. Under the regulations, the court held that, at best, the regulations provided a mechanism for a disgruntled licensee to file a motion for reconsideration. No such laws compel revision.

Finally, the appellate court addressed the finding of the lower court that it lacked jurisdiction to grant

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

nabp newsletter

### Compounding

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- concerns that a pharmacy may be exceeding the scope of 503A.

The bill also includes a requirement that HHS report such activities to the state boards of pharmacy.

The NABP membership has not taken a formal position regarding HR 3204, but the Association has expressed concerns that by simply reaffirming the existing 503A, a number of ambiguities that plagued the current law remain. Further, NABP believes that the bill does not go far enough, and lacks certain provisions needed, to address the safety of public health as it relates to compounded medications.

For example, it appears that state laws that allow pharmacy compounding for office use by a practitioner are now pre-empted by the new law, as 503A does not provide for pharmacy compounding other than pursuant to or in anticipation of a patient-specific prescription.

In addition, because a facility registered as an “outsourcing facility” could also be licensed and operating as a pharmacy – with no clear separation of personnel, space, or equipment – there may be continued confusion over regulatory jurisdiction. This gray area could potentially lead to lack of oversight over such facilities and poor public health protection. FDA

rules prohibiting facilities from operating as both an outsourcing facility and pharmacy, or state laws prohibiting an entity from operating under both

The NABP membership has not taken a formal position regarding HR 3204, but the Association has expressed concerns that by simply reaffirming the existing 503A, a number of ambiguities that plagued the current law remain.

categories would be needed to prevent confusion and ensure appropriate regulatory oversight.

Throughout the first half of 2013, NABP and other pharmacy organizations worked with lawmakers in the Senate and House in an effort to craft legislation that adequately addressed specific gray areas in current compounding law. Adopting a clear definition of traditional pharmacy compounding that included some provisions for limited office use compounding, was one of the key suggestions presented to federal lawmakers. As drafted, HR 3204 does not reflect this earlier collaborative work by NABP

As part of its work with lawmakers, NABP staff delivered testimony to

Congressional committees in May 2013 and July 2013. These documents are available as follows:

- Testimony before the Senate Committee on Health, Education, Labor, and Pensions (HELP) delivered May 9, 2013, available at [www.help.senate.gov/imo/media/doc/Catizone1.pdf](http://www.help.senate.gov/imo/media/doc/Catizone1.pdf)
- Testimony before the House Energy and Commerce Committee delivered May 23, 2013, available at <http://docs.house.gov/meetings/IF/IF14/20130523/100908/HHRG-113-IF14-Wstate-Russelle-20130523.pdf>
- Testimony before the House Energy and Commerce Committee Subcommittee on Health delivered July 16, 2013, available at <http://docs.house.gov/meetings/IF/>

*IF14/20130716/101137/HHRG-113-IF14-Wstate-CatizoneC-20130716-U1.pdf*

NABP’s position regarding its support of the Pharmaceutical Compounding Quality and Accountability Act, one of the compounding bills introduced earlier in 2013, is presented in a letter to the HELP Committee Chair, Senator Tom Harkin, and the Committee Ranking Member Senator Lamar Alexander, and is available at [www.nabp.net/system/redactor\\_assets/documents/522/Ltr\\_of\\_Support\\_Senate\\_HELP\\_23May13.pdf](http://www.nabp.net/system/redactor_assets/documents/522/Ltr_of_Support_Senate_HELP_23May13.pdf).

NABP will continue to work with its member boards, federal partners, and other organizations to address this important issue of the integrity of compounded medications for the protection of public health. ☺

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## Growing Clinical Adoption of NAR<sub>x</sub>CHECK Illustrates Value of PMP Data in Prescribing and Dispensing Decisions

As health care providers using NAR<sub>x</sub>CHECK® meet the daily challenge of making appropriate dispensing and prescribing decisions, usage rates and testimonials are illustrating the value of the software. NAR<sub>x</sub>CHECK, the software tool that generates risk-based scores reflecting a patient's controlled substance prescription medication history, has shown a positive clinical adoption rate by current users.

### Increased Clinical Adoption

Currently, the NAR<sub>x</sub>CHECK Plus software has been configured to operate in 23 hospitals, medical centers, and clinics in Indiana and Ohio, and this number is expected to rise. The NAR<sub>x</sub>CHECK Plus software tool is designed to analyze prescription monitoring program (PMP) data and provide a report on narcotic, sedative, and stimulant usage. The report includes a three-digit, risk-based NAR<sub>x</sub>CHECK Score that indicates whether there is a high or low probability that a patient is abusing a controlled substance prescription drug.

NABP data received from these health care settings in Indiana and Ohio indicate that adoption and clinical use of the software increases over time as

health care providers continue to use and see the value in the product. In one 30-day pilot, NAR<sub>x</sub>CHECK was selected over raw PMP data nine out of every 10 times a report was requested. The graph below illustrates the increase of use over an 11-month time span in a health care system where NAR<sub>x</sub>CHECK is used at eight hospitals.

In addition, NAR<sub>x</sub>CHECK users have made several positive comments on the value of the software in assisting with prescribing and dispensing decisions. An emergency medicine physician from Dayton, OH, notes "NAR<sub>x</sub>CHECK has been a great asset to my medical practice. I have frequently made changes in medical man-

agement after viewing a patient's NAR<sub>x</sub>CHECK Report. [It] makes checking narcotic prescription history extremely easy and efficient."

Other physicians have found that having the NAR<sub>x</sub>CHECK software has been beneficial to patient care as it has reduced the amount of time spent deciphering a patient's medication history. "NAR<sub>x</sub>CHECK has been great for patient care and in helping ensure that we are treating patients appropriately," noted a health care administrator in Springfield, OH. The administrator further stated, "It is much faster than having to find and type in patient information into [the prescription drug monitoring program]

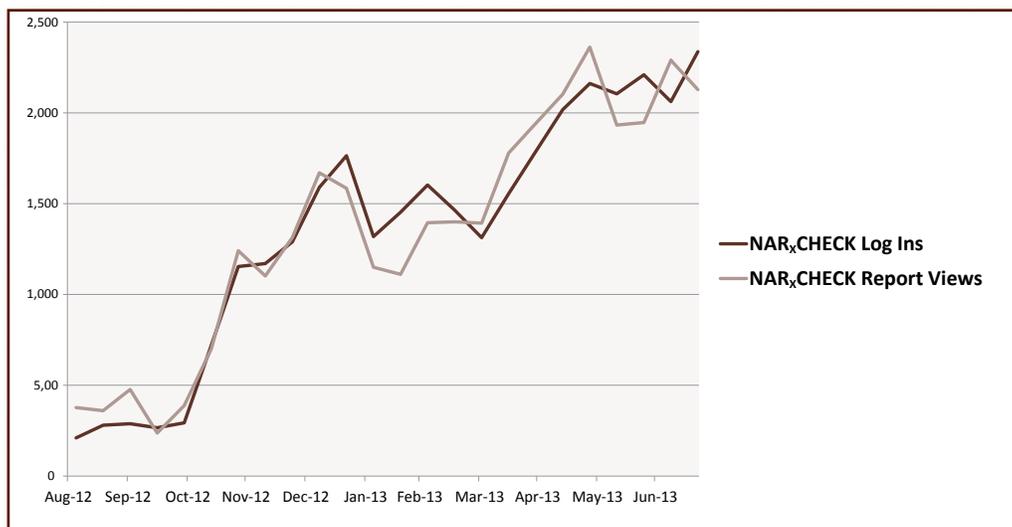
like I had done in the past. I would recommend NAR<sub>x</sub>CHECK to any [Emergency Department] physician or group without hesitation."

### Outreach Efforts

In an effort to educate about the value of NAR<sub>x</sub>CHECK and increase interest among key stakeholders, NABP Foundation™ has been attending and participating in several conferences throughout the nation over the past few months. In September 2013, NABP presented at the 2013 Harold Rogers Prescription Drug Monitoring Program National Meeting in Washington, DC. This presentation gave many key stakeholders an opportunity to learn more about the tool.

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**NAR<sub>x</sub>CHECK Clinical Adoption**



The above graph illustrates the steady increase of NAR<sub>x</sub>CHECK® use over the first 11 months of its implementation in a health care system. The number of NAR<sub>x</sub>CHECK log ins and report views nearly quadrupled from its initial introduction.

# Executive Officers Unite at NABP Interactive Forum to Collaborate and Create New Tool Sets to Protect Public Health

Thirty-one board of pharmacy executive officers gathered for the Interactive Executive Officer Forum, held September 24-25, 2013, and took part in the annual networking opportunity to discuss common challenges faced by the state boards. The forum, themed “Creating New Tools to Maintain and Enhance Board Authority,” reinforced the partnership between the boards of pharmacy and NABP and the shared mission to protect the public health.

To ensure that the forum focused on issues of special interest to the boards, a survey was sent to invitees prior to the meeting asking them what current topics they would like to discuss. The format of the meeting was divided into two days of sessions with topics developed based on attendee suggestions and centered around “tool sets” designed to provide executive officers with valuable new ideas. Throughout the forum, attendees posed challenging questions and offered a variety of relevant experiences, perspectives, and information. Panelists on each topic included executive officers, members of the NABP Executive Committee, and NABP staff. Each panelist provided a brief overview of the topic and then the floor was opened up for a discussion from all attendees.

Also taking place the first day of the forum was the New Executive Officer Orientation Program, which convened the morning of September 24, before the events of the forum began. This program allows new executive officers to get acquainted with NABP membership and governance.

### The Starting Tools

Day one of the forum kicked off with Michael A. Burleson, RPh, chairperson, NABP Executive Committee, welcoming all executive officers and emphasizing the purpose of the meeting. Burleson stressed the importance of this unique opportunity for board of pharmacy executive officers to discuss freely and honestly with their colleagues – in closed sessions – important and timely issues related to pharmacy regulation as well as the latest enhancements to NABP programs and services.

With the issue of compounding at the forefront this year, the first tool set discussed at the forum – “Compounding Blueprint” – delved into this timely topic. During this session, executive officers from various state boards of pharmacy served as panelists and discussed compounding legislation efforts on both the federal and state levels. On the state regulatory side, individual states shared how they tightened their state’s

compounding regulations in an effort to protect public health.

The second tool set of the forum – “Expanding Uniformity and Simplifying License Transfer Among States” – discussed how the boards of pharmacy can utilize NABP services to further strengthen the licensing processes for pharmacies in nonresident states and help ensure safe pharmacy practices. Panelists for this session included NABP representatives that provided information on the new Verified Pharmacy Program™.

### The Finishing Touches

Day two of the meeting began with shared discussion topics. This portion of the event featured an open microphone discussion on topics related to the synchronization of medication scheduling. Also provided was a demonstration of the online tool for boards of pharmacy to audit the continuing pharmacy education compliance of those pharmacists and pharmacy technicians who have registered for CPE Monitor®.

Following these shared discussions, information was presented on additional NABP programs and services that have been developed to assist the boards of pharmacy in setting uniform standards that will serve to protect the public health on both a national and global scale.

The session titled, “Developing a Universal Framework,” began with a discussion of the NABP PMP Inter-Connect®. A presentation provided an overview of the program and the progress NABP has made in connecting the prescription monitoring programs of over 20 states. The .PHARMACY generic Top-Level Domain program was also discussed, including an overview of the NABP initiative aimed to ensure that only legitimate pharmacies and entities would have access to the .PHARMACY domain, a safe space for consumers. The session closed with a discussion on the Pharmacist Intern License and Registration program.

The second tool set of day two – “Building Common Initiatives” – provided a look at the trends seen while reviewing and surveying facilities as part of their applications for various NABP accreditation programs. Attendees were provided background on changes to requirements in the Verified-Accredited Wholesale Distributors® program related to virtual distributors, as well as updates on NABP’s other accreditation programs. A group of panelists also discussed the training challenges for compliance officers and inspectors.

The last tool set of the forum event – “Finishing Touches” – featured discussions about practitioner

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## Interactive Forum

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dispensing and the use of fines and citations as it relates to the discipline of licensees. After both topics were discussed, panelists opened the floor up to shared discussion topics, at which time attendees could bring up any topic of interest. Topics raised during this time included issues surrounding pharmacists refusal to fill controlled substance prescriptions and issues regarding returning medications to stock.

NABP President-elect Joseph L. Adams, RPh, closed the meeting with some additional information about NABP programs and services that are available to the attendees as well as a call to submit nominees for the awards to be presented at the NABP 110<sup>th</sup> Annual Meeting.

## Future Collaboration

Continuing the theme, "Creating New Tools to



## New Executive Officers Convene for Orientation

The New Executive Officer Orientation Program, held the morning of Tuesday, September 24, 2013, prior to the events of the Interactive Executive Officer Forum, provided newly appointed executive officers the opportunity to get acquainted with NABP membership and governance. Pictured from left to right: Marcie Bough, PharmD, executive director, Montana Board of Pharmacy; Donna Burns, licensing examiner, Alaska Board of Pharmacy; Joseph L. Adams, RPh, NABP president-elect; Reginald "Reggie" Dilliard, DPh, executive director, Tennessee Board of Pharmacy; and Larry Loring, RPh, executive director/chief drug inspector, New Mexico Board of Pharmacy.

Maintain and Enhance Board Authority," the second forum held this year was the NABP Interactive Compliance Officer and Legal Counsel Forum, on December 3-4, 2013. This interactive, two-day event provided an opportunity for dialogue, presentations, and networking among board of pharmacy com-

pliance officers and legal counsel. The programming included breakout sessions for discussions on timely issues specific to challenges each group encounters as they perform their respective duties. As with previous forums, NABP covered all expenses in order to facilitate participation by as many boards as possible

and allow for increased opportunity for networking. A forum for board members will be held in fall 2014.

For more information about the NABP Interactive Forums and future meetings, visit the Meetings section on the NABP Web site at [www.nabp.net/meetings](http://www.nabp.net/meetings). ☺

## Legal Briefs

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a mandamus. As noted by the appellate court, once the Licensee settled the charges through a consent order, she no longer qualified as an "aggrieved" party given her acknowledgment that she waived her right to contest the Board findings. Since she was not aggrieved, the lower court correctly found that it lacked jurisdiction to issue

a mandamus ordering the Board to consider a request for a revision. "Here, the formerly aggrieved party [Licensee] specifically forfeited the right to the registration numbers at issue when she freely entered into the Consent Order, and that forfeiture created a jurisdictional void that the circuit court correctly declined to fill."

Consent orders must be carefully crafted to ensure all issues are resolved and

finality is recognized by all parties. Many additional factors should be taken into consideration, including admissions of wrongdoing. In the current case, the court does not make reference to any admission of wrongdoing. But, inclusion of admissions in a consent order can be very beneficial to both future board decisions regarding reinstatement, as well as helpful to additional boards of pharmacy ad-

ressing reciprocal discipline and/or licensure transfer requests. Carefully crafted consent orders can protect future board decisions and prevent requests for modifications. As stated by the court in this case, "A deal is a deal, but this appeal brings to mind the long-standing playground rule of 'no backsies.'"

**Barson v. Maryland Board of Physicians**, 211 Md. App. 602; 66 A. 3d 50 (App. Ct. MD 2013) ☺

# Expert Panelists Lead Executive Officer Forum Discussions to Help Boards Create Essential Tools for Facing Common Challenges

Board of pharmacy executive officers convened for the two-day NABP Interactive Executive Officer Forum on September 24-25, 2013, in Northbrook, IL. Themed “Creating New Tools to Maintain and Enhance Board Authority,” the interactive forum provided an opportunity for attendees to share and collaborate among peers on timely and relevant topics facing the boards of pharmacy. Discussions were led by expert panels comprised of board executive officers and NABP staff. More information on the forum is available on pages 208-209 in this *Newsletter*. 



### Panelists Spark Discussion on Federal, State Compounding Legislative Efforts

Expert panelists opened up the forum with the timely topic of federal and state regulatory efforts related to compounding during the first tool set “Compounding Blueprint.” Pictured from left to right: Edward G. McGinley, MBA, RPh, NABP treasurer; session moderator Susan Ksiazek, RPh, NABP Executive Committee member; Larry L. Pinson, PharmD, executive secretary, Nevada State Board of Pharmacy; Cody C. Wiberg, PharmD, MS, executive director, Minnesota Board of Pharmacy; and Caroline D. Juran, RPh, executive director, Virginia Board of Pharmacy.



### Addressing Uniformity and the Future of License Transfer

During the session on “Expanding Uniformity and Simplifying License Transfer Among States,” panelists led discussions on updates to the NABP inspection partnership with various states and provided information on the Verified Pharmacy Program™. Pictured from left to right: Neal Watson, BS, licensure programs manager, NABP; session moderator Karen M. Ryle, MS, RPh, NABP President; and Josh Bolin, BA, government affairs director, NABP.

## Open, Shared Discussions on Attendee Topics of Interest

A portion of the interactive forum provided the executive officers the opportunity for an open microphone discussion on additional timely and relevant topics including those submitted through the pre-meeting survey. Panelists introduced topics related to the synchronization of medication scheduling and presented a demonstration of the continuing pharmacy education auditing tool. Pictured from left to right: Robert Cowan, CPA, CAE, chief operating officer, NABP; Jeanne D. Waggener, RPh, NABP Executive Committee member; and session moderator Michael A. Burleson, RPh, NABP chairperson.



## Developing a Universal Framework to Assist Boards in Their Mission to Protect the Public Health

NABP programs and services were highlighted during the tool set “Developing a Universal Framework,” which focused on the NABP PMP InterConnect<sup>®</sup>, the .PHARMACY generic Top-Level Domain program, and the Pharmacist Intern License and Registration program. Panelists shared how these programs can assist the boards in setting uniform standards that will serve to protect the public health on both a national and global scale. Pictured from left to right: Melissa Madigan, PharmD, JD, policy and communications director, NABP; Robert Cowan, CPA, CAE, chief operating officer, NABP; session moderator Hal Wand, MBA, RPh, NABP Executive Committee member; and William John Cover, RPh, NABP Executive Committee member.

## Assembling a Plan of Action for Common Inspection Issues

During the “Building Common Initiatives” tool set, panelists covered trends seen while reviewing surveyor reports and provided updates on NABP accreditation programs. In addition, one discussion focused on the training challenges for compliance officers and inspectors. Pictured from left to right: Gay Dodson, RPh, executive director/secretary, Texas State Board of Pharmacy; John Clay Kirtley, PharmD, executive director, Arkansas State Board of Pharmacy; Denise M. Frank, RPh, accreditation and inspection services manager, NABP; Gregg Jones, RPh, CPh, accreditation compliance manager, NABP; and session moderator Mark T. Conradi, JD, RPh, NABP Executive Committee member.



nabp newsletter

## NABP Surveyors and Board Compliance Officers Attend Training Workshop to Build on Expertise and Skills

NABP surveyors and board of pharmacy compliance officers came together in October 2013, at NABP Headquarters and at the Hilton Northbrook in Northbrook, IL, to participate in training sessions, which focused on the essentials of NABP accreditation programs and on sterile compounding inspections and standards. The first day of the workshop, which took place on October 8, focused on NABP accreditation programs and was only attended by NABP surveyors. The next two days, October 9-10, featured training on sterile compounding inspections and was attended by board of pharmacy compliance officers as well as NABP surveyors who perform surveys at compounding pharmacies.

### NABP Surveyors

The NABP surveyor portion of the training focused on NABP accreditation programs.

The first day of the surveyor training workshop provided surveyors with information on new Verified-Accredited Wholesale Distributors® criteria that address virtual wholesale distributors and an overview of the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program. In addition, surveyors were provided with information on topics such as accreditation criteria, authentication of pedigrees, resurveys, off-site functions, and drug diversion.

The second day of surveyor training focused on the Health Insurance Portability and Accountability

Act of 1996 training and on an overview of United States Pharmacopeia (USP) Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

NABP utilizes various means to ensure that its surveyors are appropriately trained and prepared for each survey. Training sessions such as this workshop are designed to keep surveyors up to date with new regulations and procedures and to ensure surveyors maintain and continue to build skill sets and expertise in the necessary survey fields or programs. Such training supports surveyors in their efforts to operate consistently with the applicable standards in every jurisdiction. For example, the Centers for Medicare and Medicaid Services (CMS) mandate that certain sup-

pliers of DMEPOS maintain accreditation to obtain or maintain Medicare billing privileges. NABP surveyors are a critical component to ensuring these suppliers stay in compliance with, not only NABP's program standards, but also the CMS DMEPOS Quality Standards governing DMEPOS accreditation.

NABP surveyors contribute significantly to NABP's ability to further expand and improve the services offered to the boards. They play an integral role in ensuring the protection of public health. The surveyors represent a vast array of knowledge and experience and bring diverse backgrounds, ranging from pharmacy practice to law enforcement. Surveyors apply their broad skill sets to NABP assignments

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### NABP Surveyors Attend Training Workshop

NABP surveyors met for joint training sessions at NABP Headquarters and the Hilton Northbrook, Northbrook, IL, on October 8-10, 2013. Sessions focused on sterile compounding training including United States Pharmacopeia Chapter <797> standards and compliance, personnel and facility metrics, sterilization and quality assurance programs, and inspection algorithms. On October 9-10, the training workshop was attended by both NABP surveyors and compliance officers.

## Verified Pharmacy Program Launches, Provides Uniform Licensure Information to Facilitate Nonresident Pharmacy Licensure Among States

As member boards of pharmacy continue their efforts to strengthen regulations and systems to ensure the safety of compounded medications, many have expressed a need for more consistency among requirements including inspection protocols. In order to address this need, NABP has launched the Verified Pharmacy Program™ (VPP™), a new electronic resource developed to help state boards of pharmacy share information related to pharmacy licensure including inspection reports. The success of the Electronic Licensure Transfer Program®, along with NABP's experience in conducting accreditation surveys and assisting boards of pharmacy with inspections, served as the foundation for the development of VPP. Boards accessing VPP will be able to obtain verified inspection and related licensure information in a standardized format. Further, since NABP pharmacy inspections conducted as part of VPP will utilize consistent, standardized criteria, boards will be able to more easily utilize the reported data when considering applications for nonresident licensure. VPP was developed in partnership with member boards to ensure that boards have complete information, including consistent and qualified inspection information, needed to assess applications for nonresident pharmacy licensure.

As an information-sharing network for the boards, VPP is a central “hub.” VPP e-Profiles will provide boards with high-level detail in a uniform format, meeting individual board needs and helping to support consistent standards. By helping to ensure uniformity among data reported, VPP will support boards of pharmacy as they enforce standards and regulations.

NABP recognizes that it is optimal for a state board of pharmacy to have a robust program of timely pharmacy inspections by inspectors qualified and trained to inspect the type of activities being performed, and supports efforts by states to obtain and retain the necessary resources. VPP is an effort to supplement state resources and assist in providing coverage for gaps identified by the compounding crisis. As part of VPP, NABP will conduct a facility survey for each pharmacy applying to participate in the program, unless a resident state inspection is reviewed and meets the criteria for a VPP inspection. Additionally, states that can share inspection reports with other states, will be able to upload the reports to NABP. These reports will be made electronically available to other states that need the information to make licensing or disciplinary decisions about nonresident pharmacies. Thus, VPP will also benefit participating pharmacies dispensing to

patients in multiple states by facilitating the process of obtaining a nonresident pharmacy license. If applying for licensure in states that recognize VPP, participating pharmacies may be able to satisfy inspection requirements for multiple states.

Details about VPP and an application are available on the NABP Web site at [www.nabp.net/programs/licensure/verified-pharmacy-program](http://www.nabp.net/programs/licensure/verified-pharmacy-program).

### Iowa and New Jersey Inspection Programs Nearing Completion

The Iowa Board of Pharmacy partnered with member boards and NABP to conduct inspections of all its nonresident pharmacies including those dispensing compounded drugs to the state following the 2012 multistate fungal meningitis outbreak linked to contaminated injectable drugs compounded by the New England Compounding Center. NABP surveyors began conducting pharmacy inspections on behalf of the Iowa Board of Pharmacy in December 2012, and inspections have been completed at an average rate of 15 to 20 inspections per week. To date, more than 500 nonresident pharmacies that dispense drugs to patients in Iowa have been inspected. The program is projected to be completed by mid-December 2013.

Similarly, the state of New Jersey requested

NABP's assistance in conducting inspections of pharmacies engaged in compounding within the state. NABP is assisting the New Jersey Division of Consumer Affairs (Division) with planned inspections, under a contract with the Division and state's Attorney General Jeffrey S. Chiesa. Surveyors began inspections in July 2013 and are expected to complete them in the spring of 2014.

In addition to supporting these state efforts to expand inspections, the programs provided opportunities for collaboration among member boards and NABP. NABP surveyors and board inspectors developed strong working relationships that enabled them to learn from shared experiences of conducting inspections.

### Continued Collaboration

The input, expertise, and experience of member boards of pharmacy shaped the development of VPP and the inspection programs so that the Association could ensure that the programs address board needs. NABP Government Affairs staff reached out to member boards to learn about their challenges and needs relative to ensuring the safety of compounded medications and granting nonresident pharmacies licensure. Further, board executive officers discussed

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## Deadline Set for Proposed Constitution and Bylaws Amendments

Proposed amendments to the NABP Constitution and Bylaws must be submitted between Monday, February 17, 2014 and Thursday, April 3, 2014, to be considered during the 110<sup>th</sup> Annual Meeting, which will be held May 17-20, 2014, at the Sheraton Phoenix Downtown Hotel in Phoenix, AZ. Amendments may be proposed by any active member board of pharmacy, the

NABP Executive Committee, or the Committee on Constitution and Bylaws.

NABP requests that all amendments be submitted in writing to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056 or via e-mail at [exec-office@nabp.net](mailto:exec-office@nabp.net). Submission dates are established by

the NABP Constitution and Bylaws, which specifies that proposed amendments may be accepted no earlier than 90 days and no later than 45 days before the First Business Session of the Annual Meeting.

For more information on the proposed amendments to the NABP Constitution and Bylaws, please contact the NABP Executive Office at [exec-office@nabp.net](mailto:exec-office@nabp.net). ☺

## Sponsorship and Educational Grant Opportunities for NABP 110<sup>th</sup> Annual Meeting Now Available

Organizations have an opportunity to gain exposure through numerous sponsorship and educational grant opportunities available at the NABP 110<sup>th</sup> Annual Meeting to be held May 17-20, 2014, at the Sheraton Phoenix Downtown Hotel in Phoenix, AZ. 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.

Contributing organizations will be recognized at the podium during the appropriate sessions or events, and will also be identified in meeting program materials, the *NABP Newsletter*, on meeting signage, and on the NABP Web site at [www.nabp.net](http://www.nabp.net). 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 e-mail at [custserv@nabp.net](mailto:custserv@nabp.net) or via phone at 847/391-4406. ☺

## Pre-Order Your 2014 Survey of Pharmacy Law Today

Serving as a convenient reference source for individuals seeking an overview of the laws and regulations that govern pharmacy practice in 53 jurisdictions, the updated 2014 *Survey of Pharmacy Law* will be available in mid-December. Interested individuals may now get a head start to their purchase by pre-ordering a copy on the NABP Web site.

The *Survey*, produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure

Requirements, asks if criminal history record checks are required for wholesale distributors. In addition, two new questions were added to Section 30, Census Data, and ask the number of pharmacy interns and the number of medical oxygen distributors in the state.

Updates for the 2014 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession

of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

The *Survey* can be purchased online for \$195 by visiting the Publications section of the NABP Web site at [www.nabp.net/publications](http://www.nabp.net/publications). Individuals that pre-order the *Survey* will be mailed their copy in mid-December.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey*, please contact Customer Service via phone at 847/391-4406 or via e-mail at [custserv@nabp.net](mailto:custserv@nabp.net). ☺

## September FPGEE Score Results Are Now Available at NABP.net; Next 2014 Administration to Be Held in April

Score results from the September 30, 2013 administration of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) are now available for candidates on the NABP Web site.

The next FPGEE will be administered on April 28, 2014. NABP will open FPGEE registration for the April administration on January 7, 2014, and Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) candidates will

have until April 14, 2014, to register. Candidates must register for the examination on the NABP Web site before they can choose a location to take the FPGEE. Within a few days after registering, candidates will be e-mailed an Authorization to Test, and they may then schedule their test location with the NABP test vendor, Pearson VUE. The deadline to schedule a test location with Pearson VUE is April 21, 2014.

The FPGEE is one component required as

part of the FPGEC Certification Program. NABP developed the FPGEC as a means of documenting the educational equivalency of a candidate's foreign pharmacy education and foreign license and/or registration, which assists state boards of pharmacy in qualifying candidates for licensure in the United States.

To prepare for the FPGEE, NABP recommends that candidates take the Pre-FPGEE®, the only FPGEE practice examination writ-



ten and developed by NABP. This practice examination is designed to help familiarize applicants with the FPGEE by exhibiting the types of questions provided on the actual examination.

Additional information on the FPGEE as well as the Pre-FPGEE is available at [www.nabp.net/programs](http://www.nabp.net/programs). 

## NABP to Convene Spring 2014 MPJE Item-Development Workshop

Board of pharmacy members selected as volunteer item writers for the Association's Multistate Pharmacy Jurisprudence Examination® (MPJE®) will be invited to NABP Headquarters for an item-development workshop, which will be held on March 20-21, 2014. Attendees will have travel, lodging, and ancillary expenses paid by NABP and will receive detailed instructions and training materials describing the item-writing process and content-related requirements for the MPJE. At the workshop, writers will develop new test items that will be considered for inclusion in the MPJE.

The MPJE combines federal and state-specific questions that test an individual's knowledge in

pharmacy jurisprudence and covers the following areas:

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

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

### How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form available on the NABP Web site at [www.nabp.net/meetings/examination-meetings](http://www.nabp.net/meetings/examination-meetings), and upload a current résumé or curriculum vitae.

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

For more information about item writing, contact NABP at [NABP\\_Comp\\_Assess@nabp.net](mailto:NABP_Comp_Assess@nabp.net). 



### State Boards Convene to Review MPJE Items

Mary Inguanti, RPh, MPH, FASCP, member (left) and Kris Nasinnyk, RPh, drug control agent (right), both of the Connecticut Commission of Pharmacy, review items on the Multistate Pharmacy Jurisprudence Examination®, at NABP Headquarters September 11, 2013.



## AWAR<sub>x</sub>E Social Media Campaigns Aim to Increase Awareness of Prescription Drug Abuse Prevention; First Twitter Event Held

As part of the AWAR<sub>x</sub>E® “Keep the Holidays Merry – Move Your Medications” campaign, the program launched its new Twitter handle @AWAR<sub>x</sub>ERx and used this and other social media outlets to help inform consumers about prescription drug safety issues. The social media campaign kicked off with a Twitter party on November 14, 2013, where 119 interested users of the popular social media platform participated in a discussion on prescription drug abuse dangers and prevention efforts. While the Twitter party was an exciting event, it covered a serious, sometimes somber topic: securely storing and properly disposing of prescription drugs in order to keep your family safe from misuse during the holidays.

Over 1,600 tweets were sent on these topics, reaching more than 123,000 people.

AWAR<sub>x</sub>E’s social media campaign aims to increase awareness of prescription drug safety, and to remind those who will be hosting holiday events for loved ones that prescription drugs, especially pain pills, stimulants, and tranquilizers, should be removed from medicine cabinets and other easily accessible spots and securely stored out of reach to prevent abuse, misuse, and accidental ingestion.

In addition to the Twitter

party, the campaign includes an audio public service announcement (PSA) on Pandora Internet Radio that will air from November 26, 2013 through December 26, 2013, and will raise awareness about the danger of medications falling into the wrong hands. The PSA provides information about safe disposal methods for unneeded prescription drugs. In addition, banners displaying on both Pandora .com and Yahoo .com raise awareness and link back to [www.AWARERX.ORG](http://www.AWARERX.ORG) so that consumers can learn more. These PSAs will potentially reach millions of Internet users with the AWAR<sub>x</sub>E Web site just a click away. Pandora.com has over 50 million unique visitors per month, and Yahoo.com, 160 million unique visitors per month. A large portion of visitors to both Web sites include moms in the “sandwich generation,” a key audience for the AWAR<sub>x</sub>E message, since they are often providing care for their parents as well as their children.

To further spread information about prescription drug abuse, AWAR<sub>x</sub>E will continue its blogger outreach efforts in an effort to prompt interviews with popular bloggers that focus on parenting, senior living, and caregiving.

With Substance Abuse and Mental Health Services Administration’s (SAMHSA) latest data revealing that 54% of prescription drug abusers got the drugs from family or friends for free, the AWAR<sub>x</sub>E campaign brings timely messages to consumers. According to SAMHSA’s 2012 National Survey on Drug Use and Health report, 6.8 million people over the age of 12 admitted to non-medical use of prescription drugs within the last month. Prescription drugs continue to be among the most abused controlled substances.

### Community Outreach

AWAR<sub>x</sub>E also continues to educate and raise aware-

ness at the local level by providing flyers and other materials for awareness events, and by delivering presentations to students, seniors, civic groups, and health care organizations. Fall presentations throughout the state of Illinois included:

- Bloomingdale Neighborhood Watch Meeting, Bloomingdale, IL, September 18, 2013
- Streamwood Community Beat Meetings, Streamwood, IL, October 14 and October 22, 2013
- Lions Club of Elk Grove Village, Elk Grove, IL, October 16, 2013



Throughout the 2013 holiday season, AWAR<sub>x</sub>E® banners, featured on Pandora.com and Yahoo.com, will link to AWAR<sub>x</sub>E public service announcements (PSA) that will display through a Windows Media Player. The PSAs, as shown above, aim to increase awareness of prescription drug safety and to remind individuals hosting holiday parties to securely store or dispose of medications to keep their loved ones safe.

# NABP Releases Report Stressing the Global Health Threat by Rogue Online Drug Sellers, Continues Outreach to Key Stakeholders

In an October 2013 report, NABP stressed the continuing global public health threat posed by unapproved drug products distributed via the Internet. As detailed in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: October 2013*, most rogue online drug sellers recently identified and reviewed by NABP offer foreign drug products or medications not approved by the United States Food and Drug Administration (FDA), as do nearly half of all rogue sites NABP has reviewed since 2008. Global stakeholders – including regulators, public health organizations, and private entities – agree that drug products failing to meet national regulatory safeguards place patient health at risk. NABP and its member state boards of pharmacy continue to encourage and work with federal regulators and other public and private entities to educate the public about the dangers of unapproved drugs and other risks of buying medications from rogue Internet drug sellers.

Because many unapproved drugs fraudulently bear trademarked brand names, issues of intellectual property (IP) complicate international debates about how to stop their distribution. The report included an overview of perspectives from US regulators and various international regulatory bodies and public entities.

Both US and international stakeholders agree that medications not approved by national authorities, or circumventing approved distribution channels, pose dangers to patients. For example, the World Health Organization indicates that “spurious/falsely labelled/falsified/counterfeit” medical products can result in “treatment failure or even death.” The United Nations Office on Drugs and Crime, while distinguishing between drugs that violate IP rights and fraudulent drugs with dubious contents, notes that, for “the consumer, the results are the same.”

As indicated in the October report, “Regardless of the terminology used to describe them, drug products that circumvent supply chain safeguards place patients at risk.” Two safeguards often bypassed by rogue online sellers are sourcing medications from drugmakers that use current Good Manufacturing Practices and sourcing medications from licensed wholesale distributors. Instead, drugs subject to poor quality controls, unregulated trade zones, and rogue wholesalers are frequently distributed by rogue sites, as highlighted in the report.

As presented in the report, NABP identified an additional 109 rogue Web sites that are operating out of compliance with pharmacy laws and practice standards, bringing the total number of rogue Internet drug outlets

identified to 10,288. Of the recently identified 109 rogue sites, 84 (77%) offer foreign or non-FDA-approved medications – mostly fraudulent knockoffs of trademarked brand-name drugs – placing consumers at risk of receiving unsafe and ineffective drugs. In addition, 98% of the 84 sites do not require a valid prescription, creating the potential for dangerous drug interactions and other health risks.

In addition, the report indicated that nearly 97% of the total sites reviewed operate out of compliance with US pharmacy laws and practice standards and those of many other developed countries, and are listed as Not Recommended on the AWARE<sub>X</sub>E<sup>®</sup> Web site at [www.AWAREX.ORG](http://www.AWAREX.ORG). The 10,288 Internet drug outlets currently listed as Not Recommended are characterized as follows:

- 5,017 (49%) offer foreign or non-FDA-approved drugs
  - 9,064 (88%) do not require a valid prescription
  - 2,394 (23%) have a physical address located outside of the US, and most (62%) rogue sites post no address whatsoever
  - 1,638 (16%) do not have secure sites, exposing customers to financial fraud and identity theft
- To help US consumers find the safest sources for purchasing medicine online, NABP developed the VIPPS<sup>®</sup> (Verified Internet Pharmacy

Practice Sites<sup>CM</sup>) accreditation program. Consumers are encouraged to look for the VIPPS Seal on an accredited site and check NABP’s list of accredited sites on the AWARE<sub>X</sub>E Web site.

Detailed findings on the characteristics of rogue Web sites are available in the full report and are also highlighted in an infographic available at [www.AWAREX.ORG/get-informed/safe-acquisition/not-recommended-sites](http://www.AWAREX.ORG/get-informed/safe-acquisition/not-recommended-sites).<sup>®</sup>



To raise awareness about the deceptive practices of rogue Web sites, NABP presented the above infographic as part of the October 2013 report. The infographic may be found in the Get Informed section of the AWARE<sub>X</sub>E<sup>®</sup> Web site.

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### **NAR<sub>x</sub>CHECK**

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Attendees of the meeting included representatives of the Centers for Disease Control and Prevention, Drug Enforcement Administration, and the Substance Abuse and Mental Health Services Administration. NABP also presented information at the Midwest Injury Prevention Alliance's conference on October 1, 2013, on the NABP PMP InterConnect® program and NAR<sub>x</sub>CHECK.

Most recently, NABP was part of a panel discussion at the American Medical Informatics Association's (AMIA) Annual Symposium on November 16-20, 2013, in Washington, DC, where NABP presented on the NAR<sub>x</sub>CHECK integration success stories from pilots in Indiana. This presentation was selected by AMIA over several entries seeking to present at the conference.

NAR<sub>x</sub>CHECK is currently only configured

to work with select state PMPs. However, programming to allow access to participating states' PMP data via the NABP InterConnect is nearly complete, which will streamline deployment nationwide and ultimately lead to the capability to provide NAR<sub>x</sub>CHECK scoring based on multistate PMP data. NAR<sub>x</sub>CHECK is currently available as a subscription-based service to health care providers either registered with PMPs in participating NABP

InterConnect states, or agreeing to ensure compliance with PMP laws and regulations when providing access to users. Subscription revenues are intended to be used to continue support to state PMPs to enable their participation in the NABP InterConnect, and to support PMPs in achieving the mission to protect public health.

More information about NAR<sub>x</sub>CHECK may be found at [www.narxcheck.com](http://www.narxcheck.com). ☺

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### **Surveyor Training**

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that require, for example, verification that – through meticulous policy review and survey processes – appropriate standards and procedures are in place.

Their collective skills and expertise are instrumental in helping NABP to tailor its services to meet the needs and specifications of each survey conducted.

### **Sterile Compounding Training**

On October 9, 2013, 60 compliance officers from 38 boards of phar-

macy joined the NABP surveyors for the overview of USP Chapter <797> standards and compliance regulations presented by CriticalPoint staff. After this session, compliance officers and those NABP surveyors who perform surveys at compounding pharmacies continued on to receive specialized training on inspecting sterile compounding pharmacies. Additional sessions focused on changes to compliance standards and regulations, and detailed training on both personnel and facility metrics.

The last day of training focused on sterilization and quality assurance procedures, inspection algorithms, and how to conduct inspections. The training session ended with a question-and-answer session where the attendees were given the opportunity to receive answers to questions submitted throughout the training.

NABP provided each member board with the resources to send one compliance officer to the training focused on sterile compounding inspections. Some boards chose to utilize their own

resources to send more than one compliance officer.

CriticalPoint also offers free, online sterile compounding training programs through the State Board Assist program. For more information on this online service, contact the NABP Executive Office at [exec-office@nabp.net](mailto:exec-office@nabp.net).

NABP will continue to offer similar training and education to state boards of pharmacy as they work to regulate the practice of pharmacy and for the protection of public health. ☺

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### **Verified Pharmacy Program**

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VPP and related issues at the NABP Interactive Executive Officer Forum on September 24-25, 2013. (See pages 208-211.)

The Association will continue initiatives and outreach, such as compliance programs, training, and education programs, to further support member boards in their efforts to ensure the safety of compounded medications.

While application and inspection fees for VPP were set to cover the costs of administering the program, if any excess revenue is generated, it will be reinvested in such initiatives.

An overview of VPP is available in the September

2013 *NABP Newsletter* and in the Programs section of the NABP Web site. Additional information about the Iowa inspection program is provided in the May 2013 *NABP Newsletter* and the June-July 2013 *NABP Newsletter*. ☺

## Missouri Implements New Rules for Records and Prescription Requirements

The Missouri Board of Pharmacy recently revised rules pertaining to non-electronic manual prescription records, prescription requirements, electronic prescription records, and electronic record-keeping systems.

The new rules became effective on August 30, 2013, and are available online at <http://pr.mo.gov/pharmacists-rules-statutes.asp>. Some of the changes include:

- **Non-Electronic Manual Prescription Records (20 CSR 2220-2.017):** Pharmacies that maintain manual prescription records are required to document the identity of the pharmacist responsible for verifying the accuracy of prescription data on each original prescription as well as the pharmacist responsible for verifying the final product prior to dispensing, if different. When additional refills are added to the prescription, the method and source of the authorizing person must be documented in the manual record on the prescription hard copy.
- **Prescription Requirements (20 CSR 2220-2.018):** Rule language was updated to only reference prescription requirements. The rule also clarified that prescriptions for animal use must include the

animal's species and the owner's name to be valid for dispensing.

- **Electronic Prescription Records (20 CSR 2220-2.080):** Pharmacies maintaining an electronic prescription record must document the pharmacist responsible for verifying the accuracy of prescription data on each original prescription as well as the pharmacist responsible for verifying the final product prior to dispensing, if different. Requirements for documenting and maintaining copies of prescriptions were also revised. In addition, the Board removed the requirement that a pharmacist maintain a bound logbook or pharmacist signature log to verify prescription information entered into the electronic record was accurate. Pharmacies' electronic prescription record must now identify the pharmacist responsible for verifying the accuracy of prescription data on each original prescription. The Board noted that licenses are still required by federal law to maintain a logbook or a signed printout for verifying controlled substance refill data.
- **Electronic Record-Keeping Systems (20 CSR 2220-2.083):** This rule allows pharmacies that have an electronic record-keeping system to maintain digitized images of a prescription in

lieu of maintaining a prescription hard copy.

## Oregon Updates Immunization Protocols

Oregon's online ALERT Immunization Information System (ALERT IIS) is an important tool for all vaccine providers, especially community pharmacists who often do not have access to comprehensive patient records beyond individual pharmacy profiles. Most immunizations that are given in Oregon are stored in ALERT IIS, which provides authorized users access to millions of patient vaccination histories. By using the ALERT IIS, Oregon pharmacists can avoid immunizing patients with redundant vaccines and also learn what vaccines patients will need in the future.

The Oregon State Board of Pharmacy and the Oregon Immunization Program have worked together to include the use of these ALERT IIS functions in the Pharmacy Protocols for Immunization. The effective date for this protocol change is no later than January 1, 2014, although pharmacies are encouraged to begin using the ALERT IIS as soon as possible.

The new language that appears in each protocol is as follows:

Effective no later than January 1, 2014, prior to administering a vaccine, pharmacy personnel will look up each patient in the ALERT Immunization Information System (IIS) to determine the patient's vaccine history and to forecast vaccines needed.

Exceptions:

- This is not required when administering only influenza vaccines, but will continue to be recommended to help increase pneumococcal vaccine rates.
- This is not required when the pharmacy/pharmacist conducts a remote vaccine clinic, but will continue to be recommended when remote connectivity is available.

The revised protocols are available online at <http://public.health.oregon.gov/prevention/wellness/vaccinesimmunization/immunizationprovider/resources/pages/pharmpro.aspx>.

## Alabama Completes Database Conversion

In May 2013, the Alabama State Board of Pharmacy ended its contract with the company that provided its data support system for all office functions, e-mail, and Web support for the previous three years and began a new contract with GL Solutions, a company that works exclusively with government offices. Though the changeover meant new screens, different methods of organizing data, and the inevitable "new way of doing things," the process was successful. All data converted is intact, though it may have a new look. The Board also adopted a new support system for its e-mail and Web site. One of the Board's next steps will be to change the appearance of the Web site. ☺

## Around the Association

### Executive Officer Changes

- **Donna Burns** is now serving as the licensing examiner of the Alaska Board of Pharmacy replacing Mary Kay Vellucci.
- **Chris Gassen, PharmD**, is now serving as the program director of the Colorado State Board of Pharmacy replacing Wendy Anderson, RPh. Prior to this position, Gassen served as the Board's pharmacy inspector from 2001 to 2006. He is also currently licensed as a pharmacist in both Kansas and Colorado. Gassen received his bachelor of science degree in pharmacy and his doctor of pharmacy degree from the University of Kansas School of Pharmacy.
- **David Sencabaugh, RPh**, is now serving as the executive director of the Massachusetts Board of Registration in Pharmacy. Prior to this position, Sencabaugh served as director of pharmacy professional services at Stop & Shop and Giant Pharmacy from 2007 to 2013 and as senior director of professional affairs at Brooks Eckerd Pharmacy from 1991 to 2007. Senca-

baugh received his bachelor of science degree in pharmacy from the Massachusetts College of Pharmacy and Health Sciences.

### Board Member Appointments

- **Kevin Robertson, PharmD**, has been appointed a member of the Arkansas State Board of Pharmacy. Robertson's appointment will expire June 30, 2019.
- **Mary Jo Keefe, RPh**, has been appointed a member of the Hawaii State Board of Pharmacy. Keefe's appointment will expire June 30, 2017.
- **Kerri Okamura, RPh**, has been appointed a member of the Hawaii State Board of Pharmacy. Okamura's appointment will expire June 30, 2017.
- **Diane Milano, RPh**, has been appointed a member of the Louisiana Board of Pharmacy. Milano's appointment will expire June 30, 2019.
- **Kishor Mehta** has been appointed a public member of the Pennsylvania State Board of Pharmacy. Mehta's appointment will expire September 24, 2014.
- **Terry Blackmon, RPh**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Blackmon's

appointment will expire June 30, 2018.

- **Marvin Hyatt, RPh**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Hyatt's appointment will expire June 30, 2019.
  - **Spencer Morris, PharmD, BCPS**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Morris's appointment will expire June 30, 2018.
  - **Robert Dickenson, MBA, DPh**, has been appointed a member of the Tennessee Board of Pharmacy. Dickenson's appointment will expire July 16, 2019.
  - **Philip Trapskin, PharmD**, has been appointed a member of the Wisconsin Pharmacy Examining Board. Trapskin's appointment will expire July 1, 2017.
  - **Cathy Winters, RPh**, has been appointed a member of the Wisconsin Pharmacy Examining Board. Winters' appointment will expire July 1, 2017.
- ### Board Member Reappointments
- **Gregory Lippe, CPA**, has been reappointed a public member of the California State Board

of Pharmacy. Lippe's appointment will expire June 1, 2016.

- **Deborah Veale, RPh**, has been reappointed a member of the California State Board of Pharmacy. Veale's appointment will expire June 1, 2017.
- **Donald Johnson, RPh**, has been reappointed a member of the Colorado State Board of Pharmacy. Johnson's appointment will expire July 1, 2017.
- **William John Cover, RPh**, has been reappointed a member of the Indiana Board of Pharmacy. Cover's appointment will expire June 30, 2017.
- **James Garrelts, PharmD, FASHP**, has been reappointed a member of the Kansas State Board of Pharmacy. Garrelts' appointment will expire April 30, 2017.
- **David Schoech, RPh**, has been reappointed a member of the Kansas State Board of Pharmacy. Schoech's appointment will expire April 30, 2017.
- **Ken Wells, RPh**, has been reappointed a member of the Oregon State Board of Pharmacy. Wells' appointment will expire June 30, 2017.

(continued on page 222)

**Reminder: Use Only Licensed Wholesalers, Including VAWD-Accredited Distributors**

To ensure that patients are receiving safe, Food and Drug Administration (FDA)-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the United States as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm).

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the NABP Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP’s VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to imple-

ment other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria respond to changing business models and help safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit [www.nabp.net/programs/accreditation/vawd](http://www.nabp.net/programs/accreditation/vawd).

**FDA Reminds Health Care Providers to Not Use NuVision Pharmacy Products**

After NuVision Pharmacy refused FDA’s most recent request to recall all of its sterile products, the agency issued a reminder on August 16, 2013, for health care providers to not use NuVision sterile products. This reminder was an update to a May 18, 2013 notice recommending health care providers quarantine all NuVision sterile products, and stop giving them to patients. In April 2013, NuVision recalled

methylcobalamin injection and lyophilized injection products citing concerns about sterility in the wake of adverse event reports of “fever, flu-like symptoms, and soreness of the injection site” associated with the methylcobalamin injection product. FDA reports that it is not aware of adverse events related to any other NuVision products, but pursued a recall of all sterile products produced by the company in order to ensure the safety of public health. The full news release is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm365402](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm365402).

**FDA: Fluoroquinolone Drug Labels Must Provide Better Descriptions of Peripheral Neuropathy**

In 2013, FDA updated its label requirements for fluoroquinolone-based medications, including levofloxacin (Levaquin®), ciprofloxacin (Cipro®), moxifloxacin (Avelox®), norfloxacin (Noroxin®), ofloxacin (Floxin®), and gemifloxacin (Factive®), to require a more detailed description of a rare but serious side effect: peripheral neuropathy. The reason for the change, the agency said, is that “the potential rapid

onset and risk of permanence were not adequately described.”

Peripheral neuropathy is a nerve disorder occurring in the arms or legs. Symptoms include pain, burning, tingling, numbness, weakness, or a change in sensation to light touch, pain, temperature, or the sense of body position. It can occur at any time during treatment and can last for months or even years after a patient stops taking the drug. In some cases, FDA added, it can be permanent.

Health care providers should be certain that patients receive a medication guide with every prescription, and that they know the risks and the symptoms. If symptoms develop, the fluoroquinolone should be stopped, and the patient should be switched to another, non-fluoroquinolone antibacterial medication unless the benefit of continued treatment with the fluoroquinolone outweighs the risk. FDA encourages health care providers to report adverse events or side effects to the MedWatch Safety Information and Adverse Event Reporting Program. The FDA Safety Announcement is available at [www.fda.gov/Drugs/DrugSafety/ucm365050](http://www.fda.gov/Drugs/DrugSafety/ucm365050). ©



**Newly Approved e-Advertisers**

The following entities were granted approved e-Advertiser status through the NABP e-Advertiser Approval<sup>CM</sup> Program:

Clickverge, LLC, dba Chewy.com  
[www.chewy.com](http://www.chewy.com)

GoodRx  
[www.GoodRx.com](http://www.GoodRx.com)

HB Ventures, LLC, dba Portico Pharmacy  
[www.porticopharmacy.com](http://www.porticopharmacy.com)

A full listing of NABP approved e-Advertisers is available on the NABP Web site at [www.nabp.net](http://www.nabp.net). ©

Around the Association

(continued from page 220)

- Janice Bird, CPhT, has been reappointed a member of the Utah Board of Pharmacy. Bird's appointment will expire June 30, 2017.
Andrea Kemper, PharmD, has been reappointed a member of the Utah Board of

Pharmacy. Kemper's appointment will expire June 30, 2017.

Board Officer Changes

The Arkansas State Board of Pharmacy has elected the following officers to the Board:

- Joseph Steve Bryant, PD, President
Phillip Justin Boyd, MBA, PharmD, Vice President

- Lenora Newsome, PD, Secretary

The Delaware State Board of Pharmacy has elected the following officers to the Board:

- Joli Martini, RPh, President
Kimberly Robbins, RPh, Vice President

The Florida Board of Pharmacy has elected the following officers to the Board:

- Albert Garcia, BPharm, MHL, Chairperson
Jeffrey Mesaros, PharmD, JD, Vice Chairperson

The Oregon State Board of Pharmacy has elected the following officers to the Board:

- Penny Reher, RPh, President
Dianna Pimlott, RPh, Vice President



Newly Accredited DMEPOS Facility

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

Santa Maria Pharmacy
Perth Amboy, NJ

A full listing of the nearly 550 accredited DMEPOS companies representing nearly 27,500 facilities is available on the NABP Web site at www.nabp.net.



Newly Accredited VAWD Facilities

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

- American Regent, Inc, Shirley, NY; Luitpold Pharmaceuticals, Inc, Shirley, NY; Perrigo Pharmaceuticals Company, Duncan, SC
Bound Tree Medical, LLC, Clifton Park, NY; Medline Industries, Inc, Salt Lake City, UT

A full listing of more than 540 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.

## Task Force on Pharmacy Licensure Standards Convenes

The Task Force on Pharmacy Licensure Standards convened at NABP Headquarters on October 14-15, 2013, to develop a uniform inspection form in an effort to assist states with the inspection of resident and nonresident pharmacists. During this meeting, task force members reviewed existing state pharmacy inspection forms, reviewed relevant language from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, discussed consistent state requirements to structure a uniform inspection form, and recommended amendments to the *Model Act*. ©



Front row pictured from left to right: Gayle Cotchen, MBA, PharmD, RPh, Pennsylvania State Board of Pharmacy; Stephanie McAntee, CPhT, Wyoming State Board of Pharmacy; Joanne Trifone, RPh, Massachusetts Board of Registration in Pharmacy (chairperson); Virginia “Giny” Herold, MS, California State Board of Pharmacy; and Donna Horn, DPh, RPh, Massachusetts. Back row pictured from left to right: Ken Saunders, PharmD, RP, TTS, Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit; Cody Wiberg, PharmD, MS, RPh, Minnesota Board of Pharmacy; Michael Podgurski, RPh, Pennsylvania; William John Cover, RPh, NABP Executive Committee liaison; Mark Hardy, PharmD, RPh, North Dakota State Board of Pharmacy; and Doug Lang, RPh, Missouri.

### Registration Deadline Approaching to Participate in the March 31 to April 25 PCOA Testing Window!

The deadline for schools and colleges of pharmacy to register their students for the next available Pharmacy Curriculum Outcomes Assessment® (PCOA®) testing window (March 31 to April 25) is **December 31, 2013**.

Interested schools and colleges that would like to participate in the March 31 to April 25 testing window are encouraged to contact Gene Johannes, examination program operations manager, at 847/391-4429 or via e-mail at [gjohannes@nabp.net](mailto:gjohannes@nabp.net).

Appropriate for administration to students in all professional years, the PCOA is an excellent resource for pharmacy educators as they review pharmacy curricula and assess student performance.

More information, including registration materials and future testing windows, is available on the NABP Web site at [www.nabp.net/programs/assessment/pcoa](http://www.nabp.net/programs/assessment/pcoa). ©





## nabp newsletter

National Association of Boards of Pharmacy  
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### Save the Date for the 110<sup>th</sup> Annual Meeting!

NABP 110<sup>th</sup> Annual Meeting  
May 17-20, 2014  
Sheraton Phoenix Downtown Hotel  
Phoenix, AZ

Photo courtesy of Greater Phoenix Convention and Visitors Bureau and ©peterjordanphoto.com

Join us in Phoenix, AZ, for the NABP 110<sup>th</sup> Annual Meeting! The Annual Meeting offers attendees the opportunity to assist in shaping the future direction of NABP by participating in important business sessions during which officers and members of the NABP Executive Committee are elected and resolutions are voted upon. The meeting also provides Accreditation Council for Pharmacy Education-accredited continuing pharmacy education programs and networking opportunities. More information will be available in future issues of the *NABP Newsletter* and in the Meetings section of the NABP Web site at [www.nabp.net/meetings](http://www.nabp.net/meetings).