NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS

Updates, New Insights

Help Guide State Implementation of DSCSA

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INNOVATIONS
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EXECUTIVE COMMITTEE

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

Mark Hardy, PharmD, RPh,
Executive Director,
North Dakota State
Board of Pharmacy

Mark Hardy, Executive Director, North Dakota State Board of Pharmacy

- **How long have you served as executive director of the North Dakota State Board of Pharmacy? What was your role prior to working with the Board?**

  I have been working with the North Dakota Board for over five years now, serving as executive director since August 2014. I first began as assistant executive director. Prior to serving with the Board, I worked with a regional chain, Thrifty White Pharmacy, where I spent time practicing pharmacy in rural areas of North Dakota and Minnesota.

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

  The Board has been tackling some pretty multifaceted issues, such as prescription drug abuse, naloxone prescribing, and emergency scheduling of controlled substances, including bath salts and synthetic cannabinoids. The Board has also been strengthening its process in the operation of the North Dakota Prescription Drug Monitoring Program (PDMP).

- **What actions were taken by the Board to address these issues?**

  In an effort to tackle prescription drug abuse, the Board is in continuous operation of its PDMP. We work closely with our vendor, Appriss, Inc, to address needed upgrades for the software and maintain our connection to NABP PMP InterConnect®. The Board has also been expanding its rules to grant prescriptive privileges for naloxone to pharmacists in North Dakota. Also, the Board has partnered with the Yellow Jug Old Drugs Program to provide an option for the safe disposal of prescription drug medications. The Board has generously provided these systems and containers to eligible pharmacies in North Dakota.

- **What other key issues has the Board been focusing on?**

  The Board has been keeping an eye on key issues with the drug supply chain and compounding to ensure public safety.

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

  I think it's important to listen to the market and pay attention to what others in the practice of pharmacy are doing and survey their strategies to ensure the public's protection. Also, I encourage boards to utilize NABP as a resource. The North Dakota Board has been using NABP services for some time now, such as the Verified-Accredited Wholesale Distributors® program, Verified Pharmacy Program®, and NABP PMP InterConnect®. Allowing us to rely on NABP has provided the Board an opportunity to focus and handle other issues. ■

North Dakota State Board of Pharmacy

Number of Board Members: 5 pharmacist members, 1 public member, and 1 pharmacy technician member

Number of Compliance Officers/Inspectors: 4

Rules and Regulations Made by: State Board of Pharmacy

Number of Pharmacist Licensees: 2,319

Number of Pharmacies: 867

Number of Wholesale Distributors: 89 (in-state)

What Came First, the License or the Licensee?

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

Regulatory boards are often faced with the issue of whether they have legal authority (jurisdiction) to administratively prosecute and, if warranted, sanction persons who do not have a current license to practice the regulated profession within their state. Failure to maintain a current license may be the result of numerous circumstances, ranging from practitioners who were once licensed but no longer maintain the governmentally issued credential to persons who have never been licensed to practice the profession.

Licensed persons and entities are clearly subject to the jurisdiction of the relevant regulatory board and are subject to administrative prosecution. Many boards, however, lack the authority to administratively prosecute unlicensed persons, leaving the public protection responsibilities to the criminal prosecution authorities, who may or may not initiate actions based upon numerous factors.

Criminal prosecutions are undertaken at the discretion of the state's attorney's office and are subject to prioritization based upon budgetary constraints and numerous other criteria that may or may not stimulate action. Further, the burden of proof of beyond a reasonable doubt in criminal prosecutions exceeds the burden of proof of a preponderance of the evidence (or clear and convincing evidence in some states) in an administrative prosecution. This higher burden may act as a deterrent to criminal prosecutions.

Determining the legal basis for a board to exercise jurisdiction over a respondent is not always easily interpreted. Whether a person is deemed to have a license may, in some states, dictate whether the board has the authority to administratively act. Some boards of pharmacy do not have the authority to administratively prosecute unlicensed persons. Questions arise as to what legal rights exist for both the board and licensee if that licensee does not renew the license. Further, how are retired licenses, surrendered licenses, inactive licenses, and so forth treated? How does the board communicate with such "former" licensees? Consider the following.

A complaint was filed against a physician (Physician) licensed by the Tennessee Board of Medical Examiners (Board). Per the statutory structure in Tennessee, the Board operates under the Tennessee Department of Health (Department). In November 2013, after the investigation was completed, the assistant general counsel for the Department informed the Physician by letter of the complaint and results of the investigation. The letter also informed the Physician of the Department's intent to initiate formal administrative charges and provided him with an opportunity to show compliance with the law. The letter informed the Physician of his right to enter into a consent order, which called for a probationary period, civil and administrative penalties, and a requirement of identified continuing education.

Rather than accepting the offered consent agreement, the Physician "retired" his license by submitting an "Affidavit of Retirement from Practice" as allowed under Tennessee law. The Board acknowledged the receipt of the affidavit, recognized the placement of his license in retirement status, and informed the Physician of his rights to reinstatement. Upon notice by the Physician to the Department of his

retirement status, the Department responded, informing the Physician that the retirement status of his license would not dispose of the pending charges against him.

The Department again offered to resolve the matter under a consent order. These offers were again rejected. Thus, in December 2013 the Department filed formal administrative charges against the Physician and sent notices via United States mail, return receipt requested, to his last known address identified on his renewal application and his work address in Florida. In addition, the Department sent the notice of charges to his email address. The return receipts on the letters to his employers were returned signed by other parties. The return receipt sent to his home address was never returned. However, in response, the Physician did write to the Tennessee governor and attorney general, a reporter, the members of the Board, and the commissioner of the Department objecting to the Notice of Charges based upon subject matter jurisdiction, personal jurisdiction, insufficiency of notice, and insufficiency of service. In a formal filing with the Department, the Physician filed a motion to strike the charges, arguing that the Board "is only authorized to hold hearings upon licensed doctors in the state of Tennessee who are currently practicing in Tennessee."

In January 2014, the Board and an administrative judge conducted a contested hearing. The Physician did not appear, and the hearing was conducted uncontested. After the record was established, the Board concluded that it had jurisdiction over the license, whether it be retired or relinquished for whatever reason. It held that the Physician failed to oversee advanced practice nurses at his unlicensed pain clinic, failed to review charts of patients prescribed controlled substances, failed to develop oversight protocols, failed to make on-site visits, allowed his Drug Enforcement Administration number to be used by nurse practitioners, and voluntarily surrendered his DEA certificate in January 2013. The Board revoked his license and conditioned his reinstatement on certain stipulations. The Board also assessed a civil penalty of $4,500. The Chancery Court affirmed the Board decision, and the Physician appealed.

The Physician argued that the Board lacked personal jurisdiction over him by virtue of the fact that he lived in Florida. He also argued that the service of process by mail was insufficient to notify him of and subject him to the authority of the Board. The court first noted that board authority over the person can be based upon specific and general jurisdiction. Specific jurisdiction focuses on the cause of action, the defendant/respondent, and the forum, while general jurisdiction focuses on the continuous and systematic contacts between the defendant/respondent and the forum. In the current case, the court determined it had no difficulty in concluding that the Board has specific jurisdiction over the Physician. The Physician established significant contact with the state by applying for, receiving, and renewing his medical license and by practicing medicine in Tennessee.

> **"Determining the legal basis for a board to exercise jurisdiction over a respondent is not always easily interpreted."**

Regarding service of process, the court also found in favor of the Board. It held that service via US Postal Service certified mail was sufficient to effectuate notice on the Physician in spite of the fact that the certified mail return receipt to his identified home address was never signed and returned. The court held that the statute does not specify the need for the return receipt to be signed. Additionally, the Physician was required to notify the Board of any change of address within 30 days. Further, notice was sent to additional addresses and elicited response letters and a motion to strike from the Physician.

The Physician also argued that service of the notice by mail violated his due process rights. The court rejected this proposition and held that due process does not require that a party "receive" notice, but does require that the government choose a method of delivery that is reasonably calculated to provide notice. Based upon the current circumstances and the multiple attempts to serve the Physician with notice, the court held that the Physician's due process rights were satisfied.

Finally, the Physician argued that his retired license divested the Board of the authority to take action against a "nonexistent" credential. The court easily rejected this argument and noted that the retired license does not negate its existence, but merely relieves the license holder from biennial renewal. Importantly, a retired license is subject to reactivation. Under the statutes, the Board has jurisdiction to sanction a retired license, and the selected sanctions were within the authority of the Board. Accordingly, the court upheld the lower court and affirmed the Board sanctions.

Boards of pharmacy must be aware of the legal consequences of differing licensure recognition. Retired, inactive, surrendered, and other licensure classifications may be used in an attempt to divest the board of the authority to protect the public. Ask yourself, does the board sanction the license or the licensee?

Wyttenbach v. Board of Tennessee Medical Examiners, 2016 Tenn App LEXIS 192 (App Ct TN 2016). ■

Executive Officers Encouraged to Attend Interactive Forum, Select Attendees to Participate in Member Forum

Offering opportunities for collaboration and networking, the NABP Interactive Forum series will return this fall. Held as two separate forums, the first will be tailored to board of pharmacy executive officers and will be held October 4-5, 2016. The second will be tailored specifically to board members and will be held November 30 and December 1, 2016.

The NABP Interactive Executive Officer Forum and the NABP Interactive Member Forum will each take place over two days. Both forums will also include presentations and discussions on timely and relevant topics developed from suggestions submitted by attendees in advance of the meetings.

Executive Officers

Each state board of pharmacy executive officer is invited to attend the NABP Interactive Executive Officer Forum. As with the previous forums, travel, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting.

> "Both forums will also include presentations and discussions on timely and relevant topics developed from suggestions submitted by attendees in advance of the meetings."

Members

The NABP Interactive Member Forum invites each executive officer to select one member from his or her board to attend the forum at no charge. Like the Executive Officer Forum, travel, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting. During the forum, attendees will have the chance to meet with their peers to discuss regulatory trends and challenges faced by their boards.

Participants of past forums have noted that the events allowed "free exchange of ideas" and an opportunity to "share one-on-one with other boards." The forum events were launched in 2010 as part of an initiative to provide additional support and resources to the member boards of pharmacy.

Information on registering for the Executive Officer Forum was sent to the board of pharmacy executive directors in mid-August. Executive officers will have the chance to name the Member Forum participant at the October Forum, and follow-up participation requests will be sent by late October. Both meetings will be held at the Loews Chicago O'Hare Hotel in Rosemont, IL.

The next Executive Officer Forum as well as a forum for board compliance officers and legal counsel are scheduled for fall 2017. For more information about the Interactive Forums, contact exec-office@nabp.net. ■

Stand Up and Be Counted to Advance Our Shared Mission

NABP Interactive Executive Officer Forum
October 4-5, 2016

NABP Shares Best Practices for Registries and Registrars to Address Illegal Online Drug Sellers at Global Summit

NABP encouraged registrars and registry operators to adopt practices for protecting consumers from potential harm caused by illegally operating websites at a recent Internet Corporation for Assigned Names and Numbers (ICANN) meeting. NABP's .Pharmacy TLD Program staff participated in the Global Domains Division Industry Summit for ICANN-accredited registrars and generic Top-Level Domain (TLD) registries in Amsterdam, Netherlands, and shared recommended best practices for reporting and investigating domain name abuses. The panel discussion, "Healthy Domains Initiative (HDI) and Industry Best Practices," also addressed criteria for submitting and responding to complaints about rogue online drug sellers and utilizing verified TLDs to improve patient safety.

Responding to Rogue Activity Complaints

The recommended best practices were developed by NABP and the health care cybercrime company LegitScript and are aimed to help reduce the number of frivolous complaints submitted to registrars, clarify to complainants what information should be included in a complaint, and identify the steps that should be taken by a registrar or registry in response to a qualifying complaint.

In addition, the best practices include a recommendation that, on receipt of a valid complaint from a trusted source, the registrar would notify the domain name holder and request a pharmacy license or other authorization to dispense prescription drugs in the jurisdictions to which the drugs are offered to be shipped. If a valid license is not provided, the registrar would suspend the domain name.

As another approach to ensure best practices for addressing illegal online drug sellers, the guidelines highlight the benefits of verified TLDs. The proposed best practices introduce the .pharmacy TLD as an example of how pre-registration verification and post-registration monitoring create trusted online environments for consumers. A TLD such as .pharmacy, wherein registrants are prescreened for legitimacy, is inherently safer to consumers and has minimal chance of abuse because of its restricted nature. In addition, a restricted, or verified, TLD facilitates internet pharmacy compliance because pharmacies operating within the .pharmacy TLD have been vetted and monitored for compliance with applicable laws. For these reasons, the guidelines encourage the promotion of verified TLDs as a public health strategy.

Illegal Online Drug Sellers – A Continued Public Health Threat

The prevalence of fake online pharmacies continues to challenge regulators and put consumers at risk. Sadly, NABP's findings that 96% of online drug outlets appear to be out of compliance with state and federal laws or patient safety and pharmacy practice standards have not changed much since the Association first began its research in 2008.

Each year, INTERPOL executes Operation Pangea to take down criminal networks behind the sale of fake medicine via illicit online drug sites. In 2015, 115 countries participated in Operation Pangea VIII, and more than 2,410 websites were taken offline. Two of the websites were linked to the sale of the potentially lethal and illicit diet drug 2,4-Dinitrophenol (DNP). Operation Pangea VIII also seized a record number of 20.7 million fake and illicit medicines, including blood pressure medication, erectile dysfunction pills, cancer medication, and nutritional supplements.

Illegal online drug sellers will continue to use the global nature of the internet to their advantage to attract consumers and evade law enforcement. Through its various programs, such as the .Pharmacy TLD Program, NABP will continue to be a vigilant protector of public health.

Further, just as NABP assisted boards of pharmacy with language for the inclusion of Verified Internet Pharmacy Practice Sites® in their rules and regulations in the early 2000s, staff will be developing model language that includes the .Pharmacy TLD Program and will make it available to boards for their 2017 legislative sessions to help states combat rogue online drug sellers.

For information about the .Pharmacy TLD Program, including a list of approved .pharmacy sites, visit *www.safe.pharmacy.* ■

> **"A TLD such as .pharmacy, wherein registrants are prescreened for legitimacy, is inherently safer to consumers and has minimal chance of abuse because of its restricted nature."**

Updates, New Insights

Help Guide State Implementation of DSCSA

Resources, Tools Available to Member Boards; States Weigh In

> **"NABP has resources and tools to help states implement the requirements of the DSCSA, facilitating the continued protection of the prescription drug supply chain and patient safety."**

The Drug Supply Chain Security Act (DSCSA), also referred to as Title II of the Drug Quality and Security Act (DQSA), is legislation that significantly affects the regulation of drug distribution. The DSCSA requires authorized trading partners within the prescription drug product supply chain to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. The system will improve detection and removal of potentially dangerous drugs (eg, counterfeit, stolen, and contaminated products) from the drug supply chain to protect US patients. NABP continues to offer state boards of pharmacy guidance on the regulation of wholesale distribution, the recategorization of third-party logistics providers (3PLs), and the standardization of DSCSA requirements across states to facilitate the distribution of drug products.

Although federal rules are not yet in place, to guide states through the federal requirements, NABP has provided live educational sessions and informational webinars to assist member boards. NABP continues to offer accreditation through its Verified-Accredited Wholesale Distributors® (VAWD®) program as a solution for the boards to ensure wholesale distributors, 3PLs, and other affected entities doing business in their state meet the continually evolving DSCSA regulations.

States Share Insights

During the NABP 112th Annual Meeting, NABP provided an informative continuing pharmacy education (CPE) session on the DSCSA. Representatives from three state boards of pharmacy – California, North Dakota, and Tennessee – led the session and presented on the legislative measures each state has taken to conform to the federal requirements. With the enactment of the DSCSA, part of the implementation process includes separate licensure categories for repackagers, wholesalers, and 3PLs in addition to the track and trace provisions and notification process required of licensees.

California State Board of Pharmacy Executive Director Virginia Herold, MS, discussed the actions taken by the Board to begin implementing the federal provisions of the DSCSA into the state's statutes. Although preempted by the DSCSA's text, the Board sought legislation to

repeal statutory provisions for California's electronic pedigree requirements that were set to take effect on a staggered basis starting January 1, 2015. This repealing legislation was enacted in 2014. The Board also withdrew pending regulations and stopped work on regulations needed for the electronic pedigree implementation.

Regarding the regulation of wholesalers and 3PLs, the DSCSA indicates that states cannot regulate 3PLs as wholesalers (section 584 of the DQSA). Thus, the California Board sponsored legislation in 2014 to license 3PLs and their designated representatives with separate licensure provisions; these provisions took effect on January 1, 2015. Further, Herold indicated that the state of California has moved to enforce the provisions of the federal product tracking and tracing. A small team of Board inspectors was formed to work on training and implementation for all inspectors.

In North Dakota, wholesale distributors are licensed under the state's Century Code 43-15.3, which has similar standards to many other states. North Dakota State Board of Pharmacy Executive Director Mark Hardy, PharmD, RPh, explained how the state regulates wholesale distributors with one license and that many subtypes of businesses are licensed under this category, including manufacturers, durable medical equipment facilities, and 3PLs. For eligible facilities, the Board has required (since the early 2000s) VAWD accreditation as a condition of licensure. Further, Hardy explained North Dakota has pedigree requirements that were set to go into place that were initially passed in the late 2000s and are similar to California's requirements as far as electronic track and trace, but because of the enactment of the DSCSA, those requirements were exempted.

Due to the passage of the DSCSA, North Dakota regulators had to incorporate provisions of the DSCSA into their state law regarding the licensure of 3PL facilities (since the DSCSA states 3PLs could not be licensed as wholesale distributors). Therefore, the North Dakota Board introduced Senate Bill (SB) 2086, which was passed by the legislature. SB 2086 amended the state's statutes to create a separate category of licensure for 3PL facilities while keeping the standards of licensure consistent with the state's expectations for wholesalers. This included continuing to require VAWD accreditation for these facilities. Hardy noted that VAWD accreditation is an important component to ensure safety of the drug supply chain. Under the new definition, 3PLs must be licensed independently. After the adoption of the law, the Board transitioned those entities currently licensed as 3PLs under wholesale statutes to the new 3PL licensure category that was created by the law.

During the CPE session, Hardy continued to discuss the importance of VAWD for supporting proper oversight of the wholesale distribution chain. Hardy noted that VAWD accreditation provides a valuable process for conducting inspections of wholesale distributors. "VAWD provides a strong assurance for our state so that we can keep those bad actors out of operation in North Dakota. We feel very strongly that the FDA's language does not preempt or does not stop a state from requiring VAWD accreditation."

Tennessee Board of Pharmacy Executive Director Reggie Dilliard, DPh, also provided insight on the DSCSA's impact within his state. He noted that the Board has broad statutory authority to regulate prescription drugs and devices in order to support public health and safety. The actions taken by the Tennessee Board include amending statutory definitions and adding new definitions to match federal definitions. The changes to Tennessee's statutes included extending the Board's statutory authority to license and regulate newly defined entities, such as 3PLs.

Dilliard noted during his presentation that until final rules are issued, states may continue to license and regulate wholesale distributors and 3PLs as they are doing now. However, once rules are published, states must follow federal standards. Boards of pharmacy need to determine whether a state's statutes or rules conflict with the DSCSA.

"Untangling the DSCSA" Webinars

NABP has resources and tools to help states implement the requirements of the DSCSA, facilitating the continued protection of the prescription drug supply chain and patient safety. Earlier this year, NABP offered informational webinars to assist states in their responsibility to know the contents of the DSCSA and FDA's DSCSA-related guidance and standards. Held on March 31, 2016, the first webinar in a series of four webinars offered participants information on the enactment of the DSCSA. NABP staff described the major sections, definitions, and requirements in the DSCSA. In addition, NABP staff discussed important provisions of the DSCSA, including the impact of section 585 and Uniform National Policy (also known as state preemption).

NABP's second informational webinar, held on June 8, 2016, provided a thorough overview of these requirements and highlighted the importance of increased product tracing validation efforts to improve supply chain security and patient safety. During the second webinar, NABP staff explained the product tracing exemptions applicable to dispensers under section 582(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, NABP staff discussed the standards for exchanging product tracing information contained in FDA's November 2014 draft guidance document and explained how state product tracing requirements were impacted by the DSCSA's preemption provision. Key differences between the pedigree requirements of the Prescription Drug Marketing Act of 1987 and the product tracing requirements of the DSCSA were also addressed. The third and fourth sessions of NABP's webinar series, "Untangling the DSCSA," are scheduled for fall and winter 2016. Board of pharmacy staff and compliance officers are encouraged to participate. To register for the upcoming sessions or for recordings of the previous webinars,

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DSCSA Requirements

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email NABP's Member Relations and Government Affairs department at GovernmentAffairs@nabp.net.

VAWD Remains Valuable Compliance Tool for Boards

The VAWD program remains an effective tool for states to ensure wholesale distributors continually meet state and federal licensing standards. VAWD staff, in conjunction with NABP Professional Affairs staff and Member Relations and Government Affairs staff, consistently research and stay abreast of updates in the implementation of the DSCSA, as well as update VAWD criteria as appropriate to be in alignment with federal regulations established by FDA; therefore, states that require VAWD can trust that they and their accredited facilities conform with the DSCSA. Since its implementation, VAWD has been a source of uniformity and consistency among the states.

Find Out How VAWD Can Help Your Board. Contact NABP Today!

For VAWD program information, contact the Accreditation department at vawd@nabp.net. To discuss an inspection program customized to your state's needs, contact the Member Relations and Government Affairs department at GovernmentAffairs@nabp.net.

The states that recognize or require NABP's VAWD program are in harmony with federal law and support the ongoing public-private partnership among the states, FDA, and NABP to verify the compliance of wholesale distributors with federal and state laws, rules, and criteria for secure medication distribution. To address these requirements, all changes to the VAWD criteria are aimed at providing consistency with the new law while maintaining the continued integrity and high standards of the VAWD program.

The DSCSA requires any facility planning to conduct wholesale distribution to undergo a mandatory physical inspection. To satisfy the inspection requirement of the law, a state can designate a third-party accreditation or inspection service for wholesale distributors seeking licensure. VAWD is the premier drug wholesale distribution oversight program in the country and is recognized and required by many states. NABP can also work with states seeking to augment their current inspection processes by customizing an inspection program for wholesale distributors and 3PLs to satisfy inspection requirements. If choosing to require a third-party inspection for wholesale distributors, states are encouraged to designate NABP as the provider of choice. ■

NABP Continues to Update VAWD Criteria to Align With DSCSA Provisions

The Drug Supply Chain Security Act, Title II of the Drug Quality and Security Act, went into effect on January 1, 2015. Changes to Verified-Accredited Wholesale Distributors® (VAWD®) criteria are detailed below.

VAWD wholesale distributors that engage in transactions involving product, consistent with the definitions of transaction and product in section 581 of the Federal Food, Drug, and Cosmetic Act (FD&C Act):

- Shall achieve, maintain, and demonstrate compliance with the Product Tracing requirement under section 582(c)(1).
- Shall achieve, maintain, and demonstrate compliance with the Authorized Trading Partners requirement under section 582(c)(3).
- Shall achieve, maintain, and demonstrate compliance with the Verification requirements under section 582(c)(4). In June 2014, Food and Drug Administration (FDA) issued draft guidance pertaining to the identification of suspect product and illegitimate product notifications under section 582 of the FD&C Act.

VAWD wholesale distributors that engage in the wholesale distribution of prescription drugs, consistent with the definition of wholesale distribution in section 503(e)(4) of the FD&C Act:

- Shall achieve, maintain, and demonstrate compliance with the Wholesale Distributor Licensing and Reporting requirements under section 503(e) of the FD&C Act. In December 2014, FDA issued draft guidance pertaining to annual reporting for wholesale distributors under section 503(e)(2)(A) of the FD&C Act.

Once regulations are released by FDA, NABP will begin the process of formally revising current VAWD criteria to ensure compliance. ■

VPP Inspection Data Provides Support to Boards in Assessing Pharmacy Compliance

The Verified Pharmacy Program® (VPP®) allows state boards of pharmacy to share critical information, including inspection reports, for pharmacies and other facilities operating in multiple states. When a VPP inspection is conducted, the NABP inspector collects his or her observations on site and records these in a final report. The report findings are then made available within 30 calendar days to all the state boards of pharmacy where a pharmacy is licensed and where a pharmacy is seeking licensure. These reports are available in the VPP section of NABP e-Profile Connect.

At this time, the pharmacy also receives an electronic copy of the inspection report along with a cover letter detailing further instructions. The pharmacy then has the opportunity to provide a response to any of NABP's findings listed in the report, which may include steps taken to correct any noncompliant items. These responses must be received within 30 calendar days from the date the report is provided.

Upon receipt of the follow-up documentation and responses, NABP will make this information available to all applicable state boards of pharmacy directly through NABP e-Profile Connect. The original VPP inspection report will not be changed; however, any follow-up documentation provided by the pharmacy will serve as a supplement to the report. These documents are made available to the states to assist the boards of pharmacy when making decisions regarding licensing and renewal. Determination of compliance with a particular state's regulations is left to the authority of that state's board of pharmacy.

In addition to the inspection report and responses, if provided, a VPP pharmacy's e-Profile will also contain the original VPP application detailing the overall activities of the pharmacy and any applicable correspondence pertaining to the pharmacy.

At press time, at least 483 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. Developed by NABP in partnership with member boards of pharmacy, VPP facilitates the communication of important inspection and licensure information between the state boards of pharmacy and serves as an information hub that provides verified data to support boards' licensure processes for nonresident pharmacies.

For more information about VPP or the inspection sharing network, contact VPP staff at vpp@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.*

Total VPP Pharmacies

Of the 483 VPP pharmacies, more than 70 have reapplied for a more current inspection, having previously been inspected through the program. Additionally, of approximately 483 pharmacies:

- 232 pharmacies engage in only nonsterile compounding;
- 50 pharmacies engage in only sterile compounding (two of which are also registered as outsourcing facilities);
- 139 pharmacies engage in both sterile and nonsterile compounding (four of which are also registered as outsourcing facilities);
- 59 pharmacies are general retail or mail-order pharmacies with no compounding; and
- 3 pharmacies are nuclear pharmacies.

Newly Accredited VAWD Facilities

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

Den-Mat Holdings, LLC
Lompoc, CA

Dental Health Products, Inc
New Franken, WI

McKesson Medical-Surgical, Inc
Elgin, IL

A full listing of more than 560 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*

Register Now for Final 2016 Sterile Compounding Inspector Training, Opportunity for Certification Available

NABP has partnered with CriticalPoint, LLC, to expand the Sterile Compounding Inspector Training (SCIT), providing inspectors with a more engaging, hands-on experience. The final 2016 training session will be held October 18-20, 2016, at the CriticalPoint Center for Training and Research (CCTR) located in Totowa, NJ. The CCTR offers a state-of-the-art classroom as well as a functioning physical plant, which is compliant with United States Pharmacopeia (USP) Chapters <797> and <800>.

The training agenda includes all aspects of sterile compounding, such as hand hygiene and garbing; environmental sampling, aseptic technique, and first air; and bubble point and sterility testing.

In addition to Kate Douglass, MS, RN, APN, C, CRNI, and Eric S. Kastango, MBA, RPh, FASHP, past and current members of the USP Sterile Compounding Expert Committee, Patricia Kienle, MPA, RPh, FASHP, and Jim Wagner have joined the CriticalPoint faculty. Wagner is the principal architect of the facility requirements for both USP Chapters <797> and <800>, and Kienle led the USP Hazardous Drug Subcommittee in the development of USP Chapter <800>.

The live portion of the program offers 20.5 hours of continuing pharmacy education, including six hours on hazardous drug handling that will assist inspectors in becoming more familiar with USP Chapter <800>. Participants who complete the Sterile Compounding eLearning Series (within a year prior to the live training), attend the on-site training, and successfully pass the post-test may earn the NABP/CriticalPoint Certification in Sterile Compounding for Inspectors.

To register for CriticalPoint's Sterile Compounding eLearning Series, participants may visit *www.criticalpoint-lms.com.* The eLearning Series is free of charge to board of pharmacy inspectors and compliance officers. For more information, contact CriticalPoint at sandresen@criticalpointce.com.

The NABP Executive Committee has approved for NABP to continue to reimburse $1,500 per board to help defray costs associated with this valuable training. Registration is $1,495 per person, which includes light breakfasts, snacks, and lunches, as well as shuttle transportation to and from the hotel and training center and transportation back to the airport. Attendees will be responsible for their own transportation from the airport to the hotel; however, a discounted rate is available through one of CriticalPoint's vendors. A special group rate of $155/night, plus taxes and fees, has been secured at a local Hilton property. ■

Sterile Compounding Inspection Training Highlights

- Opportunity to earn NABP/CriticalPoint Certification in Sterile Compounding for Inspectors by:
  - Completing eLearning Series and on-site training
  - Passing post-test
- Registration fee may be reimbursed by NABP
- Register on the CriticalPoint website: *https://www.criticalpoint.info/sterile-compounding-inspector-training*
- October 18-20, 2016, Totowa, NJ

NABP Secures Exclusive Rights for Outlier Detection Tool to Help Maintain Integrity of Association's Exams

As a developer of high-stakes examinations, NABP has heightened awareness of testing security to ensure that candidates' scores are reflective of their mastery of pharmacy practice knowledge. As part of this effort, NABP developed a proprietary tool that allows the Association to screen test records for evidence of unusual or unexpected outcomes.

On May 31, 2016, the Outlier Detection Tool methodology was granted a utility patent by the United States Patent and Trademark Office, and the patent is effective through approximately 2035. This is the first patent NABP has earned for an Association invention. The Outlier Detection Tool is a customized program that allows test results data to be reviewed to identify performance outliers and anomalous response patterns.

Further, the tool may be used to detect response patterns that may indicate cheating or non-authentic test sessions. The objective of analyzing response data from examinations is to assess possible threats to the security and integrity of NABP licensure and certification programs. NABP is committed to providing the boards of pharmacy with exceptional examinations and continuously seeking to ensure valid test scores are defensible.

Registration Now Open for October 14 FPGEE

Registration is now available for the next Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), which will be administered on **October 14, 2016**. Foreign Pharmacy Graduate Examination Committee™ candidates who have been accepted to take the FPGEE may register using the link in the FPGEE section of the NABP website.

Candidates have from July 1, 2016, to September 30, 2016, to register for the FPGEE with NABP. Within one week of registering with NABP, candidates will receive an Authorization to Test, and they may then schedule their test location with the NABP test vendor, Pearson VUE. Candidates have from July 7, 2016, to October 7, 2016, to schedule an appointment with Pearson VUE. NABP encourages early registration for optimal scheduling options as certain test centers fill up quickly.

To prepare for the FPGEE, NABP recommends that candidates take the Pre-FPGEE®, the practice examination for the FPGEE designed to help familiarize candidates with the types of questions on the actual examination.

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

Pharmacists and Pharmacy Faculty Needed to Volunteer as Item Writers for NABP Examinations and Assessments

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

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

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

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

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

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

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

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

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

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

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

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

The PARE is a multidimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist remediations or brief departures from practice.

The content areas are:

- Medication safety and the practice of pharmacy,
- Professional ethics/pharmacist judgment, and
- Clinical pharmacy practice.

How to Apply

Interested individuals should complete the online NABP Item Writer Volunteer Interest Form on the NABP website at *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.

The blueprint for each examination and assessment program may be found in the Programs section of the NABP website at *www.nabp.net*. For more information about item writing, contact NABP at NABP_Comp_Assess@nabp.net. ■

PMP InterConnect Steering Committee Convenes to Review and Discuss Program Development

The NABP PMP InterConnect Steering Committee, which is composed exclusively of representatives of the prescription monitoring programs (PMPs) participating in the NABP PMP InterConnect® program, met July 20-21 in Northbrook, IL. The meeting agenda included presentations, state PMP updates, PMP InterConnect technical updates, and networking opportunities. Attending the event were 40 state attendees representing 38 states, six guests, and six NABP staff members.

Protecting PMP Data

(Left) Mike Menkhaus, RPh, EPRN project manager at The Kroger Co, Louisville, KY, shares information with the Steering Committee about Kroger's prescription drug monitoring program data protection policies and procedures.

Learning From Other State PMPs

(Right) PMP InterConnect Steering Committee meetings offer state PMPs an opportunity to network and learn from other states' experiences. Participating in the July 2016 meeting were Ellen Mitchell, investigations support coordinator, Idaho State Board of Pharmacy, Boise, ID (seated, left); Gary Garrety, PMP operations manager, Washington State Pharmacy Quality Assurance Commission, Olympia, WA (seated, right); Kate Jackson, PDMP manager, Maryland Department of Health and Mental Hygiene, Behavioral Health Administration, Catonsville, MD (standing, left); and Hannah Hauser, Vermont Prescription Monitoring System manager, Vermont Department of Health, Burlington, VT (standing, right).

Newly Approved e-Advertisers

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

Capsule Corporation, dba Capsule Pharmacy
www.capsulecares.com

University of Utah Health Care
www.healthcare.utah.edu/pharmacy

Petroglyph Animal Hospital, LLC
www.pahvets.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*.

Redesigned NABP Website to Launch Soon

NABP is pleased to announce that the Association will be launching a redesigned website, featuring improved navigation and a cleaner look and feel, in late September 2016. With visual cues and concise content, the newly designed site will make it easier for users to quickly locate pertinent information.

At the time of the launch, NABP will begin using the .pharmacy domain for its website and emails. The NABP website address will change to *www.nabp.pharmacy* and all of NABP's emails will end in @nabp.pharmacy. NABP will soon begin notifying its members of specifics about the email address changes. Emails sent to the .net email extension will be forwarded for a period of time to ensure that there is no lapse in communication between NABP and its members, customers, or other key stakeholders.

Additional information on the new website and domain name change will be provided in the September issue of *Innovations* and in other member communications. ■

NABP Newsletter Receives Award for Editorial Excellence

NABP was presented a 2016 EXCEL Award during Association Media & Publishing's (AM&P's) 36th Annual EXCEL Awards Gala, held June 27, 2016, at the Ronald Reagan Building and International Trade Center in Washington, DC. AM&P's prestigious EXCEL Award program recognizes excellence and leadership in nonprofit association media, publishing, marketing, and communications.

NABP received the honor in the Newsletters: Editorial Excellence (Print) category based on three articles published in the November-December 2015 *NABP Newsletter*: "Several States Pass Right-to-Try Legislation in 2015, Expanding Access to Experimental Drugs," "MPJE Undergoes Thorough Evaluation to Ensure Examination Meets Current Standards For the Application of Pharmacy Law in Practice," and "Supporting Efforts to Fight Diversion and Abuse, PMP InterConnect Works in Tandem With PMP Gateway as It Automates Requests, Brings Data Into Workflow." NABP received the Bronze award level.

AM&P's 2016 EXCEL Awards program drew more than 870 entries in seven broad categories ranging from digital publishing and magazines to books and promotional campaigns. Of those, the judges selected 227 entries to receive EXCEL Awards. During the Awards Gala, AM&P announced the award levels for each of the awards (Bronze, Silver, and Gold). The 2016 EXCEL Award winners are featured in the July/August issue of AM&P's *Signature* magazine. ■

Next PARE Testing Window Will Be September 13-24, 2016

The next available Pharmacist Assessment for Remediation Evaluation® (PARE®) testing window is scheduled during the two-week period of September 13-24, 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. As an added convenience, boards of pharmacy 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 the PARE, 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.

An additional PARE testing window for 2016 is scheduled during the two-week period of November 29 to December 10, 2016. More information about the PARE, including future testing windows, may be found in the Programs section of the NABP website at *www.nabp.net*. ■

Around the Association

Board Member Appointments

- **Reginal Bellamy, PharmD, RPh,** has been appointed a member of the District of Columbia Board of Pharmacy. Bellamy's appointment will expire March 12, 2018.
- **Lisa Harris, MBA, BSN,** has been appointed a member of the Georgia State Board of Pharmacy. Harris' appointment will expire November 1, 2020.
- **Joshua Cox, PharmD, RPh,** has been appointed a member of the State of Ohio Board of Pharmacy. Cox's appointment will expire June 30, 2017.
- **Jennifer Rudell, RPh,** has been appointed a member of the State of Ohio Board of Pharmacy. Rudell's appointment will expire June 30, 2018.

Board Member Reappointments

- **James Appleby, MPH, RPh,** has been reappointed a member of the District of Columbia Board of Pharmacy. Appleby's appointment will expire March 12, 2019.
- **Daphne Bernard, PharmD, RPh,** has been reappointed a member of the District of Columbia Board of Pharmacy. Bernard's appointment will expire March 12, 2019.
- **Eddie Curry** has been reappointed a public member of the District of Columbia Board of Pharmacy. Curry's appointment will expire March 12, 2018.
- **Sharon Meyer, MS, PharmD, RPh,** has been reappointed a member of the Iowa Board of Pharmacy. Meyer's appointment will expire April 30, 2019.
- **Michael Lonergan, RPh,** has been reappointed a member of the Kansas State Board of Pharmacy. Lonergan's appointment will expire April 30, 2020.
- **John Worden, PharmD, RPh,** has been reappointed a member of the Kansas State Board of Pharmacy. Worden's appointment will expire April 30, 2020.
- **Diane Halvorson, CPhT,** has been reappointed a member of the North Dakota State Board of Pharmacy. Halvorson's appointment will expire May 8, 2021.
- **Gayle Ziegler, RPh,** has been reappointed a member of the North Dakota State Board of Pharmacy. Ziegler's appointment will expire May 8, 2021.
- **Leonard Petrik, PharmD, RPh,** has been reappointed a member of the South Dakota State Board of Pharmacy. Petrik's appointment will expire October 31, 2018. ■

Gay Dodson Appointed to Serve as a Member of the NABP Executive Committee, Representing District 6

Gay Dodson, RPh, executive director of the Texas State Board of Pharmacy, has been appointed to serve as a member of the NABP Executive Committee representing District 6, effective August 1, 2016. As an active member of NABP, Dodson served on many of the Association's task forces and committees, including the Committee on Law Enforcement/Legislation and Committee on Constitution and Bylaws, where she served as chair. She also served as chair on several task forces, including the Miscellaneous Topics Subgroup of the Task Force to Review and Recommend Revisions to the Controlled Substances Act and the Task Force on Prescription Monitoring Program Standards. In 2014, Dodson was named NABP's Honorary President, and in 2007, she received the Lester E. Hosto Distinguished Service Award from NABP. Prior to becoming executive director of the Texas Board in 1997, Dodson held various positions with the Board, including senior compliance officer and director of compliance, and she also practiced pharmacy for 13 years. Dodson earned her bachelor of science degree in pharmacy from the University of Texas at Austin College of Pharmacy. The Executive Committee appointed Dodson after Dr John A. Foust, PharmD, DPh, executive director of the Oklahoma State Board of Pharmacy, resigned from his positions on the Oklahoma Board and the Executive Committee to manage health issues. Dodson will serve until the NABP Annual Meeting in May 2017, when elections will be held for open officer and member positions. NABP greatly appreciates Foust's dedication to NABP over the years and thanks him for his service on the Executive Committee. ■

**Gay Dodson, RPh,
Executive Director,
Texas State Board of Pharmacy**

South Carolina Approves Two New Facility Permit Classifications

In response to the Drug Quality and Security Act, the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy has approved two new permit classifications: outsourcing facility for 503B facilities and third-party logistics provider (3PL). In-state 3PLs will be issued non-dispensing drug outlet permits. Out-of-state 3PLs previously permitted as nonresident wholesalers/distributors will now receive the new 3PL permit. Facilities registered with Food and Drug Administration as a 503B outsourcing facility must obtain an outsourcing facility permit as well as a pharmacy permit or a wholesale/distributor/manufacturer (non-dispensing drug outlet permit for in-state facilities) permit.

MPJE Now Required in Virginia for Pharmacist Licensure

As of July 1, 2016, Virginia became the 49th jurisdiction to require candidates seeking pharmacist licensure to successfully pass the NABP Multistate Pharmacy Jurisprudence Examination® (MPJE®). The Virginia Board of Pharmacy has historically administered its own jurisprudence examination, the Virginia Federal and State Drug Law Examination (FSDLE). However, as a result of the increasing number of complex issues facing the Board and its limited resources, it was determined that resources used to administer the FSDLE would be better utilized in addressing other issues. Therefore, the Board ceased administering the FSDLE on June 30, 2016. Additional information on Virginia's transition to the MPJE may be found at *www.dhp.virginia.gov/pharmacy/news/MPJE_transition.pdf*.

Oregon Board Adds Two Technician Members

During the 2015 Oregon Legislative Session, the Oregon Legislative Assembly voted Senate Bill 148 into law, which amends Oregon Revised Statute 689.115 and adds two voting pharmacy technician members to the Oregon State Board of Pharmacy. The law requires each pharmacy technician member to be licensed and in good standing, have at least three years of experience performing the duties of a technician, and be actively engaged in the duties of a pharmacy technician in Oregon. The Board welcomed Pharmacy Technicians Cyndi Vipperman and Dianne Armstrong to the Board. Both were appointed by Governor Kate Brown and confirmed by the Legislative Senate Rules Committee. Their appointments began February 17, 2016, and run until February 16, 2020.

Ohio Board Clarifies Law on Dispensing Emergency Refills

The State of Ohio Board of Pharmacy provided pharmacists guidelines in its May 2016 newsletter on how to deal with difficult decisions, such as when they are asked to dispense an emergency refill of a medication that no longer has a current prescription (ie, no refills left or refills have expired). Ohio Revised Code Section 4729.281 – which was recently amended – permits a pharmacist to dispense medication, other than a Schedule II controlled substance (CS), without a written or oral prescription if all of the following conditions are met:

1. The pharmacy where the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted for providing refills has elapsed.

2. The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care.

3. In the exercise of the pharmacist's professional judgment, the drug is essential to sustain the life of the patient or continue therapy for a chronic condition, and failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

Upon completion of these steps, the Board notes that a pharmacist is permitted to dispense the following:

1. Up to a 72-hour supply for any prescription drug, including Schedule III-V CS; or

2. Up to a 30-day supply for a non-controlled prescription drug or, if the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold does not exceed the standard unit of dispensing.

More information on emergency dispensing in Ohio may be found on the Board's website at *www.pharmacy.ohio.gov/emergency*. ■

FDA Warns of Counterfeit Version of Cancer Drug Detected in Some Foreign Countries

Food and Drug Administration (FDA) is alerting health care providers that a counterfeit version of BiCNU (carmustine for injection) 100 mg, an FDA-approved cancer drug, has been detected in some foreign countries. BiCNU is manufactured by Emcure Pharmaceuticals, Ltd, and distributed in the United States by Heritage Pharmaceuticals, Inc. To date, there is no indication that counterfeit BiCNU has entered the US drug supply chain and no indication that any US patients have received counterfeit BiCNU. The counterfeit product has been found in distribution in India, Ireland, and Israel, reports the Heritage Pharmaceuticals press release available on the company's website at *www.heritagepharma.com* under the News section.

Health care providers are advised to carefully inspect the BiCNU vial as an added precaution to ensure the product administered to patients is authentic. BiCNU is available as a vial of BiCNU and dehydrated alcohol co-packaged together. Although the National Drug Code on the outer package of the authentic and counterfeit versions might match, FDA notes that the best way to distinguish a counterfeit is to look at the BiCNU vial inside the packaging. The product may also be counterfeit if the vial displays the lot numbers, batch numbers, manufacturing dates, and expiration dates provided in the FDA safety alert available at *www.fda.gov/Drugs/DrugSafety/ucm500705.htm*.

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and FDA, is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the US. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Well Care Compounding Issues Statewide Recall of All Sterile Compounded Products

Well Care Compounding Pharmacy of Las Vegas, NV, is voluntarily recalling all unexpired sterile compounded products distributed between January 1, 2016, and April 29, 2016, throughout Nevada due to FDA's concern over lack of sterility assurance after an inspection. The recalled products have a label that includes the Well Care Compounding Pharmacy name, logo, drug name, and expiration date. Customers are advised to immediately stop using the recalled products and contact the pharmacy to arrange a return. To date, Well Care Compounding Pharmacy has not received any reports of adverse effects or injuries related to this recall. Animal adverse drug events may be reported to FDA by submitting a Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report (Form FDA 1932a). More information is available in the press release on FDA's website at *www.fda.gov/Safety/Recalls/ucm501543.htm.*

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

Fresenius Kabi USA is recalling a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers that have been shipped or may have been shipped the recalled product. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm.*

CDC Hosts Webinar Series on Guideline for Prescribing Opioids for Chronic Pain

CDC is hosting a seven-part series of free continuing education (CE) webinars for health care providers on the *CDC Guideline for Prescribing Opioids for Chronic Pain.* The webinars will be available as a live broadcast and will also be archived on the CDC website at *http://emergency.cdc.gov/coca/calls/index.asp.* CE credit may be earned after participating in the live webinars. ■

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

INNOVATIONS

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

UPCOMING EVENTS

September 11-14, 2016
NABP/AACP Districts 6, 7, & 8 Meeting
Portland, OR

September 13-24, 2016
PARE Administration

September 15-17, 2016
NABP/AACP Districts 1 & 2 Meeting
White Sulphur Springs, WV

October 4-5, 2016
NABP Interactive Executive Officer Forum
Rosemont, IL

November 2-4, 2016
NABP/AACP District 4 Meeting
Chicago, IL

November 30-December 1, 2016
NABP Interactive Member Forum
Rosemont, IL