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National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056 • 847/391-4406
www.nabp.pharmacy • help@nabp.pharmacy

Carmen A. Catizone
Executive Director/Secretary

Amy Suhajda
Communications Manager

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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.

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Association News

Board of Pharmacy Members to Collaborate During Upcoming NABP Interactive Member Forum

Offering a unique opportunity for collaboration and networking among boards of pharmacy members from across the country, the NABP Interactive Member Forum returns this fall. Taking place on November 30 and December 1, 2016, in Rosemont, IL, the forum will focus on the theme “Stand Up and Be Counted to Advance Our Shared Mission.”

Each state board of pharmacy executive officer was invited to select one member from his or her board to attend the Interactive Member Forum.

The goal of the interactive forums is to facilitate interaction among member boards and provide closed sessions to discuss important and timely issues related to pharmacy practice regulation. A forum for executive officers was held on October 4-5, 2016. Forums for executive officers as well as board compliance officers and legal counsel are scheduled to return in fall 2017. For more information about the interactive forums, contact ExecOffice@nabp.pharmacy.

Interactive Member Forum Highlights

- Tailored specifically for board members
- Topics developed from suggestions submitted by attendees in advance of the meeting
- Sessions designed to encourage discussion and interaction among attendees
- No registration fee
- Travel, meals, and hotel accommodations paid by NABP

Newly Accredited VIPPS Facility

The following internet pharmacy was accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) program:

Fortis Holding Company
www.smdrugstore.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP website at www.nabp.pharmacy.
Is It a Crime?

The interplay between administrative prosecutions and criminal prosecutions can present interesting challenges as to what “criminal charges” apply to potential inappropriate or illegal activities of a respondent. Persons being involved in activities that violate pharmacy statutes and/or regulations may also implicate elements that constitute criminal behavior. Under some circumstances, the intent of the accused may be relevant as to the state of mind necessary to commit the crime(s) alleged to have been committed. Consider the following.

A pharmacist (Licensee) was licensed by the Texas State Board of Pharmacy (Board) in 1993. The Licensee was employed by a chain drug store from 2004 until 2011. During this employment period, the Licensee was disciplined by the Board for failure as a pharmacist-in-charge (PIC) to properly supervise an employee technician who was not duly registered. In January 2011, the Licensee started a new pharmacy called Accent Pharmacy 1 (AP1). At least two additional employees worked at AP1.

In May 2013, a Drug Enforcement Administration (DEA) investigator inquired into the practices of AP1. During the investigation, both employees provided false identities by representing themselves as either a pharmacist, a physician, or a pharmacy technician although neither employee was licensed by any regulatory board in Texas. Further, the Licensee was not on the premises of AP1 during customary work hours and admitted such absences were due to his need to work at another hospital pharmacy for financial reasons. A Voluntary Surrender of Controlled Substances Privileges was signed, giving the DEA agent access to records.

Based upon the investigation, in October 2014 a grand jury indicted the Licensee and the two AP1 employees on one singular count of conspiracy to manufacture, distribute, and possess with intent to manufacture and distribute a controlled substance, namely hydrocodone, in violation of applicable federal law. In April 2016, the two AP1 employees agreed to and signed plea agreements disposing of their criminal prosecutions.

The Licensee’s criminal case went to trial before a jury whereby the government presented evidence that hydrocodone pills were purchased without the proper precautions; dispensing occurred without valid prescriptions; one employee had contacts with a physician who wrote invalid prescriptions; there were several break-ins at AP1; and in the Licensee’s absence, unlicensed employees were responsible for the distribution of hydrocodone.

At the close of the government’s case, the Licensee through his lawyer submitted a Motion and Brief for Judgment of Acquittal. Such a motion alleges that the government has not presented evidence to support a conviction in that the necessary elements of the alleged crime have not been substantiated. The court reserved judgment on the motion, and the Licensee called one character witness and then rested his defense. The jury returned a guilty verdict, and the Licensee renewed his motion and also asked for a new trial.

In order to prove a conspiracy as charged in this case, the government is
required to establish that the Licensee did “knowingly or intentionally manufacture, distribute, or dispense . . . a controlled substance” or conspired to do so. The indictment also noted that under the Texas Pharmacy Act, a pharmacist shall exercise professional judgment to determine the prescription is valid and that it shall be unprofessional conduct for a pharmacist to dispense a prescription not issued for a legitimate medical purpose or in the usual course of business. The government used the relationship among the two employees and the Licensee to substantiate the conspiracy and, in part, relied upon an alleged written agreement. However, such written agreement was not produced, and the credibility of the two employees who testified against the Licensee was challenged. In short, the Licensee argued that there was no evidence that the Licensee and employees agreed or conspired to undertake an illegal enterprise.

Under a second theory, it was argued by the government that a conspiracy existed because the two employees were not licensed and the Licensee as the PIC was not on the premises when the dispensing occurred. The court noted that using the state regulatory laws and unlicensed personnel as a basis to substantiate a conspiracy would trigger culpability for “any pharmacist who is aware of, and does not immediately act upon, any regulatory violation involving his pharmacy or one of his employees . . . ” Such a “strict liability” approach establishing a conspiracy for every pharmacy regulatory violation would expand federal conspiracy liability “to a tremendous degree, unconceived of by lawmakers or by the boards of pharmacy across the nation.” After extensive conspiracy analyses consisting of two different approaches, the court held that the unlawful purpose of the conspiracy was clearly to attempt to profit from the illegal purchase and distribution of hydrocodone.

After reviewing the jury instructions, the court addressed the Motion for Judgment of Acquittal. It reviewed the testimony of the two employees and their credibility along with the alleged agreement to operate the illegitimate pharmacy. The court held that the evidence supports the misrepresentation of the two employees as licensed personnel. The evidence further supports an “agreement” among the parties, but only to the extent that it was not revealed to the Board that unlicensed personnel were employed and that the Licensee was absent as the PIC. While the weight of the evidence supports the conclusion that illegal activities resulted in the purchase of an expensive home, luxury cars, and an armored limousine, such benefits flowed to the two employees and not to the Licensee. A lack of participation in the profits of the illegal venture suggest a lack of intent on the part of the Licensee to participate in the charged conspiracy.

As a result and to avoid a miscarriage of justice, the court found that the weight of the evidence does not support the intent by the Licensee to join an agreement. Thus, the Licensee’s Motion for Judgment of Acquittal was granted.

The elements of certain criminal allegations require an analysis of one’s “state of mind” or intent. In this case, the pharmacist, although an active participant in the scheme, lacked the intent to conspire with the other codefendants. Under such circumstances, the public protection aspect will be left to the board of pharmacy in an administrative disciplinary proceeding.

2017 Survey of Pharmacy Law Available in December

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 2017 Survey of Pharmacy Law will be available in late December.

The Survey, which is produced as a digital PDF, will be provided on a USB drive beginning with the 2017 edition. The Survey consists of four sections – a state-by-state overview of organizational law, licensing law, drug law, and census data. In addition, the updated Survey includes four new questions. The new questions and their corresponding sections are listed below.


2. Section 17, Wholesale Distributor Licensure Requirements: “Does State Have a Third-Party Logistics Provider Law?”


4. Section 29, Minimum Standards of Practice: “Does Board Require Compliance With USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings?”

Updates for the 2017 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 23 and 24 and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 25 and 26.

The Survey can be purchased online for $195 by visiting the Publications and Reports section on the NABP website at www.nabp.pharmacy.

Reminder to Update NABP Digital Contact Information on Your Materials for Students, Licensure Candidates

In September 2016, NABP transitioned its website to the .pharmacy domain. At the same time, NABP also updated its email addresses with the .pharmacy domain.

In addition to changing from @nabp.net to @nabp.pharmacy, several NABP email addresses were updated to help make them more user-friendly.

If you have questions about any changes to email addresses, please contact Customer Service at help@nabp.pharmacy.

Reminder: Update NABP Information as Follows

- Update links on your websites to www.nabp.pharmacy
- Update links on your forms to www.nabp.pharmacy
- Update NABP email addresses in your records to @nabp.pharmacy
- Update email addresses for the following NABP departments:
  - Customer Service: help@nabp.pharmacy
  - Executive Office: ExecOffice@nabp.pharmacy
  - Competency Assessment: CompAssess@nabp.pharmacy
NABP Publishes White Papers Related to Examinations

In 2016, NABP is publishing two white papers to share with state boards of pharmacy. The results of a 2015 United States schools and colleges of pharmacy curricular survey is now available, and the outcomes of the content domain allocations for the 2016 Pharmacy Curriculum Outcomes Assessment® (PCOA®) will soon be published.

2015 Curricular Survey Summary Report
Outcomes of the curricular survey are presented in The 2015 United States Schools and Colleges of Pharmacy Curricular Survey – Summary Report. The outcomes evaluate and inform the content domains and blueprints for the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and PCOA.

2016 PCOA School Outcomes Summary Report
The results from the PCOA administrations for the 2016 School Outcomes Reporting cohort are presented in PCOA School Outcomes for Students Nearing the End of Their Didactic Curriculum. The report provides the results for the total scaled score and content area scores for the ACPE reporting cohort, which consists of students testing at or near the end of the didactic curriculum as a “third-year” PharmD student.

The white papers are available for download in the Publications and Reports section on NABP’s website.

Registration Open for Second 2017 PCOA Testing Window

Schools and colleges of pharmacy preparing for an administration of the Pharmacy Curriculum Outcomes Assessment® (PCOA®) are advised to review the PCOA Registration and Administration Guide for Schools and Colleges of Pharmacy, available on the PCOA Information for Administrators page of the NABP website at www.nabp.pharmacy/programs. The guide includes detailed instructions on the registration and administration process, as well as contact information.

A total of 62 schools and colleges signed up to participate in the first 2017 PCOA testing window, to be held January 11 to February 10. Registration for this testing window is now closed.

More information about the PCOA is available in the Programs section at www.nabp.pharmacy. ■

PCOA Highlights
- School registration deadline for the April 10 to May 12, 2017 PCOA is January 10, 2017.
- Provided at no cost for all students nearing the completion of their didactic curriculum. ($75 per student for an additional administration.)
- Cost of administration to students other than those nearing the completion of their didactic curriculum is $75 per student.
- School or college is responsible for providing the testing facility, and meeting technical and hardware requirements for computer-based testing.

2017 PCOA Testing Windows
- April 10, 2017 – May 12, 2017
  School registration deadline: January 10, 2017
- June 19, 2017 – June 30, 2017
  School registration deadline: March 21, 2017
- August 21, 2017 – September 15, 2017
  School registration deadline: May 23, 2017
- November 13, 2017 – December 8, 2017
  School registration deadline: August 15, 2017
Inspection of nonresident pharmacies has long posed a challenge for the boards of pharmacy. Without an easy way to access data from recent inspections carried out by the resident state, or large budgets that would finance a wide-traveling team of inspectors, the state boards evaluating the licensure request could not easily gain the insights a physical inspection would provide.

These difficulties – along with ambiguities revolving around state versus federal oversight of facilities that engaged in compounding – were highlighted in analyses of the deadly 2012 multistate fungal meningitis outbreak that originated from contaminated methylprednisolone acetate injections distributed by the New England Compounding Center.

Among a number of efforts by federal and state legislators and regulators to avert future such tragedies, the state boards of pharmacy and NABP collaborated to determine that tools and resources were needed that would permit the acquisition and sharing of more comprehensive inspection information to support states’ pharmacy licensure decisions. In response to this collaborative effort, NABP developed the information-sharing network available to boards via NABP e-Profile Connect, the Verified Pharmacy Program® (VPP®), the Multistate Pharmacy Inspection Blueprint and universal inspection form, and hands-on inspection training, including sterile compounding training. (A review of the current tools and resources and their development is discussed in the October 2016 Innovations article “Retracing the Road—The Development of Inspection and Data Sharing Tools to Support Pharmacy Licensure Decisions,” which was the first part of this three-part article series.)

Since late 2012, when NABP began conducting nonresident pharmacy inspections on behalf of the Iowa Board of Pharmacy, nearly every state board of pharmacy has utilized the new tools in some fashion. Many states, like Iowa, have gone further,
partnering with NABP in state-specific programs and collaborations. This article, the second of a three-part series, highlights efforts in several states that are contributing to filling in information gaps that impact boards’ pharmacy licensure decisions.

VPP

VPP, both by itself and in combination with the other tools, is proving central to efforts that bridge the pharmacy inspection information gap. As NABP has reported in the past, VPP is meant to enhance existing licensure processes by facilitating states’ data-sharing capabilities. Through the program, the Association reviews a requesting facility’s application and, if a qualified inspection is not on record, NABP conducts an inspection using consistent, standardized criteria determined by the boards. Inspection data are combined with the facility’s relevant licensing and disciplinary information and then made available via e-Profile Connect for the relevant boards of pharmacy to use when rendering a licensing decision. Facilities reapply to VPP when they are required to obtain a more current inspection.

Pharmacies’ e-Profiles and the associated VPP reports are available to all boards of pharmacy through NABP e-Profile Connect. States where a facility holds licensure or is seeking licensure are notified via an alert when a new VPP report for that facility becomes available. State inspection reports made available by a board can also be accessed by other boards through the secure e-Profile Connect platform. Idaho, Kansas, Louisiana, Nevada, and Oklahoma, for example, were among the states to make their reports available to other boards early on by this means.

States Recognize VPP for Nonresident Pharmacy Licensure

At least 48 boards utilize VPP in some fashion, and many recognize the VPP inspection as meeting state licensure requirements. For example, in mid-2013, Virginia was a relatively early adopter, updating state regulations to recognize VPP inspections as meeting state requirements if a nonresident pharmacy had not been inspected by the regulatory or licensing agency of the jurisdiction where it was located. Other states have followed suit, including Pennsylvania, which in 2015 began requiring nonresident pharmacies shipping medication into Pennsylvania to obtain licensure in the state; new applications require an inspection report from VPP or from the pharmacy’s home state regulatory or licensing agency.

Other states allow or even require VPP inspections for certain types of nonresident pharmacies, particularly compounding pharmacies. The emphasis on compounding pharmacies is made clear by the numbers. Of the 602 pharmacies that at press time had applied to VPP and have, or soon will have, verified VPP data available for the boards to view, the majority, 530, engage in either nonsterile or sterile compounding, or both.

For some of these states, VPP provides one avenue for nonresident compounding pharmacies to seek inspections. For example, in 2014, the Texas State Board of Pharmacy adopted rules requiring nonresident sterile compounding pharmacies to obtain an inspection from a Board-designated inspector as part of the license renewal process; NABP, through VPP, is one of the authorized inspectors. The State of Ohio Board of Pharmacy is another such state, allowing nonresident compounding pharmacies to document their compliance with United States Pharmacopeia (USP) Chapters <795> and/or <797> via VPP as one of several options.

Other states require nonresident compounding pharmacies to work through VPP exclusively. Michigan is one such state. Out-of-state pharmacies shipping sterile compounded products into Michigan must obtain biennial inspections from VPP. Noncompounding, nonresident pharmacies wishing to be licensed by the Michigan Board of Pharmacy may submit a recent inspection report from either VPP or their resident state board of pharmacy.

At press time, the New Mexico Board of Pharmacy was considering similar rules that would require nonresident sterile compounding pharmacies to obtain an inspection within 12 months of applying for licensure in New Mexico, either through VPP or from the facility’s resident state—provided that the state’s inspection form shows compliance with the USP chapters relevant to sterile compounding.

Emerging Trends

Although VPP was initially established to assist with nonresident pharmacy inspections, some states are exploring different ways of using the program, such as related uses with in-state pharmacies, including in-state inspections and specialized training for state inspectors.

One way states may use VPP with resident pharmacies is to outsource “on-demand” inspections. Many state boards of pharmacy face limited financial means with which to carry out their many required duties as they fulfill their role of protecting the public health. Tasks such as inspecting a facility upon that facility’s request, for nonresident licensure application to another state board, may strain already stretched budgets. The Arizona State Board of Pharmacy addressed this issue in its quarterly newsletter to licensees. “[To help determine if a nonresident pharmacy is operated in a safe or even legal manner, many] states are requiring that a recent copy of an inspection by the state of domicile accompany an initial or renewal nonresident application,” the Board stated in the April 2015 issue of the Arizona State Board of Pharmacy.

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NABP Report Finds Denying Consumers Access to Patient Care Is Common Among Rogue Internet Drug Outlets

In October, NABP issued a report titled Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: October 2016 that stresses the importance of critical patient care provided through legitimate online pharmacies and the dangers posed by lack of such patient care options through rogue internet drug outlets. As pharmacists continue to be the most accessible professionals in health care, the patient care services they provide play a crucial role in medication safety for patients. Legitimate online pharmacies always provide a means for accessing patient care services, indicates the report. Further, pharmacists are well positioned to help educate patients about the dangers of rogue online drug outlets.

NABP has reviewed 11,415 internet drug outlets selling prescription medications since 2008 and determined that 96% of these websites are operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards. Such sites are identified as Not Recommended and are listed on the Association’s website in an effort to protect consumers who may otherwise unknowingly purchase medication from such a rogue internet drug outlet. Among other dangers, more than half (62.1%) of rogue internet drug sellers do not provide contact information on their websites, leaving consumers without a way to reach a pharmacist with questions about the medicine that they have purchased. This removes an important part of consumer-pharmacist interaction: patient care.

NABP started the .Pharmacy Top-Level Domain (TLD) Program so that consumers could easily identify legitimate online pharmacies and related entities using a method that rogue internet drug outlets could not replicate. When consumers see the fraud-proof .pharmacy domain in a website’s address, they can be sure that the website has been verified as safe and legitimate. Pharmacists are key in educating patients about medications; therefore, patient services is one of the 10 core safety standards required in order for a website to qualify for a .pharmacy domain name. Websites with a .pharmacy TLD must provide consumers with a way to contact or consult with a pharmacist or medical practitioner regarding complaints or concerns or in the event of a possible adverse event involving their medication. The full report is available on the Not Recommended Online Pharmacies page in the Acquire Safely section of www.AWARERx.pharmacy.

To see the list of approved entities with registered .pharmacy domain names, visit the Buying Safely section of www.safe.pharmacy.

Inspection, Data Sharing Tools

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Newsletter. “This puts a hardship on the state of domicile at a time when budgets prohibit most states from performing what has come to be known as the ‘on-demand’ inspection. Fortunately . . . [NABP] has developed the Verified Pharmacy Program® (VPP®), which can assist nonresident pharmacies in meeting the inspection requirement for some states.” Indeed, NABP is seeing an emerging trend of states referring facilities requesting such inspections to VPP.

Inspector Training

Inspector training is another emerging trend. Massachusetts is one state that has leveraged VPP and NABP inspection expertise to enhance its in-state inspections. In this instance, the state invited NABP to perform initial inspections for nuclear pharmacies in the state, creating a baseline inspection and simultaneously providing training for state inspectors. NABP is in discussions with several states about similar partnerships.

Leveraging VPP and NABP’s inspection expertise to provide targeted training for state inspectors is not confined to Massachusetts. As NABP has reported previously, both Idaho and Vermont, for example, have utilized hands-on training for nonsterile and sterile compounding inspections; Vermont’s training also included inspections of nuclear pharmacies.

As mentioned, additional states have indicated interest in setting up inspector training through NABP, and a new grant program will make it possible for the Association to provide in-state training for up to 15 states in 2017 and 2018. NABP will report more on the grant and expanded training possibilities in future issues of Innovations.

The quest to increase states’ access to quality, uniform inspection information for in- and out-of-state pharmacies, particularly compounding pharmacies, has made tremendous progress in the last four years. The state boards of pharmacy are utilizing the tools and resources created in cooperation with NABP to good effect, but the journey to improved compounding safety continues. Part three of this article series will take a look at what the future may hold.
State prescription monitoring programs (PMPs) have been working tirelessly to curb prescription drug abuse. Such efforts are having an impact on the opioid overdose epidemic as indicated in a recent study published in *Health Affairs* and based on IMS Health’s National Prescription Audit and government mortality data. The study found that efforts to mandate provider review of state PMP data along with state pain clinic laws decreased the amount of opioids prescribed by 8% and reduced prescription opioid overdose death rates by 12%.

The NABP PMP InterConnect® program has supported state PMP efforts for over five years. In January 2011, NABP developed PMP InterConnect, a program designed to facilitate interoperability and interstate data sharing between state PMPs by providing a secure communications exchange platform for participating states. The program became operational in August 2011 with data exchanges in Indiana and Ohio. Since then, numerous PMPs have connected to PMP InterConnect, bringing the total number of participating states securely sharing prescription drug data through the information platform to 37 in 2016. Participating states include Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Hampshire, New Mexico, New York, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, and Wisconsin.

PMP InterConnect is expected to see continued growth moving into the new year. Six states have signed a memorandum of understanding (MOU), and one state has an MOU under review. (For a full breakdown continued on page 12

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**NABP PMP InterConnect – 2016 Highlights**

- **February**
  - Alaska goes live with NABP PMP InterConnect®.

- **March**
  - New York and Vermont go live with PMP InterConnect.
  - NABP participates in a National Public Radio interview titled “49 States Combat Opioid Epidemic With Prescription Database.”

- **May**
  - NABP Executive Committee announces continued funding to support participation in PMP InterConnect at no cost to state PMPs beyond 2018.

- **June**
  - Texas and Massachusetts go live with PMP InterConnect.

- **September**
  - New Hampshire goes live with PMP InterConnect.

- **October**
  - NABP attends a meeting with the National Conference of State Legislatures in New Orleans, LA.

State efforts to combat prescription drug diversion and abuse through participation in the PMP Interconnect program are highlighted during the 2016 National Rx Drug Abuse and Heroin Summit in Atlanta, GA.
PMP InterConnect
continued from page 11

of PMP InterConnect participation in 2016, see the timeline on page 11.)

The number of interstate prescription drug data requests also has grown significantly over the past five years. In 2011, only a few thousand transactions were supported each month. In 2016, the program began processing more than 3.5 million interstate requests each month.

2016 PMP InterConnect Highlights

Throughout 2016, NABP highlighted the integral role that state PMPs play in the fight against prescription drug abuse. In February, NABP staff met with representatives from the United States Department of Justice – Bureau of Justice Assistance; Office of the National Coordinator for Health Information Technology; Substance Abuse and Mental Health Services Administration; and the US Senate Committee on Health, Education, Labor, and Pensions. During the meetings, NABP provided these stakeholder organizations with an update on PMP InterConnect.

In May 2016, NABP participated in an interview with National Public Radio (NPR). During the NPR segment “49 States Combat Opioid Epidemic With Prescription Database,” NABP provided insight into the growing epidemic and what the state PMPs are doing to combat this issue.

Also in May, NABP attended a meeting with the National Conference of State Legislatures in New Orleans, LA. During the event, the Association presented information on how states are increasing their use of PMP data, including connecting to PMP InterConnect, passing mandatory registration and use laws, and promoting in-workflow access to PMP data through electronic medical records of vendors, health information exchanges, health care systems, and pharmacy software systems.

In June 2016, NABP announced that PMP InterConnect will remain free to participating states past 2018, enabling states to focus their resources and federal grants to support their PMP operations. The commitment by NABP to fully support PMP InterConnect is expected to remove any resource roadblocks that states face to identifying patients with prescription drug abuse and misuse problems, especially if patients are crossing state lines to obtain drugs. “NABP PMP InterConnect is the only national network of state-based PMPs. It furthers the mission of the boards of pharmacy and NABP, as well as other state agencies, to protect public health by assisting health care providers in identifying doctor shopping and diversion of controlled substances, as well as confirming which patients are legitimately receiving such prescriptions,” noted NABP President Hal Wand, MBA, RPh.

Both participating state PMPs and those showing interest in reviewing an MOU were able to learn more about PMP InterConnect and its continued availability at no cost during the 2016 NABP PMP InterConnect Steering Committee meeting in July. In addition, several participating state PMPs shared with meeting attendees how they have implemented the program to combat prescription drug abuse. More of this meeting was highlighted in the September 2016 issue of Innovations.

More information about PMP InterConnect is available in the Initiatives section of the NABP website.

Newly Accredited VAWD Facilities

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

- **AmerisourceBergen Drug Corporation**
  - Olive Branch, MS
  - Shakopee, MN

- **Cardinal Health 110, LLC, dba Parmed Pharmaceuticals**
  - Memphis, TN

- **HMPG Pharmacy, LLC**
  - Zelienople, PA

- **Independent Pharmacy Distributor, LLC**
  - Lexington, NC

- **Kremers Urban Pharmaceuticals, Inc**
  - Seymour, IN

- **Kroger Limited Partnership I, dba Peyton's Southeastern**
  - Cleveland, TN

- **Leading Pharma, LLC**
  - Fairfield, NJ

- **Medical Specialties Distributors, LLC**
  - Compton, CA

- **Owens & Minor Distribution, Inc**
  - Edwardsville, IL

- **Taro Pharmaceuticals USA, Inc**
  - Cranbury, NJ

A full listing of more than 560 accredited VAWD facilities is available on the NABP website at www.nabp.pharmacy.
Volunteer Item Writers Gather to Develop NAPLEX Questions

Volunteer item writers convened in September 2016 to develop examination questions that will be considered for the North American Pharmacist Licensure Examination® (NAPLEX®). Pictured left are Jennifer Beall, PharmD, RPh, Samford University McWhorter School of Pharmacy (left), and Leslie Richard, RPh, Hillcrest Convalescent Center (right). Pictured below (left to right) are E. Paul Holder, PharmD, RPh, Texas A&M Rangel College of Pharmacy; Gary Gonza, RPh, St John Fisher College; William A. Kehoe, MA, PharmD, FCCP, BCPS, University of the Pacific; and Anita T. Mosley, PharmD, RPh, PhD, University of the Incarnate Word.

NABP Shares .Pharmacy Program Initiative at 2016 Pharmacy and Internet Stakeholder Events, in US and Abroad

Throughout 2016, NABP staff promoted the .Pharmacy Top-Level Domain (TLD) Program through various international and professional outreach efforts. The .pharmacy TLD helps patients to easily identify legitimately operating websites authorized to provide services in their country, and to know that the medications, information, and services they obtain from those sites are authentic and safe. NABP staff shared information on the program at the following events in North America and abroad.

US Events
- American Pharmacists Association Annual Meeting and Exposition March 2016; Baltimore, MD
- Cardinal Retail Business Conference June 2016; Chicago, IL
- McKesson ideaShare June 2016; Chicago, IL
- ThoughtSpot2016 July 2016; Las Vegas, NV
- Meeting with US Department of Justice Computer Crime and Intellectual Property Section and other verified TLDs August 2016; Washington, DC
- National Community Pharmacists Association Convention October 2016; New Orleans, LA
- American Society for Pharmacy Law Seminar November 2016; Austin, TX

International Events
- Access to Safe Medicines Europe January 2016; London, UK
- Global Domains Division Industry Summit for Internet Corporation for Assigned Names and Numbers May 2016; Amsterdam, Netherlands
- Canadian Pharmacists Conference June 2016; Calgary, Alberta

Upcoming Events
- American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition December 2016; Las Vegas, NV
Wholesale-Style Transactions Represent Significant Portion of Revenue Through Online Cryptomarkets

Nearly 25% of the drug-related revenue generated through illegal commercial websites known as cryptomarkets were from wholesale-style purchases in excess of $1,000, according to an August 2016 report prepared for the Netherlands Ministry of Security and Justice, Research and Documentation Centre (WODC). Of those illegal transactions, approximately 16% were for prescription drugs. While most transactions were for smaller amounts, indicating that the drugs were likely intended for personal use, the wholesale-style transactions may suggest that a significant number of drugs trafficked through cryptomarkets are intended for resale.

While most transactions were for smaller amounts, indicating that the drugs were likely intended for personal use, the wholesale-style transactions may suggest that a significant number of drugs trafficked through cryptomarkets are intended for resale.

Internet-facilitated Drugs Trade: An Analysis of the Size, Scope and the Role of the Netherlands was prepared by RAND Europe, a nonprofit institution that helps improve policy and decision making through research and analysis. The study investigated the size and scope of internet-facilitated drug trading with special focus on the role of Dutch actors in facilitating this trade. More specifically, RAND Europe examined the characteristics of vendors, buyers, and other actors involved in online drug trading. The study also gathered data on the types of drugs being sold and the size of the online drugs trade. The report offers information on ways in which law enforcement might be able to address the issue.

Silk Road

The term “cryptomarkets” refers to illegal black market websites that operate on the dark web. These websites provide a platform for users to buy and sell illicit items, including illicit drugs, and are often difficult for law enforcement to combat because they require specific software, configuration, or other authorization to access.

In 2013, a now infamous cryptomarket website known as Silk Road was shut down following an investigation and raid by the Federal Bureau of Investigation. The site’s founder and operator, Ross Ulbricht, was ultimately sentenced to life in prison for related charges. During the trial, held in federal court, prosecutors argued that Silk Road was involved in more than $200 million worth of business and was used for over 1.5 million illicit transactions before it was shut down.

Despite the severe sentence levied against Ulbricht, similar copycat websites have taken Silk Road’s place. In fact, a new Silk Road emerged.
only a month after the first was shut down. According to the RAND Europe report, cryptomarket transactions of illegal drugs have tripled and revenue has doubled since 2013, even with law enforcement interventions and decreased levels of trust between buyers and vendors on cryptomarkets.

Wholesale Connection

Silk Road and other cryptomarkets have often been characterized as “eBay for drugs,” allowing users to make small purchases for individual use. And while many users of these websites use them for this purpose, earlier studies have also indicated that a significant number of transactions are taking place at prices and quantities that suggest an intent to resell.

In 2014, a study published on the Social Science Research Network finds that, excluding opioids, 31-45% of revenue generated by Silk Road in September 2013 was composed of “high price-quantity sales,” suggesting that sales to drug dealers were a key part of the Silk Road drugs trade. The research also finds that “clear and substantial discounts” were available to users who purchased in larger quantities. The researchers noted that their findings provided clear evidence that many Silk Road customers were drug dealers who were using the website to source their stock of illicit drugs, including prescription drugs such as Xanax®.

Another study, published in The International Journal of Drug Policy, confirms that while the most numerous listings on Silk Road were priced at less than $100, indicating an intent for personal use, roughly 26% of all estimated monthly revenue generated on Silk Road came from wholesale-level transactions in excess of $1,000. Two of the authors of these studies collaborated with RAND Europe in preparing their report for the WODC, and all three used much of the data collected from Silk Road in September 2013.

Other Findings

In addition to this information about wholesale-like transactions, the RAND Europe report found that general monthly revenues from drugs on cryptomarkets are in excess of $10 million. In January 2016, monthly revenue was approximately $14.2 million, or $12 million when prescription drugs, alcohol, and tobacco were excluded. More than half of the total listings across the eight analyzed cryptomarkets offered some type of drug.

Most revenues were generated by vendors who claimed to be operating from Anglo-Saxon countries or western Europe, as well as the United States and Canada. This includes the United Kingdom, Germany, Spain, France, and the Netherlands. Notably, revenues from vendors operating from the Netherlands were by far the largest on a per capita basis.

Detection and Disruption Strategies

Though cryptomarkets have been difficult for law enforcement to disrupt, the RAND Europe report identified four broad strategies that may be available.

1. Traditional investigation techniques applied in the drug chain, including surveillance and undercover operations.

2. Postal detection and interception, requiring collaboration between law enforcement agencies and postal services.

3. Online detection and monitoring of internet marketplaces.

4. Online disruption such as that used to shut down Silk Road.

It should be noted that despite the growth in cryptomarkets’ revenue and transactions, sales of illicit and prescription drugs on cryptomarkets are still relatively small when compared to offline sales. Nevertheless, the data suggests that cryptomarkets are being used to source drug dealers at an international level.

NABP Efforts

Over the past eight years, NABP has worked proactively to identify illegally operating websites and provide a list of these sites to consumers as another tool to help them stay safe when purchasing prescription medication online. Currently, 11,299 online drug outlets that sell prescription medications have been reviewed by NABP, and 95.79% have been classified as Not Recommended given that the websites are selling prescription medications out of compliance with state and federal laws and/or Association patient safety and pharmacy practice standards. NABP’s most recent report, as well as the list of Not Recommended sites, is available on the Not Recommended Online Pharmacies page in the Acquire Safely section of the AWARE,E® Prescription Drug Safety website at www.AWARErx.pharmacy.

Most recently, NABP launched the .Pharmacy Top-Level Domain (TLD) Program to assist consumers in easily identifying safe online pharmacies and pharmacy-related resources. Recognizing the rapidly evolving internet marketplace, as well as the increased sophistication of cybercriminals, NABP anticipated the need for its own online verification and approval programs to evolve (Verified Internet Pharmacy Practice Sites®, Veterinary-Verified Internet Pharmacy Practice Sites® and e-Advertiser Approval Program™) and .Pharmacy was launched in 2014. NABP will continue to review information about cryptomarkets as part of its ongoing efforts to monitor rogue internet drug outlets. The Association will also continue to promote safe and legal methods of filling prescriptions online through its .Pharmacy Top-Level Domain Program. More information on the RAND Europe report, including the full text, is available at www.rand.org/randeurope/research.
Opportunities to Sponsor Annual Meeting Educational Activities Available

- Opportunities to support NABP’s annual meeting activities through a sponsorship or educational grant are available for the NABP 113th Annual Meeting.

- Such support helps NABP provide quality educational programs for board of pharmacy members, executive officers, and compliance staff.

- For more details, organizations may contact NABP via email at Prof-Affairs@nabp.pharmacy or via phone at 847/391-4406.

Deadline Set for Submitting Proposed Amendments to the NABP Constitution and Bylaws

Proposed amendments to the NABP Constitution and Bylaws must be submitted between Monday, February 20, 2017, and Thursday, April 6, 2017, to be considered for the 113th Annual Meeting, to be held May 20-23, 2017, in Orlando, FL. Additional submission guidelines are as follows:

- Amendments may be proposed by any active member board of pharmacy, the NABP Executive Committee, or the Committee on Constitution and Bylaws.

- Submission dates are established by the NABP Constitution and Bylaws. 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.

- 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 email at ExecOffice@nabp.pharmacy.

Save the Date for the NABP 113th Annual Meeting!

May 20-23, 2017
Hyatt Regency Orlando, Orlando, FL

The NABP 113th Annual Meeting website will soon be available, and can be accessed from the link in the Meetings section of the NABP website. The event offers members 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 Innovations.
NABP Mourns Passing of Sister Margaret Wright, RSM, PhD

NABP is sad to announce that Sister Margaret Wright, RSM, PhD, a Sister of Mercy for 63 years and a former member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy, passed away on Sunday, October 16, 2016. Her contributions to NABP, state boards of pharmacy, and the protection of public health were significant.

Sister Margaret showed ongoing commitment to NABP by serving on numerous task forces and committees, including serving on the Foreign Pharmacy Graduate Equivalency Examination Review Committee for over 10 years. She also served on the Advisory Committee on Examinations and the Multistate Pharmacy Jurisprudence Examination Review Committee. Sister Margaret also consulted as a subject matter expert by reviewing the annual updates to the Survey of Pharmacy Law from 2010 to 2014.

In recognition of her dedication to the Association’s mission and goals, NABP named Sister Margaret as its 1994-1995 honorary president. She was also awarded the Association’s Lester E. Hosto Distinguished Service Award in 1987. In 1980, Sister Margaret was the first woman and first from a hospital setting to be named the Pharmacist of the Year by the Illinois Pharmacists Association. The American Pharmacists Association awarded the Gloria Niemeyer Francke Leadership Mentor Award to Sister Margaret in 2004 for her contributions to the pharmacy profession, including mentoring new pharmacists.

Sister Margaret was the president and chief executive officer of Palos Community Hospital for 35 years.

Sister Margaret Wright accepts the 1994-1995 honorary president award from Edward Duffy, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy.

She earned her bachelor of pharmacy degree from Creighton University in 1962, master of science degree in pharmacy administration from the University of Colorado in 1971, and PhD in pharmacy from the University of Illinois at Chicago in 1998.
Ohio Requires Reporting of Gabapentin Products to PMP

In Ohio, the following entities are required to submit the specified dispensing, personal furnishing, or wholesale sale information on all products containing gabapentin to the Ohio prescription monitoring program (PMP), known as the Ohio Automated Rx Reporting System, beginning on December 1, 2016.

- All pharmacies located outside Ohio and licensed as a terminal distributor of dangerous drugs that dispense gabapentin to outpatients residing in the state.
- All pharmacies located within the state and licensed as a terminal distributor of dangerous drugs that dispense gabapentin to all outpatients.
- All wholesalers licensed as a wholesale distributor of dangerous drugs that sell gabapentin at wholesale shall report those drug transactions.
- All pharmacies licensed as a terminal distributor of dangerous drugs that sell gabapentin at wholesale shall report those drug transactions.
- All prescribers, except veterinarians, located within Ohio who personally furnish gabapentin to outpatients, including samples.

Additional information is available on the State of Ohio Board of Pharmacy website at www.pharmacy.ohio.gov.

Utah Board Reports Legislation Updates Related to Controlled Substances

The Utah Board of Pharmacy reported the following legislative updates related to controlled substances and opiate abuse. The legislation was passed by the Utah State Legislature in the 2016 General Session.

House Bill (HB) 192, “Opiate Overdose Response Act – Pilot Program and Other Amendments,” renames the Emergency Administration of Opiate Antagonist Act as the Opiate Overdose Response Act, amends liability provisions, and creates the Opiate Overdose Outreach Pilot Program within the Utah Department of Health. HB 192 also authorizes the Department to make grants through the program to persons who are in a position to assist an individual who is at increased risk of experiencing an opiate-related drug overdose event and specifies how grants may be used.

HB 239, “Access to Opioid Prescription Information via Practitioner Data Management Systems,” requires the Utah Division of Occupational and Professional Licensing to make opioid prescription data information in its Controlled Substance Database accessible to an opioid prescriber or pharmacist via the prescriber’s or pharmacist’s electronic data system. HB 239 also limits access to and use of the information by an electronic data system to a prescriber or a pharmacist in accordance with rules established by the Division. In addition, HB 239 requires the Division to periodically audit use of the information and amends Controlled Substance Database Act penalty provisions.

Additional details on these and other bills are available on the Utah State Legislature website at http://le.utah.gov and may be searched by bill number or keywords.

South Carolina Board Clarifies Beyond-Use Dates for Nonsterile Compounded Products

The newly posted Non-Sterile Compounding Inspection Form states:

- BUDs are assigned from the day of preparation.
- BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of an [active pharmaceutical ingredient] and not later than six months.
- BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).
- BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.
- Extended BUDs are supported by testing data and professional judgment.

The South Carolina Compounding Committee recommended to the full Board that compounders consider the last bullet point above and rely on literature citations and their own testing data and professional judgment to extend the expiration dates of nonsterile compounded products past those recommended by United States Pharmacopeia Chapter <795> as stated above. Therefore, reliable references on compounded formulation expirations may be considered for extension of BUDs.

The full Board accepted the recommendation of the Compounding Committee at its June 15, 2016 meeting. The Non-Sterile Compounding Inspection Form may be found on the Board’s website in the Applications and Forms section at www.llr.state.sc.us/POL/Pharmacy/index.asp?file=pub.htm.
FDA Requires Boxed Warnings and Medication Guides Related to Combined Use of Certain Opioid Medications and Benzodiazepines

Food and Drug Administration (FDA) is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzo-diazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, which is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm.

Novo Nordisk, Inc, Recalls Six Batches of GlucaGen HypoKit Due to Detached Needles

In September 2016, Novo Nordisk, Inc, of Plainsboro, NJ, voluntarily recalled six batches of the GlucaGen® HypoKit® from wholesalers, pharmacies, and patients in the United States because of the possibility of defective syringes. The recall was initiated following two customer complaints from the United Kingdom and Portugal involving detached needles on the syringe with sterile water for injection. The affected batch numbers are listed in the press release posted to FDA’s website at www.fda.gov/Safety/Recalls/ucm519872.htm. The recalled products were distributed in the US starting February 15, 2016. To date, Novo Nordisk is not aware of any known adverse events related to this recall. Health care providers and patients are encouraged to report adverse events or quality problems to FDA’s MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch.

FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the Center for Drug Evaluation and Research presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA

and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of prescription drug promotion and FDA’s expanded access program. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.

December DEA Conferences on Preventing Drug Diversion Scheduled in New York

Drug Enforcement Administration (DEA) is offering two regional one-day Pharmacy Diversion Awareness Conferences (PDACs) in Buffalo, NY, with one on Friday, December 9, 2016, and another on Saturday, December 10, 2016. Each one-day conference is open to pharmacy personnel (pharmacists, pharmacy technicians, or loss prevention personnel) who are employed by pharmacies or hospitals/clinics that are registered with DEA in the state of New York. The conference is designed to assist pharmacy personnel in identifying and responding to potential diversion activity. Location details, a conference agenda, and a link to the online registration form are available on the DEA website. There is no registration fee for these conferences. Upon completion of the one-day conference, pharmacists and pharmacy technicians may receive up to seven Accreditation Council for Pharmacy Education-accredited continuing pharmacy education hours (0.7 CEUs). Additional information on these and other upcoming PDACs is available on the DEA’s Diversion Control Division website at www.deadiversion.usdoj.gov/mtgs/pharm_awareness.

Latest Drug Info Rounds Training Videos Available on the FDA Website

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the Drug Info Rounds video “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.
INNOVATIONS
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

UPCOMING EVENTS

PARE Administration
November 29-December 10, 2016
Rosemont, IL

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

Task Force on the Pharmacist Integrated Communication Skills Examination
December 13-14, 2016
Rosemont, IL

Committee on Law Enforcement/Legislation
January 24-25, 2017
Rosemont, IL

Committee on Constitution and Bylaws
April 12, 2017
Teleconference

FPGEE Administration
April 25, 2017

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