newsletter

National Association of Boards of Pharmacy®

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April 2015 / Volume 44 Number 4

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Upcoming Events

April 20, 2015
FPGEE Administration

April 23, 2015
PCOA Forum
NABP Headquarters

May 16-19, 2015
NABP 111th Annual Meeting
New Orleans, LA

August 6-8, 2015
NABP/AACP District 5 Meeting
Fargo, ND

August 15-18, 2015
NABP/AACP District 3 Meeting
St Augustine, FL

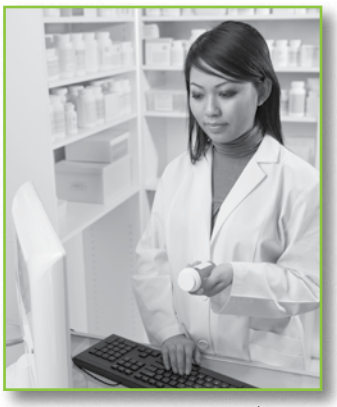
September 14-17, 2015
NABP/AACP Districts 6, 7, & 8 Meeting
Incline Village, NV

Limited .Pharmacy Registration Period for Dispensing Pharmacies to Begin in April

NABP will begin accepting applications for .pharmacy domain names from all dispensing pharmacies beginning April 1, 2015. Meanwhile, the Association continues to evaluate applications submitted during earlier limited application periods. The registration period for dispensing pharmacies is the last of the limited registration phases and ends June 2. General availability, when any company with a pharmacy or pharmacy-related website may apply and, if approved, register for a .pharmacy domain name, will begin on June 3, 2015.

Those eligible to apply for names in the .pharmacy domain include pharmacies, pharmacy benefit management companies, prescription drug information and pharmacy referral sites, prescription drug-related patient advocacy and consumer education sites, medical professionals' offices, schools and colleges of pharmacy, continuing pharmacy education providers, wholesale drug distributors, and pharmaceutical manufacturers. Organizations who receive authorization to obtain a requested domain name will be able to register through an approved registrar.

NABP began accepting the first .pharmacy applications in December 2014 from trademark holders who had entered their trademarks into the Internet Corporation for Assigned Names and Numbers (ICANN) Trademark Clearinghouse (TMCH). Known as the Sunrise Registration Period, this phase was mandated by ICANN to protect intellectual property rights by allowing eligible trademark holders to apply for domain names that exactly match their trademark names in the TMCH prior to the general public. As of press time, NABP received 59 domain name requests as part of the Sunrise Registration period, which included those from pharmacies, manufacturers, referral sites, and at least one consumer education organization.



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An additional limited registration phase was

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In This Issue. . . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 64 member boards of pharmacy to the profession and the public. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABP or any board unless expressly so stated. The subscription rate is $35 per year.

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.Pharmacy Registration

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also offered to entities that have been previously accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval℠ Program. During this phase, over 250 .pharmacy domain name requests were received. To receive accreditation or approval under these programs, VIPPS, Vet-VIPPS, and NABP e-Advertiser websites have undergone a thorough review process establishing their compliance with NABP standards for legitimate online practice. As such, all previously accredited or approved content is considered prequalified and is eligible for a .pharmacy domain name without the usual .pharmacy application and fee.

> Boards of pharmacy that have not yet requested a .pharmacy domain name may still send a request by email to info@safe.pharmacy. It is anticipated that these domain names will continue to be available at no cost to the boards.

As these approved companies register their .pharmacy domain names, they will join the ranks of 23 boards of pharmacy in providing high-quality, trustworthy information available on .pharmacy websites. Boards of pharmacy that have not yet requested a .pharmacy domain name may still send a request by email to info@safe.pharmacy. It is anticipated that these domain names will continue to be available at no cost to the boards.

On January 29, 2015, NABP hosted a .Pharmacy Supporter Advisory Committee meeting via teleconference to review the execution of the .Pharmacy Top-Level Domain (TLD) Program's launch phases, public outreach efforts, and collaborative efforts with international partners, and to determine recommendations for the .Pharmacy Executive Board to consider during its April 2015 meeting. Additional advisory committee meetings, either by teleconference or in person, will be held quarterly. Additional information on these meetings will be available in future *Newsletter* articles.

More information about the .Pharmacy TLD Program is available at *www.safe.pharmacy*. NABP's most recent research on rogue online drug sellers is available on the Not Recommended page in the Safe Acquisition section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARErx.org*.

Newly Accredited DMEPOS Facilities

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

Brewer Medical Center Pharmacy
Brewer, ME

Desna Pharmacy, Inc
Wheeling, IL

Horizon Pharmacy III
Elmhurst, NY

Sims Pharmacy
Brooklyn, NY

The Prescription Pad Pharmacy
Monticello, AR

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

NABP Report Highlights Rogue Internet Drug Activity, Need for .Pharmacy Domain

In January 2015, NABP issued a report underscoring the need for the .Pharmacy Top-Level Domain (TLD) Program as a public health initiative to help consumers distinguish legitimate online pharmacies from rogue online drug sellers. As detailed in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: January 2015,* the two most common characteristics of sites NABP has identified as rogue Internet drug sellers are dispensing prescription drugs without a valid prescription and offering foreign and unapproved drugs. Such factors place public health at risk and undermine regulations put in place to safeguard the drug supply chain, highlighting the need for the .pharmacy domain.

To explore trends related to this issue, NABP conducted a review of data collected on websites selling medicine illegally online to United States patients since the Association began reviewing websites in 2008. Over the last seven years, NABP has reviewed nearly 11,000 Internet drug outlets, finding that nearly 97% (10,521) of the sites reviewed operate out of compliance with US pharmacy laws and practice standards. During that time period, the average percentage of "Not Recommended" sites selling drugs without a prescription was 93.4%. Current data show that over 62% of Not Recommended sites do not post a physical address. These sites tend to be most likely to dispense counterfeit drugs. Further, of the 10,521 Not Recommended sites, 91% appear to have affiliations with rogue networks of Internet drug outlets, and 12% dispense controlled substances.

The frequency of such characteristics among online drug sellers poses a danger to public health, creating a need for consumer education and resources to help identify safe online pharmacies. To protect consumers buying medications online, NABP launched the .Pharmacy TLD Program. Only legitimate Internet pharmacies and related entities will qualify for .pharmacy domains, giving consumers a way to distinguish safe and legal online pharmacies and resources from rogue sites. NABP began accepting applications for .pharmacy domain names in late 2014, and several boards of pharmacy have now registered and activated their .pharmacy domain names. Following a series of special registration periods that will continue through the first half of 2015, general availability will open for eligible pharmacy community members on June 3, 2015.

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The full report with detailed findings on the characteristics of rogue websites and the list of Not Recommended sites are available on the Safe Acquisition page in the Get Informed section of the AWAR$_X$E® Prescription Drug Safety website, *www.AWARERX.ORG*.

To find the safest sources for purchasing medicine online, consumers are encouraged to choose from NABP's list of Verified Internet Pharmacy Practice Sites® (VIPPS®)-accredited sites on the AWAR$_X$E website. More information about the .pharmacy TLD is available at *www.safe.pharmacy,* and .pharmacy sites will be listed there as approved entities register .pharmacy domain names.

Executive Committee

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Chairperson
One-year term

Joseph L. Adams
President
One-year term

Edward G. McGinley
President-elect
One-year term

Hal Wand
Treasurer
One-year term

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

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

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

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

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

Jeanne D. Waggener
Member, District 6
Serving third year of a three-year term

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

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

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

Defendant Has Fill of Pill Mill

Language is an important tool in the legal community and has the power to establish the scope of practice and authority granted to boards of pharmacy. Through the enactment of the practice acts, the legislatures create and empower the boards of pharmacy. Under that platform, the boards promulgate rules/regulations using the expertise of practitioner and regulator perspectives. Statutory and regulatory language provide the basis for the boards to regulate the profession in the interest of consumer protection. At times, certain words or phrases are the subject of debate as to their meaning and whether the use of language is prejudicial to an adverse party. Consider the following.

In December 2010, the owner and operator (Defendant) of the Maryville Pain Management, LLC (MPM) in Maryville, TN, was arrested for and eventually charged with 57 counts of conspiring to distribute and possession with intent to distribute oxycodone, hydrocodone, alprazolam, diazepam, and zolpidem in violation of federal law. The Defendant was also charged with six counts of money laundering and 49 counts of structuring financial transactions, also in violation of federal law. The activities that led to the indictment and eventual charges involved the Defendant's operations of MPM.

The Defendant was a high school dropout with a GED, no formal medical training, no medical license, and no Drug Enforcement Administration (DEA) license to issue prescriptions. She started MPM, and by word of mouth and paper flyers, the business grew. Because she could not prescribe, the Defendant hired a succession of nurse practitioners and doctors by placing ads on Craigslist and sending faxes to medical practices. According to the court, the MPM operations "bore all of the hallmarks of an illegal operation, quickly attracting the attention of surrounding businesses because of the customer traffic it generated and the drug deals that were witnessed in [the] parking lot."

As the business grew, MPM was moved to a medical office park where the suspect activities were observed by its new neighbors. Cars and customers lingered with "patients" holding tailgate parties and requesting to use the bathroom facilities of the neighboring professionals when the Defendant's facilities were occupied. Numerous medical practices in the vicinity testified that they had to lock their doors during business hours and lost patients and referrals. In addition, one police officer testified that pill use "skyrocketed" in the county and the number of thefts increased.

Regarding its internal operations, MPM activities also indicated a suspect business as customers mingled in crowded waiting rooms, sometimes sitting on the floor. MPM at first only accepted cash, but later moved to credit cards, and never once processed payments through insurance companies. Evidence indicated that the Defendant, although untrained and unlicensed, saw customers and issued prescriptions using forms that had been pre-signed by employed nurses and doctors. MPM staff also testified that these prescriptions were issued based upon speed, not a meaningful medical examination. On average, 150 to 170 customers were seen and received prescriptions per day. Bank employees testified that the Defendant regularly deposited thou-

sands of dollars in cash at the local bank.

After the opening of MPM, local pharmacists noticed an increase in the number of Schedule II narcotics that were dispensed. Indeed, groups of people often entered the pharmacies together and presented prescriptions for the same medications or combinations of medications. Customers always paid cash, regularly up to $1,500, and never presented insurance cards. According to the pharmacists, these customers were between the ages of 25 and 40 and showed no visible signs of pain or other infirmities.

In 2009, the Defendant initiated the process of establishing a pharmacy at MPM. Using the DEA number of the employed physician, the Defendant ordered more than $24,000 worth of controlled substances. Even after the physician and nurse resigned from employment, the operations continued using pre-signed prescription forms. Finally, a nurse practitioner hired by the Defendant who was concerned over the activities of MPM contacted and cooperated with DEA. As a result of the investigations, an indictment was returned and the Defendant was charged with the numerous counts referenced above.

MPM generated gross receipts of over $2.1 million, and a random sample showed 97.5% of prescriptions were for Schedule II narcotics, predominantly oxycodone, with 1.6% for Schedule III medications. Testimony indicated that during a 320-day period, 11,333 customers were seen with 634,648 dosage units of Schedule II drugs prescribed. At trial, the prosecution called scores of witnesses to corroborate the activities. In her defense, the Defendant produced her mother and three former employees as character witnesses. The Defendant absconded on the last day of her jury trial, leading to the issuance of an arrest warrant. In her absence, the jury convicted the Defendant as charged and she was sentenced to 258 months of imprisonment, inclusive of an 18-month sentence for failure to appear. The Defendant appealed her conviction.

The Defendant based her subsequent appeal on many factors, but in particular argued that the lower court erred in denying her motion to prohibit the use of certain terms in the trial. The Defendant had requested that the court "prohibit the Government or any of its witnesses from referring to the [MPM] as a 'pill mill' or as a 'pain clinic' or any other pejorative reference aimed at the Government's vouching or bolstering a claim of illegality in the operation of the pain management clinic." The Defendant argued that "pill mill" carries with it a stereotypical, derogatory connotation and that its use at trial was prejudicial and inflammatory. The appellate court noted that it reviews such an appeal for an "abuse of discretion." An abuse of discretion occurs if the lower court relies on "clearly erroneous findings of fact, applies the wrong legal standard, misapplies the correct legal standard when reaching a conclusion, or makes a clear error of judgment."

The lower court denied the motion by the Defendant to exclude the use of these phrases. It held that the phrase "pain clinic" does not have any negative connotation and that while "pill mill" may have some negative connotation, the use of that term is not substantially outweighed by the danger of unfair prejudice. The lower court noted that "pill mill" is a phrase of common usage not only in law enforcement, but in the media to "describe the activity charged in this indictment and the conduct of which the Defendant is accused."

On appeal, the appellate court agreed with the lower court and emphasized that the Defendant cited no authority for her arguments and further failed to explain why the use of the term "pain clinic" is pejorative in any sense or why "pill mill" is unduly deprecatory. The appellate court also cited previous jurisprudence whereby arguments attempting to prohibit the use of the phrase "pill mill" in a criminal trial have been uniformly rejected. In fact, previous cases have recognized lay witnesses who

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

NABP Submits Comments to FDA Regarding Proposed Rule on the Regulation of Liquid Nicotine Products

Acting on Resolution 110-6-14, passed at the 110th Annual Meeting in Phoenix, AZ, NABP submitted comments to Food and Drug Administration (FDA) regarding the agency's proposed rule to regulate electronic cigarettes and liquid nicotine products. Submitted on behalf of the Association's member boards, the comments expressed support for FDA's proposed rule. Further, NABP also urged state boards of pharmacy to examine state regulations to determine if liquid nicotine products used in electronic cigarettes and vapor-based products should be regulated and categorized as poison.

During the 110th Annual Meeting in May 2014, NABP's member boards approved Resolution 110-6-14, "Regulation of Electronic Cigarettes and Liquid Nicotine Products," which states that the Association will "support the FDA's efforts to regulate liquid nicotine products including, but not limited to, requiring proper labeling and child-resistant containers," and that NABP will urge state boards of pharmacy to "examine their state regulations and work with the appropriate state agencies to determine if the liquid nicotine products used in electronic cigarettes and vapor-based products should be regulated and categorized as poison."

In April 2014, FDA released proposed rules that would place new classes of tobacco products, including liquid nicotine products and electronic cigarettes, under the agency's authority to regulate. Under the proposed rules, such products would be considered subject to the Federal Food, Drug, and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The Tobacco Control Act already gives FDA authority to regulate most tobacco products, and to extend that authority to other products. In its comment letter, NABP cited that the following facts informed the Association's support of the FDA rule:

- Electronic cigarettes, liquid nicotine, and similar vapor-based products are gaining popularity.
- The dangers posed by inhaling these nicotine products are unknown.
- Liquid nicotine products currently available for sale may pose a significant threat to public health, especially if ingested by children.
- Liquid nicotine products for electronic cigarettes are being imported and manufactured without appropriate FDA oversight.

Additional information on FDA's proposed rules is available on the *Federal Register* website at *www.federalregister.gov/a/2014-09491*. The full text of Resolution 110-6-14 is available in the Members section of the NABP website at *www.nabp.net*.

Legal Briefs

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offer opinions based upon personal perceptions and such courts have allowed the use of phrases like "drug organization," "drug house," "stash house," and others. Further, the phrase "pill mill" is not a legal conclusion and the fact that a term has a negative connotation does not mean it violates the applicable rules of evidence. As a result, the appellate court agreed with the lower court that the use of the phrase "pill mill" is not excludable under evidentiary rules. The denial of Defendant's motion to prohibit its use was affirmed.

The appellate court also rejected the Defendant's arguments that the multiplicitous counts propounded by the prosecution were violative of the Double Jeopardy Clause of the Fifth Amendment to the United States Constitution. The court held that the Defendant must allege a defect in the indictment before trial and did not do so in this case. Regardless, the Defendant cannot meet the necessary test to establish plain error. Accordingly, the court rejected the Double Jeopardy Clause arguments.

Finally, the court rejected arguments by the Defendant that evidence was insufficient to sustain her convictions for certain identified counts and held that the government's case supported the beyond a reasonable doubt standard. In addition, the court rejected the Defendant's argument that the government suppressed evidence favorable to the defense in violation of her due process rights. The court questioned the timeliness of the suppression motion and also noted that the Defendant's allegations were premised on mere speculation and conjecture. Based on the foregoing, the appellate court affirmed the lower court and upheld the convictions and sentencing of the Defendant.

This case illustrates how terminology may form the basis for challenges to due process rights of criminal defendants. The court cited additional cases whereby the use of the phrase "pill mill" was acceptable and not in violation of the rights of the accused. At what point might the use of various words or phrases be relevant in an administrative proceeding against a physician or pharmacist?

United States of America v. Guzman, 571 Fed. Apps. 356, 2014 U.S. LEXIS 12715 (6th Cir. 2014)

PCOA Added as Component of ACPE Standards

NABP's Pharmacy Curriculum Outcomes Assessment® (PCOA®) has been added as a component to Standard 24 of the Accreditation Council for Pharmacy Education's (ACPE) *Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016).* NABP submitted comments on the drafted ACPE standards in December 2014. In addition to highlighting the value of the PCOA in helping to assess curricula, NABP's comments noted the importance of educating pharmacy students about pharmacist-in-charge (PIC) responsibilities as they relate to securing controlled substances (CS) and the need to improve veterinary pharmacy education.

ACPE's *Draft Revised Standards for the Professional Program Leading to the Doctor of Pharmacy Degree (Draft Standards 2016)* was developed over the course of three years to ensure pharmacy education program graduates are "prepared to directly provide patient care in collaboration with other healthcare providers," according to ACPE. The revised standards were made available for public comment in February 2014, and were created based on input from a broad range of stakeholders, including over 1,000 individuals that participated in the standards revision process through surveys, ACPE's 2012 Invitational Conference, and by sharing best practices.

As ACPE recognizes the importance of curricula assessment as a key component of the new standards, NABP's comments strongly encouraged ACPE to require pharmacy degree programs to utilize the PCOA as an assessment tool for assisting with curriculum development and review of individual student performance and progress. NABP noted that the PCOA may also be utilized to implement standardized progression guidelines for student advancement, and may also be used to detect gaps in student comprehension. As the ACPE guidelines indicate, progression policies may help identify students that require early intervention.

Because the draft standards indicated a clear requirement for pharmacy degree programs to document and provide evidence of outcome measures and achievement of the required standards, NABP also noted that the PCOA facilitates the ability for pharmacy degree programs to comply with such a requirement and may provide an additional level of quality assurance. The Association provided a technical summary document on PCOA assessment measures to support the comments.

In addition, NABP requested that ACPE revise the draft standards to devote more attention to PIC responsibilities, particularly in relation to pharmacists' responsibility to identify "red flags" and other aberrant behavior when determining the appropriateness of a CS prescription. NABP also explained that some members have expressed concerns regarding a growing number of new graduates who may be accepting PIC positions without fully understanding the scope of associated responsibilities. For example, some board members have identified recent graduates who do not understand that PICs must maintain adequate pharmacy security to protect drugs from internal and external diversion from theft. Such responsibilities are particularly important in light of the alarming rise of prescription drug abuse that is often related to drug diversion.

The Association also referenced member board concerns that some pharmacy graduates lose sight of the corresponding responsibility placed on them by Drug Enforcement Administration to discern legitimate and appropriate CS prescriptions.

Finally, NABP asked ACPE to consider revising the draft standards to include additional requirements for veterinary pharmacology education at colleges and schools of pharmacy. The letter also included language related to Resolution 110-5-14, "Veterinary Pharmacy Education" passed at NABP's 110th Annual Meeting in Phoenix, AZ, concerning factors related to veterinary patient care.

In February 2015, ACPE released the final *Standards 2016* document that included the requirement that schools and colleges of pharmacy document annual performance metrics for students nearing completion of the didactic curriculum. Going forward, NABP is committed to partnering with the colleges and schools of pharmacy to ensure that implementation of the PCOA is effectively and seamlessly accomplished. Moreover, NABP will ensure, working with all stakeholders, that the implementation plan addresses all the concerns that may exist and all aspects of administering the PCOA to eligible pharmacy students. For example, NABP will communicate with the appropriate individuals at the schools and colleges of pharmacy to verify and register eligible students; ensure appropriate administration periods and administrations, scoring, score reporting; and provide the information desired by the schools and colleges to utilize and interpret PCOA results.

The *Standards 2016* will become effective on July 1, 2016. The *Standards 2016* document is available on the ACPE website at *www.acpe-accredit.org/deans/StandardsRevision.asp.* The full text of NABP Resolution 110-5-14 is available in the Members section of the NABP website, *www.nabp.net.* Additional information about the PCOA requirement will be provided in a future update.

NABP Announces the 2015-2016 NAPLEX Review Committee

NABP is pleased to announce the members of the 2015-2016 North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee, introducing three new members and commending 24 returning members.

Composed of faculty and pharmacists who are representative of the diversity of pharmacy practice, the NAPLEX Review Committee is responsible for reviewing the examination questions, attending and participating in meetings, and developing new test questions. Acting under the policy and planning guidance of the Advisory Committee on Examinations and the NABP Executive Committee, these dedicated volunteers share the task of safeguarding the integrity and validity of the Association's examination. NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements.

The NAPLEX Review Committee members (listed below) began their terms on February 1, 2015.

NAPLEX Review Committee Members

- Marie Abate, PharmD, RPh, West Virginia University
- Jennifer Beall, PharmD, RPh, BCPS, Samford University
- Christopher Betz, PharmD, RPh, BCPS, Sullivan University
- Michael Cockerham, MS, PharmD, RPh, BCOP, University of Louisiana – Monroe
- Ariane Conrad, PharmD, RPh, Oak Ridge, TN
- Dosha Cummins, PharmD, RPh, BCPS*, University of Arkansas for Medical Sciences Northeast
- Mark Decerbo, PharmD, RPh, BCPS, BCNSP, Roseman University of Health Sciences
- Betty Dong, PharmD, RPh, University of California – San Francisco
- Darla Gallo, RPh, Philadelphia, PA
- W. Franklin Gilmore, PhD, professor emeritus, Montana Tech of The University of Montana
- Robert P. Henderson, PharmD, RPh, BCPS, Samford University
- William A. Hopkins, Jr, PharmD, RPh, Big Canoe, GA
- Tom M. Houchens, RPh, London, KY
- Arthur I. Jacknowitz, PharmD, RPh, professor emeritus, West Virginia University
- William Kehoe, Jr, MA, PharmD, RPh, BCPS, University of the Pacific
- Susan C. Lutz, RPh, Altoona, IA
- Christina "Tina" Minden, PharmD, RPh, CGP, FASCP*, Little Rock, AR
- David W. Newton, PhD, Shenandoah University
- Roy Parish, PharmD, RPh, BCPS, University of Louisiana – Monroe
- Benjamin Prewitt, PharmD, RPh, Lebanon, OH
- David B. Roll, PhD, professor emeritus, University of Utah
- Eric F. Schneider, PharmD, BCPS, University of Waterloo
- Cynthia Sieck, PharmD, RPh, Vancouver, WA
- John L. Szarek, PhD, The Commonwealth Medical College
- Susan Cunha Villegas, PharmD, RPh*, Long Island University
- Neal F. Walker, RPh, Hibbing, MN
- Siu-Fun Wong, PharmD, RPh, Chapman University

*Denotes new members

NAPLEX Review Committee Members Gather at NABP Headquarters

In January 2015, members of the North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee met at NABP Headquarters to review and develop examination questions. Pictured clockwise: Tom M. Houchens, RPh, London, KY; Neal F. Walker, RPh, Hibbing, MN; John L. Szarek, PhD, The Commonwealth Medical College; and Marie Abate, PharmD, RPh, West Virginia University.

PCOA Data Continue to Demonstrate Positive Correlations in Content Areas, Successful Measurement of Student Growth

Six years of Pharmacy Curriculum Outcomes Assessment® (PCOA®) data show a step progression in knowledge as students advance in their studies, and continue to demonstrate that PCOA score results provide reliable and valid information about students' abilities and knowledge. With over 24,000 assessments administered across 61 colleges and schools of pharmacy, the PCOA has provided an external measure of student performance for use as a curricular evaluation tool. Now in its seventh year, the PCOA remains the only independent, objective, and national assessment that enables schools and colleges of pharmacy to assess their curriculum, measure their students' knowledge, and compare their results to other schools and colleges throughout the United States.

Scores Increase as Students Advance

Continuing a trend from 2009, PCOA data obtained from 2011 to 2014 show that overall scores increase as students advance from the first year through fourth year of the professional curriculum (see Figure A). This step progression of knowledge, reflected in the six-year score result trends, provides evidence that the PCOA is a valid measure of the expected increase in students' knowledge in US pharmacy school curricula.

Figure B on page 82 also illustrates this progression of student knowledge over the four content areas of the assessment as described by Accreditation Council for Pharmacy Education (ACPE) (basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences). For example, as educators would expect, P1 students tested highest in basic biomedical sciences compared to more advanced content areas such as clinical sciences. However, as students progress in their educational career, P4 students tested higher in more advanced content areas such as clinical sciences. (See Figure B.)

Content Validity

The content validity for the PCOA is supported by the relationship between examination questions, the PCOA blueprint, and the rigorous content development process. The assessment's content is developed and revised by accredited US schools and colleges of pharmacy faculty and practitioners. These subject matter experts are evaluated regularly on their academic and professional credentials and are also routinely evaluated in terms of their geographic location, college of pharmacy characteristics, academic specialization, and demographics. The PCOA questions and examination forms are written and reviewed by subject matter experts from more than 60 ACPE-accredited colleges of pharmacy. The design, development, administration, and scoring of the PCOA align with US pharmacy curricula and also align with professional standards for test development and psychometrics used in education and high-stakes test development.

Reliability

The PCOA's form-level reliability measure represents that questions are conceptually related, supporting the measure of a single construct (knowledge in the pharmacy curriculum). In addition, high form-level reliability indicates that scores are expected to be consistent and reproducible. The less random error contributes to an individual's score,

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Figure A.
Data from 2011 to 2014 indicates that there is a progression of student scores across program years P1 through P4.

PCOA Data

(continued from page 81)

the more confidence can be placed in the scores. Each year of administration, the PCOA's reliability measure meets professional testing industry standards for high-stakes examinations such as the North American Pharmacist Licensure Examination® (NAPLEX®) or the Multistate Pharmacy Jurisprudence Examination®.

Assisting the Schools and Colleges

As part of the schools and colleges of pharmacy's efforts to ensure the highest quality of education for their doctor of pharmacy (PharmD) students, the PCOA may be used to:

- Evaluate whether curricula meet the desired outcomes of their programs,
- Measure the overall performance of pharmacy students and compare their scores to a representative national sample,
- Evaluate the strengths and weaknesses of students,
- Track scores from year to year in order to track student growth,
- Monitor improvements in student performance after curricula have been modified or updated, or
- Conduct research studies, such as comparing academic proficiency (eg, grade point average or completion of the PharmD program) with PCOA and NAPLEX scores to provide insight into performance measures and trends. (Note that while the PCOA does not measure the same information as the NAPLEX, there is some overlap in content. The NAPLEX measures the student's ability to apply his or her knowledge and skills necessary for entry-level pharmacy practice while the PCOA measures a student's mastery of pharmacy knowledge in US pharmacy curriculum.)

The PCOA can also help the schools and colleges to track and maintain compliance with the ACPE standards and to compare results with peer institutions. Specifically, the PCOA is a required documentation for Standard 24 – Assessment Elements for Section I: Educational Outcomes in the ACPE *Standards 2016*.

PCOA Forum

As in years past, NABP will host a forum on April 23, 2015, to further cultivate a communicative, educational, and collegial environment for current PCOA users, prospective

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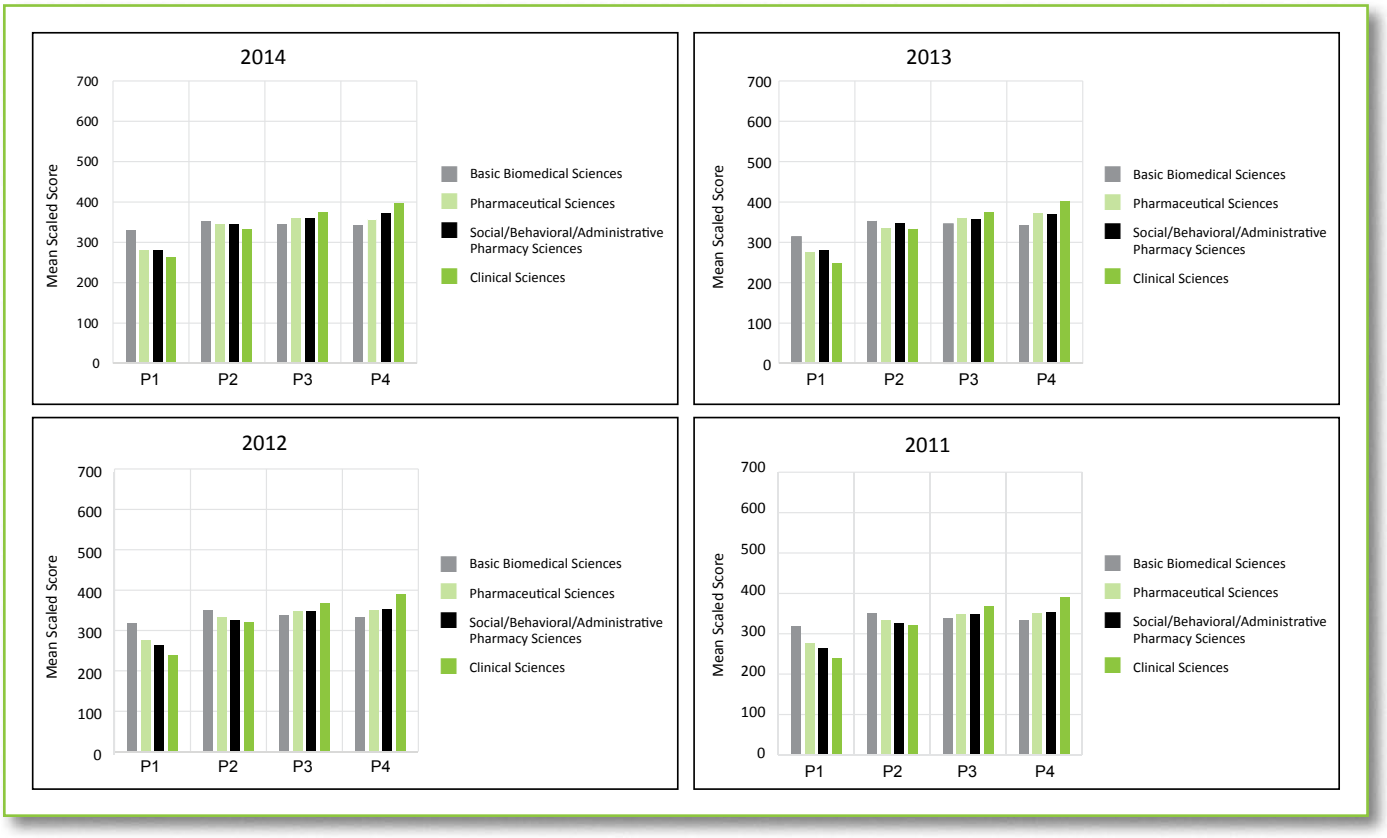
Figure B.

Data from 2011 to 2014 demonstrate progression and retention of knowledge in the four core competency areas as students progress through the professional curriculum.



Boards Report 5,218 Actions to NABP Clearinghouse in 2014; Numbers Increase for Second Consecutive Year

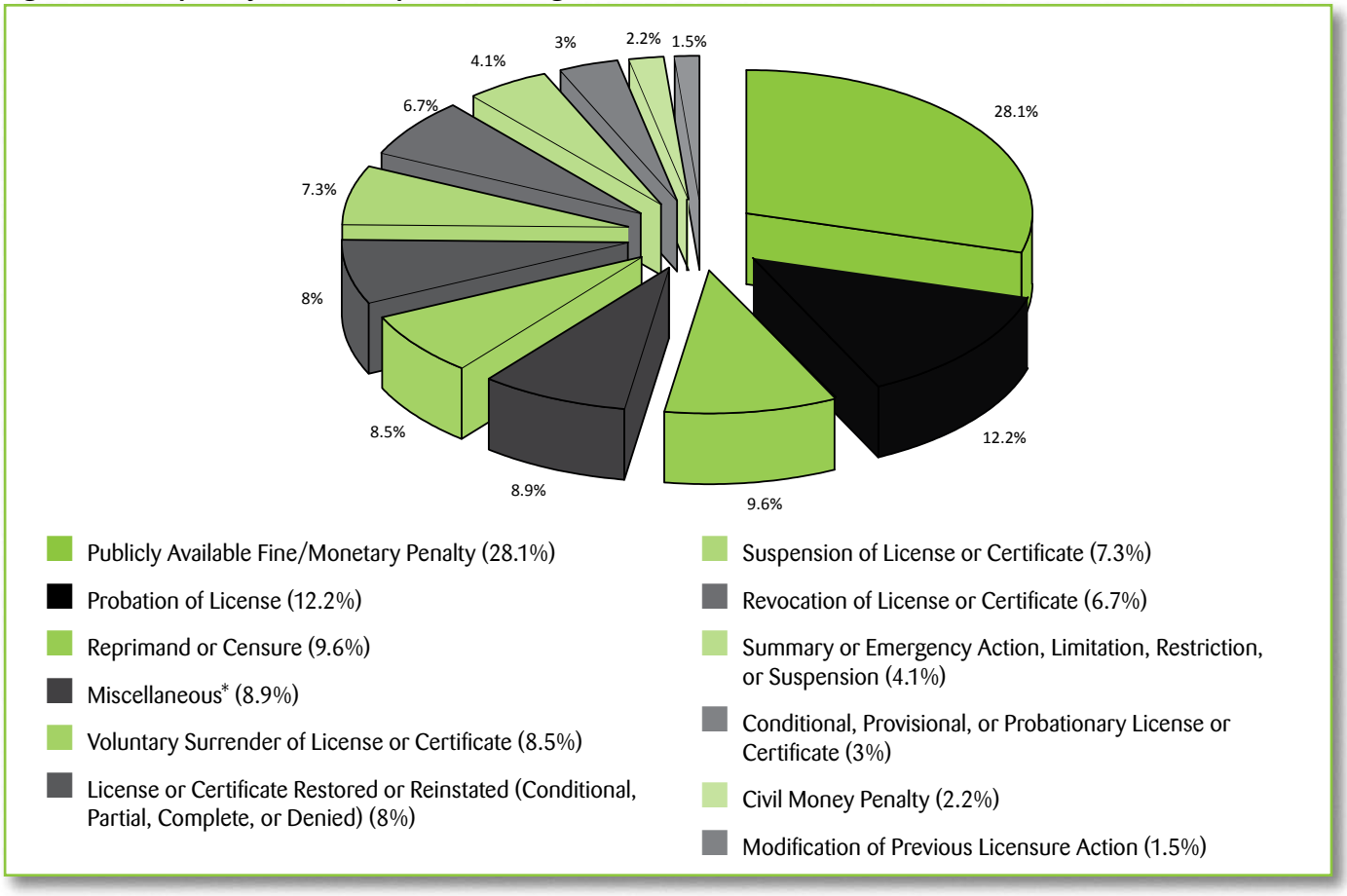
For the second consecutive year, the Association's year-end data results show an increase in the number of disciplinary actions reported to the NABP Clearinghouse. In 2014, a total of 5,218 actions were reported, which represents an increase of 5.7% when compared to the 4,938 actions reported in 2013. The ongoing efforts of the state boards of pharmacy to strengthen the regulation and inspections of compounding and nonresident pharmacies are likely related to the influx of actions the NABP Clearinghouse has received over the past two years.

Of the 5,218 actions reported in 2014:

- 2,639 actions (50.6%) were taken on pharmacists;
- 1,359 actions (26%) were taken on pharmacy technicians;
- 972 actions (18.6%) were taken on pharmacies;
- 98 actions (1.9%) were taken on wholesalers and manufacturers;
- 87 actions (1.7%) were taken on pharmacy interns;
- 51 actions (1%) were taken on other licensees;
- 10 actions (0.2%) were taken on mail-order pharmacies; and
- 2 actions (0.03%) were taken on controlled substance licensees.

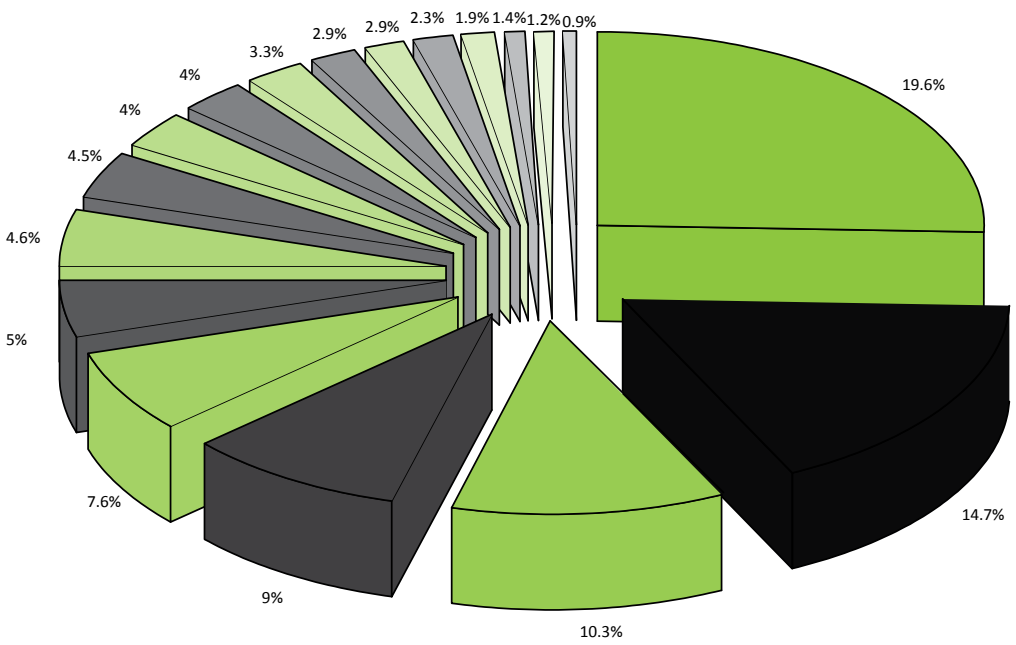
For a full breakdown of the actions taken and the bases for actions taken during 2014, see Figure A (below) and Figure B (page 84). Additional information about the NABP Clearinghouse, including how to designate NABP as a reporting agent for the National Practitioner Data Bank, is available under Member Services in the Programs section of the NABP website at *www.nabp.net.*

Figure A: Disciplinary Actions Reported During 2014



*The miscellaneous category includes closure of facility; denial of initial license or certificate; denial of license renewal; directed in-service training; directed plan of correction; extension of previous licensure action; interim action; limitation or restriction on license; monitoring; on-site monitoring; other licensure action – not classified; publicly available negative action or finding; reduction of previous licensure action; restrictions on admissions or services; and voluntary limitation or restriction on license.

Figure B: Bases for Disciplinary Actions Reported During 2014



- Violation of Federal or State Statutes, Regulations, or Rules (19.6%)
- Miscellaneous* (14.7%)
- Diversion of Controlled Substances (10.3%)
- Failure to Comply with Continuing Education or Competency Requirements (9%)
- Unable to Practice Safely by Reason of Alcohol or Other Substance Abuse (7.6%)
- Error in Prescribing, Dispensing, or Administering Medication (5%)
- Unauthorized Prescribing, Dispensing, or Administration of Medication (4.6%)
- Criminal Conviction (4.5%)
- License Revocation, Suspension, or Other Disciplinary Action (4%)
- Fraud (4%)
- Narcotics Violation or Other Violation of Drug Statutes (3.3%)
- Failure to Maintain Records (2.9%)
- Practicing or Operating Without a License or Permit or Without a Valid License or Permit (2.9%)
- Allowing or Aiding Unlicensed Practice (2.3%)
- Unprofessional Conduct (1.9%)
- Violation of or Failure to Comply With Licensing Board Order (1.4%)
- Failure to Meet Licensing Board Reporting Requirements (1.2%)
- Failure to Cooperate With Board Investigation (0.9%)

*The miscellaneous category includes breach of confidentiality; default on health education loan or scholarship obligations; deferred adjudication; diverted conviction; drug screening violation; expired drugs in inventory; exploiting a patient for financial gain; failure to comply with patient consultation requirements; failure to maintain equipment/missing or inadequate equipment; failure to maintain supplies/missing or inadequate supplies; failure to meet the initial requirements of a license; failure to pay child support/delinquent child support; failure to take corrective action; financial insolvency; immediate threat to health or safety; improper or abusive billing practices; improper or inadequate supervision or delegation; inadequate or improper infection control practices; inadequate security for controlled substances; incompetence; lack of appropriately qualified professionals; misappropriation of patient property or other property; misbranding drug labels/lack of required labeling on drugs; misleading, false, or deceptive advertising or marketing practices; misrepresentation of credentials; negligence; nolo contendere plea; operating beyond scope of license; other action not classified; patient abandonment; practicing beyond the scope of practice; sexual misconduct; substandard or inadequate care; unable to practice safely; unable to practice safely by reason of physical illness or impairment; unable to practice safely due to psychological impairment or mental disorder; and violation of federal or state tax code.

VPP Interface and Inspection Sharing Network Continue to Support Member Boards in Making Nonresident Licensure Decisions

The Verified Pharmacy Program™ (VPP™) and inspection sharing network interface were recently updated with features for boards of pharmacy to utilize when accessing important pharmacy data, including licensure, inspection, and disciplinary action information.

The verified data continues to be made available to authorized individuals through VPP and the secure inspection sharing network. In addition, boards can upload their own state inspection reports directly through the system. A tagging feature that identifies whether a pharmacy is a VPP participant has also been added to the system.

At press time, at least 243 pharmacies have applied to VPP and currently have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies.

Of the 243 VPP facilities:

- 103 pharmacies engage in nonsterile compounding;
- 32 pharmacies engage in sterile compounding;
- 77 pharmacies engage in both sterile and nonsterile compounding;
- 30 pharmacies are general retail or mail-order pharmacies; and
- 1 pharmacy is a nuclear pharmacy.

On January 13, 2015, the appointed VPP Working Group met in Rosemont, IL, to examine and assess the current needs of states in relation to VPP, and to recommend what NABP can provide through VPP to further assist state boards with their existing pharmacy inspection processes and sharing of inspection information. In addition, the working group reviewed a draft of the pharmacy inspection blueprint, which is meant to serve as a tool for state boards of pharmacy that they can implement into their own inspection processes.

In addition to the VPP Working Group review, an Inspection Blueprint Development Workshop was held on January 14-15, 2015, where representatives from 42 states met to further review and discuss the draft blueprint. In addition to reviewing the blueprint, the group shared how state boards were approaching the issue of outsourcing facilities, discussed the possibility of additional inspection blueprints, and provided feedback regarding output from VPP inspections. In February 2015, a draft inspection blueprint was sent to all member boards along with a worksheet for the states to cross walk their existing inspection reports with the blueprint items. More information will be provided in future communications and at the NABP 111th Annual Meeting.

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 the Member Relations and Government Affairs Department at GovernmentAffairs@nabp.net. Additional information is also available in the Programs section of the NABP website at *www.nabp.net.*

New Online 'Gateway' Resource Provides Canadian Licensure Information to International Pharmacy Graduates

Pharmacy graduates from around the world desiring to practice pharmacy in Canada may now use Pharmacists' Gateway Canada, a new online resource, to find important information about the steps to be licensed as a pharmacist in Canada. In addition to licensing information, Pharmacists' Gateway Canada also provides self-assessment tools and serves as a Canadian document repository for international pharmacy graduates. Before this website became available, international pharmacy graduates were required to submit the same documents, such as proof of identity, transcripts, and reference letters, to many different organizations. Pharmacists' Gateway Canada allows applicants to submit documents only once so they can be stored in a central repository.

The Pharmacists' Gateway Canada program was developed by the National Association of Pharmacy Regulatory Authorities in collaboration with the Pharmacy Examining Board of Canada and with funding from Employment and Social Development Canada. Additional information is available on the Pharmacists' Gateway Canada website at *www.pharmacistsgatewaycanada.ca.*

111th Annual Meeting Early Registration Rates End April 20

Online registration is available for the NABP 111th Annual Meeting to be held May 16-19, 2015, at the Roosevelt New Orleans hotel in New Orleans, LA. Attendees are encouraged to register on or before April 20, 2015, in order to receive the early registration rates.

Registration is available in the Meetings section of the NABP website at *www.nabp.net*, with new fees now in effect. The last fee change was in 2010. Please note, the fees for students remain at $125 for early registration and $150 for standard registration.

NABP offers attendees three payment options:

- Using a credit card (American Express, MasterCard, or Visa)
- Mailing in the payment
- Paying in New Orleans

More information about the 111th Annual Meeting is available in the Meetings section of the NABP website.

Photo courtesy of New Orleans Convention and Visitors Bureau and Richard Nowitz

Information about the Roosevelt New Orleans is also available, including a link to the NABP special group page for attendees to reserve a room online.

Newly Approved e-Advertisers

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

Hopkinton Drug, Inc
www.rxandhealth.com

Marsh Drugs, LLC
www.marsh.net

MJM Medical Services dba Skycare Pharmacy
www.skycarepharmacy.com

PetSmart, Inc
www.petsmart.com
http://pets.petsmart.com/vetsource

A full listing of NABP-approved e-Advertisers is available on the NABP website at *www.nabp.net.*

PCOA Data

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users, stakeholders, and developers to convene and share their own perspectives and experiences with the assessment. This interactive event also provides attendees a unique networking opportunity to join representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and ACPE.

The next available testing window for the 2015 PCOA is August 25 to September 18, 2015. Registrations for this testing window ends May 26, 2015. The winter 2015 PCOA administration had 27 participating schools. More information about the PCOA is available in the Programs section of the NABP website at *www.nabp.net.*

For information about the 2015 PCOA Forum, please contact Maria Incrocci, competency assessment senior manager, by sending an email to pcoa@nabp.net.

Exciting, Timely Topics to Offer Attendees Up to Eight Contact Hours of CPE Credit at the NABP 111th Annual Meeting

The NABP 111th Annual Meeting, "Boards of Pharmacy and NABP – Marching In Together and Stronger," to be held May 16-19, 2015, at the Roosevelt New Orleans in New Orleans, LA, offers attendees the chance to earn up to eight contact hours (0.8 continuing education units (CEUs)) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit. The CPE is designed to address current issues affecting the regulation of pharmacy practice. All Annual Meeting participants will have the opportunity to attend four joint CPE sessions as well as one of two concurrent sessions: one geared for state board of pharmacy executive officers and members, and the other for compliance staff. In addition, there will be one pre-meeting CPE session.

Saturday, May 16

Pre-Meeting CPE
Combating Prescription Drug Abuse – Together We Are Making a Difference

By working together, health care regulators and providers have made progress in the prescription drug abuse epidemic gripping the United States. Attendees will learn from individuals on the front line about the legal responsibilities surrounding the prescribing and dispensing of controlled substances and strategies for successful interprofessional communications. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit.

Sunday, May 17

Joint CPE
Educational Poster Session – Protecting the Public Together

Continuing to be an annual favorite, the Educational Poster Session offers participants the opportunity to earn CPE credit. Board of pharmacy and school and college of pharmacy representatives will present various poster displays as they relate to partnerships created to increase public protection. CPE is earned in this session through interactive participation with presenters for one hour during the three-hour offering and by completing a post-session test. Participants will earn 1 contact hour (0.1 CEU) of CPE credit.

Joint CPE
Continuing Pharmacy Education – So Close Yet So Far

CPE requirements were enacted to ensure that pharmacists maintain their currency and competency to practice in lieu of periodic reassessments. CPE programs that are well constructed and appropriately overseen can certainly achieve this objective. Academic and regulatory experts will discuss what is working and what needs to change to continue to ensure that CPE achieves this important objective. Participants will earn 1 contact hour (0.1 CEU) of CPE credit.

Monday, May 18

Joint CPE
DQSA – Are We There Yet?

Since the enactment of Title I of the Drug Quality and Security Act (DQSA), many boards have struggled with rulemaking in regard to outsourcing facilities to ensure that they are appropriately licensed and regulated. State board of pharmacy regulators will share what their states have done to ensure public safety in conjunction with recently enacted federal law and implementing regulations. Participants will earn 1 contact hour (0.1 CEU) of CPE credit.

Tuesday, May 19

Executive Officer and Board Member CPE
Drug Supply Chain Integrity – What Will the Future Hold?

The Drug Supply Chain Security Act (DSCSA) has changed the regulation of wholesale distribution and has pre-empted safeguards enacted at the state level. Questions have arisen as to whether the DSCSA will improve the integrity of the drug supply distribution chain and how states will be able to protect patients. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Compliance Officer CPE
Inspection Tools – Update on the Uniform Inspection Blueprint

Because of the devastation caused by the New England Compounding Center tragedy, the state boards of pharmacy have been challenged with increased inspection vigilance and the need for uniformity across state lines. To answer that challenge, 42 states participated in the Inspection Blueprint Development Workshop in January 2015 and worked together to create a uniform inspection form. Participants will discuss the updates on this joint endeavor and how it is and can be used as a uniform inspection tool that can be shared among the states to uniformly enforce pharmacy laws and regulations. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Joint CPE
Team-Based Care – Where Do We Start?

While the US is implementing the many facets of the Patient Protection and Affordable Care Act, the concept of team-based health care is a critical tenet and buzzword for the emerging health care jargon. How team care is defined and regulated in the best interest of the patient are significant challenges facing licensing boards. Participants

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Meeting Program

May 16-19, 2015 — Roosevelt New Orleans — New Orleans, LA

Saturday, May 16, 2015

10 AM - 6 PM
Registration/Information Desk Open

1:30 - 3:30 PM
Pre-Meeting CPE
Combating Prescription Drug Abuse – Together We Are Making a Difference
Sponsored by CVS Health
ACPE #0205-0000-15-001-L03-P
(0.2 CEUs – 2 contact hours)

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

6 - 9 PM
President's Welcome Reception
Sponsored by Express Scripts
Honoring NABP President
Joseph L. Adams, RPh
Dinner will be served
Dress: business casual

Sunday, May 17, 2015

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

7:30 - 8:30 AM
NABP AWAR$_X$E Fun Run/Walk
Sponsored by Rite Aid Corporation

8:30 - 11:30 AM
Hospitality Brunch
Sponsored by Omnicare, Inc
Educational Table Top Displays

8:30 - 11:30 AM
Joint CPE
Educational Poster Session – Protecting the Public Together
Sponsored by Pearson VUE
ACPE #0205-0000-15-002-L04-P
(0.1 CEU – 1 contact hour)

Noon - 3:15 PM
First Business Session
Presiding: Joseph L. Adams, RPh, NABP President

- Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/ Secretary
- Presentation of Colors
- National Anthem
- Keynote Address
  Lt General Russel L. Honoré (Ret)
  Sponsored by Humana Pharmacy Solutions
- Call to Order
- Greetings from the Host State
  Louisiana Board of Pharmacy
- Recognition of Sponsors
- Report of the Executive Committee
  Karen M. Ryle, MS, RPh, Chairperson, NABP Executive Committee
- President's Address
  Joseph L. Adams, RPh, NABP President
- Report of the Treasurer
  Hal Wand, MBA, RPh, NABP Treasurer
- Announcement of Candidates for Open Executive Committee Officer and Member Positions
- Open Microphone Session
  (Time permitting.)

3:30 - 4:30 PM
Joint CPE
Continuing Pharmacy Education – So Close Yet So Far
Sponsored by Walgreen Co
ACPE #0205-000-15-003-L03-P
(0.1 CEU – 1 contact hour)

Monday, May 18, 2015

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

7:30 - 9 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

9:15 - 10:15 AM
Joint CPE
DQSA – Are We There Yet?
ACPE #0205-0000-15-004-L03-P
(0.1 CEU – 1 contact hour)

10:30 AM - Noon
Second Business Session
Presiding: Joseph L. Adams, RPh, NABP President

- Report of the Executive Director/ Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/ Secretary
- Report of the Committee on Resolutions
  Edward G. McGinley, MBA, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  - First Reading of Resolutions
- Report of the Committee on Constitution and Bylaws
  LuGina Mendez-Harper, PharmD, RPh, Chairperson, Committee on Constitution and Bylaws
  - Presentation of Proposed Amendments to the Bylaws
- Candidate Speeches for Open Executive Committee Officer and Member Positions

Noon - 12:30 PM
Informal Member/Candidate Discussion

Free Afternoon
(No programming)

Tuesday, May 19, 2015

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

7:45 - 8:45 AM
NABP Breakfast
Sponsored by Teva Pharmaceuticals

8:45 - 10:15 AM

Executive Officer and Board Member CPE

Drug Supply Chain Integrity – What Will the Future Hold?

ACPE #0205-0000-15-005-L03-P

(0.15 CEUs – 1.5 contact hours)

8:45 - 10:15 AM

Compliance Officer CPE

Inspection Tools – Update on the Uniform Inspection Blueprint

ACPE #0205-0000-15-006-L03-P

(0.15 CEUs – 1.5 contact hours)

10:30 AM - Noon

Joint CPE

Team-Based Care – Where Do We Start?

Sponsored by Walgreen Co

ACPE #0205-0000-15-007-L03-P

(0.15 CEUs – 1.5 contact hours)

Noon - 1:30 PM

Lunch Break

(On your own)

1:30 - 4 PM

Final Business Session

Presiding: Joseph L. Adams, RPh, NABP President

- Election of 2015-2016 Executive Committee Officers and Members
- Remarks of the Incoming President
  Edward G. McGinley, MBA, RPh, NABP President-elect
- Installation of 2015-2016 Executive Committee Officers and Members
- Final Report of the Committee on Constitution and Bylaws
  LuGina Mendez-Harper, PharmD, RPh, Chairperson, Committee on Constitution and Bylaws
  - Discuss and Vote on Proposed Amendments to the Bylaws
- Final Report of the Committee on Resolutions
  Edward G. McGinley, MBA, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  - Discuss and Vote on Resolutions
- Invitation to the 2016 Annual Meeting in San Diego, CA
  Virginia Herold, MS, Executive Officer, California State Board of Pharmacy

5:45 - 6:45 PM

Awards Dinner Reception

7 - 10 PM

Annual Awards Dinner

Presiding: Edward G. McGinley, MBA, RPh, 2015-2016 NABP President

- Presentation to 2015 Honorary President
- Presentation to Joseph L. Adams, RPh, 2015-2016 Chairperson, NABP Executive Committee
- Presentation of the 2015 Fred T. Mahaffey Award
- Presentation of the 2015 Henry Cade Memorial Award
- Presentation of the 2015 John F. Atkinson Service Award
- Presentation of the 2015 Lester E. Hosto Distinguished Service Award

Dress: semiformal

Note: The 111th Annual Meeting schedule is subject to change.

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

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

Annual Meeting CPE

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will learn what team-based care is as defined in pharmacy, nursing, and medical practice acts, as well as what roles the respective licensing boards should assume to oversee team-based care. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Additional information about the 111th Annual Meeting is available in the Meeting section of the NABP website at *www.nabp.net.*

Deadline Approaching to Designate Official Voting Delegates for the 111th Annual Meeting in New Orleans, LA

The deadline for active member boards to designate official voting delegates and alternate voting delegates for the NABP 111th Annual Meeting is Thursday, April 16, 2015.

Pursuant to policies set forth by the NABP Executive Committee, each executive officer of an active member board shall provide credentials for the delegate and alternate delegates and return them to NABP no later than 30 days prior to the Annual Meeting.

Voting delegates are responsible for voting at the business sessions during the NABP Annual Meeting and transmitting the board's position on all matters brought before the convention. Only current board of pharmacy members or chief administrative officers qualify to serve as delegates or alternate delegates. Only one individual may serve as the official voting delegate; however, there is no limit on how many individuals may serve as an alternate delegate.

Active member boards are encouraged to submit their signed Official Delegate Certificates by the April 16 deadline in order to qualify for the Annual Meeting Travel Grant.

Associate member boards are not eligible to vote during the Annual Meeting per the NABP Constitution; however, associate member boards are encouraged to also submit their signed Official Delegate Certificates. All NABP members, active and associate, may participate in discussions during the business sessions.

Executive officers of the boards may submit their signed Official Delegate Certificate to Lisa Braddy, Executive Office supervising coordinator, via mail to NABP Headquarters or may scan and email the certificate to exec-office@nabp.net.

For more information, please contact the NABP Executive Office at exec-office@nabp.net.

Submit voting delegate and alternate voting delegate selections by **Thursday, April 16**

Active Member Boards of Pharmacy Encouraged to Apply for 111th Annual Meeting Travel Grant

The NABP Foundation™ is once again offering active member state boards of pharmacy travel grant opportunities to attend the NABP 111th Annual Meeting to be held May 16-19, 2015, at the Roosevelt New Orleans hotel in New Orleans, LA. One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer.

The grant was established to assist boards in sending voting delegates to the Annual Meeting so they may participate in important business, including discussing and voting upon resolutions and amendments to the NABP Constitution and Bylaws, electing NABP Executive Committee officers and members, and attending educational sessions regarding current issues facing pharmacy regulators. In order to receive reimbursement, active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions.

The NABP Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for travel expenses, including travel, hotel rooms, meals, taxis, parking, and tips. Eligible individuals can receive up to $1,500 in grant monies to attend the NABP 111th Annual Meeting. The grant does not include Annual Meeting registration fees.

Grant applications may be obtained from NABP upon the direct requests of executive officers of the state boards of pharmacy. Applications can be submitted by mail to NABP Headquarters or via email at exec-office@nabp.net. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether they have qualified for the grant. Last year, 42 state boards of pharmacy applied and were approved for the NABP 110th Annual Meeting Travel Grant.

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

Implementation of DSCSA Supports VAWD Accreditation Requirements

On January 1, 2015, several key requirements of the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act (DQSA), went into effect, many of which will impact NABP's Verified-Accredited Wholesale Distributors® (VAWD®) program. Relevant DSCSA requirements immediately affecting drug wholesale distributors include provisions relating to product tracing, authorized trading partners, verification, and wholesale distributor licensing and reporting. To address these requirements, all changes to the VAWD accreditation process are aimed at providing consistency with the new law while maintaining the continued integrity and high standards of the VAWD program until the program's criteria are revised.

Note that the DSCSA includes several requirements that the VAWD program already encompasses, including inspection of third-party logistics providers. Accordingly, each VAWD wholesale distributor is required to achieve, maintain, and demonstrate compliance with each of the DSCSA-related requirements which took effect on January 1, 2015 (see Changes to VAWD Criteria in 2015).

In addition, each VAWD wholesale distributor shall thoroughly review and promptly revise any applicable policies and procedures to ensure consistency with new and revised definitions contained in section 581 of the Federal Food, Drug and Cosmetic Act (FD&C Act), as well as the definition of wholesale distribution in section 503(e)(4).

Food and Drug Administration's (FDA) recent guidance pertaining to the January 1, 2015 deadline and its May 1, 2015 compliance extension is available on the FDA's website at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM427867.pdf.*

Changes to VAWD Criteria in 2015

Since its implementation, VAWD has been a source of uniformity and consistency among the states. 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 requirements and standards for secure medication distribution.

As of January 1, 2015, VAWD requirement changes are in effect as detailed below.

VAWD wholesale distributors that engage in transactions involving product, consistent with the definitions of transaction and product in section 581 of the FD&C Act, shall achieve, maintain, and demonstrate compliance with the Product Tracing requirement under section 582(c)(1). FDA draft guidance pertaining to the exchange of product tracing information was released in November 2014. Note that compliance with this requirement is extended to May 1, 2015.

VAWD wholesale distributors that engage in transactions involving product, consistent with the definitions of transaction and product in section 581 of the FD&C Act, shall achieve, maintain, and demonstrate compliance with the Authorized Trading Partners requirement under section 582(c)(3).

VAWD wholesale distributors that engage in transactions involving product, consistent with the definitions of transaction and product in section 581 of the FD&C Act, shall achieve, maintain, and demonstrate compliance with the Verification requirements under section 582(c)(4). In June 2014, 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.

FDA Regulations to be Developed

Signed into law on November 27, 2014, the DSCSA amended section 503(e) of the FD&C Act and also added new sections 581 through 585 as Subchapter H of the Act. Under the new law, FDA is required to establish regulations for national wholesale distributor licensing standards no later than November 27, 2015, which will not take effect until two years after the regulations are published by FDA. Also of note, language in the DSCSA specifically requires NABP to assist the FDA in developing these regulations. Once the regulations are released by the agency, NABP will begin the process of formally revising current VAWD criteria to ensure compliance.

Information on the DQSA's impact on the state boards of pharmacy, written by Jack W. "Jay" Campbell IV, JD, RPh, executive director, North Carolina Board of Pharmacy, and member, NABP Executive Committee is available in the August 2014 and September 2014 issues of the *NABP Newsletter.* Specific questions about the VAWD program may be emailed to vawd@nabp.net.

AWARxE Revitalizes Its Efforts to Provide Resources to Corporations for Educating Employees on Prescription Drug Abuse

It may come as a shock that nearly 69% of Americans aged 18 or older who use illicit drugs are employed full-time or part-time; this includes the use of prescription drugs for recreational purposes or to "get high," according to the Substance Abuse and Mental Health Services Administration. The AWARxE® Prescription Drug Safety Program understands the need to educate employers and their employees about the dangers of prescription drug misuse and abuse.

Many companies are starting to promote health and wellness programs for their employees in an effort to decrease health care premium costs and increase the overall health of their employees, thereby improving the performance of their workforce. Educating employees on the dangers of prescription drug abuse and misuse is vital. All industries can benefit from the knowledge that the AWARxE program can provide, especially industries with high risks for injury and high stress levels. For example, transportation workers, assembly line workers, and construction workers need to remain alert and focused on their job to prevent injuries to themselves and others. The program can help to improve the health of employees and the knowledge that employees gain can be communicated to their family and friends, preventing misuse and abuse on a larger scale.

The AWARxE website has a page specifically dedicated to empowering corporations in their efforts to educate employees about prescription drug safety. The Corporations web page offers interested parties access to AWARxE materials when they contact an AWARxE team member. Offerings include a PowerPoint presentation that details the dangers of prescription medication misuse and abuse, fact sheets that can be hung in communal areas such as cafeterias or break rooms, FAQs that can be used by management or human resources to answer questions from employees, and sample newsletter content that can be used for blast emails or e-newsletters. Corporations can receive access to AWARxE artwork for use in their corporate communications, upon approval from AWARxE. Branded hats, t-shirts, and pill boxes are also available to order.

A customized package of materials can be arranged for corporations to best suit the needs of their employees. Available topics include prescription drug abuse, over-the-counter drug abuse, prescription drug abuse trends among adults and teens, how prescription drug abuse affects employers, proper medication disposal, safe storage, and the risks of counterfeit medications when buying prescriptions online. AWARxE has revised the current offerings and now provides updated materials that reflect the current landscape of prescription abuse and misuse.

AWARxE will also be reaching out to corporations near NABP Headquarters with the offer to give presentations on prescription drug safety to employees. This will provide the opportunity to reach more members of the community and gain feedback about the prescription drug abuse epidemic.

In addition to the corporate presentations, AWARxE continues to staff resource tables at local events. The most recent resource table was at the Waukegan Township Health & Wellness Fair in January 2015. The table included flyers on the dangers of misuse and abuse, branded pill boxes to help people keep track of medication dosing, and wristbands to spread the word about AWARxE. There were more than 25 vendors at the event, which was attended by over 100 people. AWARxE plans to host more resource tables at events throughout the year.

AWARxE Resource Tables Continue to Spread Knowledge at Local Events

In January 2015, the AWARxE® Prescription Drug Safety Program hosted a resource table at the Waukegan Township Health & Wellness Fair (pictured above). Attendees that stopped by the table were provided flyers, branded pill boxes, and wristbands.

Working Group on Verified Pharmacy Program Convenes

In January 2015, NABP convened the Working Group on Verified Pharmacy Program™ (VPP™) to further refine programmatic criteria and policies for VPP. The working group also thoroughly reviewed and provided input on a draft inspection blueprint, which is meant to serve as a tool that state boards of pharmacy can implement into their own inspection processes. Front row pictured from left to right: James T. DeVita, RPh, NABP Executive Committee liaison; Brenda McCrady, RPh, Arkansas State Board of Pharmacy; Barbara Ellen Vick, PharmD, JD, RPh, North Carolina Board of Pharmacy; and Gay Dodson, RPh, Texas State Board of Pharmacy. Back row pictured from left to right: Tony Qi, PharmD, RPh, New Jersey State Board of Pharmacy; Dennis K. McAllister, RPh, FASHP, Arizona State Board of Pharmacy; Mike Podgurksi, RPh, Pennsylvania; Tim Koch, RPh, Arkansas; Ed L. Sperry, Idaho State Board of Pharmacy; Reginald B. "Reggie" Dilliard, DPh, Tennessee Board of Pharmacy (chairperson); and Mark T. Conradi, JD, RPh, Alabama.

Around the Association

Executive Officer Changes

- **Charles Fanaras, RPh,** is currently serving as acting executive secretary of the New Hampshire Board of Pharmacy. Fanaras also serves as the Board's president. He is also the owner and operator of The Prescription Center in Concord, NH, and serves as president and chief executive officer of Fanarian Enterprises, LLC (hospital outpatient pharmacy), Northeast Pharmacy Services, LLC (institutional pharmacy), and Mytilini Enterprises, LLC (medical office retail pharmacy). Fanaras received his bachelor of science degree at the Massachusetts College of Pharmacy and Health Sciences.
- **Ben Kesner, RPh,** is now serving as executive director/chief drug inspector of the New Mexico Board of Pharmacy, replacing Larry Loring who retired in January 2015. Prior to this position, Kesner served as the Board's drug inspector.

Board Member Appointments

- **Donna Yeatman, RPh,** has been appointed a member of the Alabama State Board of Pharmacy. Yeatman's appointment will expire December 31, 2019.
- **Sheila Castin** has been appointed a public member of the Arkansas State Board of Pharmacy. Castin's appointment will expire June 30, 2015.
- **Ricardo Sanchez** has been appointed a public member of the California State Board of Pharmacy. Sanchez's appointment will expire June 1, 2018.
- **Margaret Greenwood, RPh,** has been appointed a member of the Guam Board of Examiners for Pharmacy. Greenwood is serving at the discretion of the appointing body.

Board Member Reappointments

- **Kishor Mehta** has been reappointed a public member of the Pennsylvania State Board of Pharmacy. Mehta's appointment will expire October 14, 2020.

FDA Warns of Counterfeit Cialis Tablets Entering US

In January 2015, Food and Drug Administration (FDA) warned that potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a United States consumer. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used. FDA reminded US consumers to only buy prescription medications from state-licensed pharmacies located in the US, and noted that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provided guidelines in a Drug Safety Announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The FDA Drug Safety Announcement and links to additional information are available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm.*

FDA Approves Non-Opioid Injectable Painkiller

FDA recently approved Dyloject™ solution for injection, a proprietary nonsteroidal anti-inflammatory drug meant for adults to manage mild to moderate pain and moderate to severe pain alone or in combination with opioid analgesics, reports the drug's manufacturer, Hospira, Inc. The drug is an injectable therapy that can be administered in 15 seconds. It comes at a time when federal and local governments are working to reduce abuse of prescription opioid medications, with related deaths surpassing 16,500 in 2010, reports Reuters. Additional details are available from a Hospira press release at *www.prnewswire.com/news-releases/hospira-receives-us-fda-approval-of-proprietary-analgesic-dylojectdiclofenac-sodium-injection-300014476.html.*

New FDA Drug Info Rounds Training Video Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning. 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. The video is available on the FDA website *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm429508.htm.*

FDA's New Database Simplifies Searching for Guidance Documents

FDA has unveiled a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments. The database can be accessed on the FDA website at *www.fda.gov/RegulatoryInformation/Guidances/default.htm.*

Newly Accredited VAWD Facilities

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

Alcon Laboratories
Fort Worth, TX

Strategic Pharmaceutical Solutions, Inc, dba VetSource
Harrisburg, PA

A full listing of more than 530 accredited VAWD facilities is available on the NABP website at *www.nabp.net.*

Oklahoma Board Warns Against Phantom PICs

The Oklahoma State Board of Pharmacy has received several questions from Oklahoma-licensed pharmacists who have been approached by out-of-state pharmacies asking them to be employed as their pharmacist-in-charge (PIC) for their Oklahoma license, and suggesting to the pharmacists that they do not have to actually work at the pharmacy. A term for this might be an "absent" or "phantom" PIC. This situation is no doubt occurring more frequently due to the new requirement in Oklahoma that nonresident pharmacies that do sterile compounding must have an Oklahoma-licensed PIC. In one case, the Oklahoma-licensed pharmacist was not even living in the United States at the time of the employment offer; the pharmacy just wanted a pharmacist with an Oklahoma license to sign its application or renewal in a fraudulent attempt to meet the legal requirement. The required PIC duties for an Oklahoma-licensed pharmacist include accepting the full responsibility for all aspects of the pharmacy's operation, responsibility for controlled and non-controlled drugs in the pharmacy, as well as supervision of all employees as they relate to the practice of pharmacy, in addition to other requirements.

Notably, Oklahoma Administrative Code (OAC) 535:15-3-2(b)(4) states: "A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager."

OAC 535:15-3-2(c)(1) states: "Where the actual identity of the filler of a prescription is not determinable, the manager of the pharmacy and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board of Pharmacy." And OAC 535:15-3-2(c)(4) states that the pharmacy manager must "[e]stablish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules."

It would not be possible for a PIC to exercise and fulfill these responsibilities without being physically present in the pharmacy a substantial amount of time. Keep in mind the legal aspects of the responsibilities that are assumed if you are approached by a pharmacy for a position as "phantom" or "absent" PIC.

Proposed Rule to Change Louisiana PMP Reporting Deadline

The Louisiana Board of Pharmacy provided an update on Regulatory Project 2015-1 ~ Dispenser Reporting to Prescription Monitoring Program; this rule will revise the Louisiana Prescription Monitoring Program (PMP) reporting deadline.

As indicated in the October 2014 *Louisiana Board of Pharmacy Newsletter,* the 2014 Louisiana State Legislature passed Act 472, which amended the Louisiana PMP law to revise the deadline by which pharmacies and other dispensers of prescriptions for controlled substances are required to report those prescription transactions to the PMP database from the previous deadline of seven days after the date of dispensing to the next business day after the date of dispensing. That law became effective on August 1, 2014.

The Board published its Notice of Intent to amend §2911 – Reporting of Prescription Monitoring Information in Chapter 29 – Prescription Monitoring Program of the Board's rules to make the same change required by the legislative act. The board plans to hold a public hearing to receive comments and testimony on the proposed rule.

Arizona Optometrists and Naturopathic Physicians May Prescribe Hydrocodone Combination Products

In 2014, naturopathic physicians and many optometrists were granted prescriptive authority for hydrocodone prescription drug products by the Arizona State Legislature. The legislation was passed in anticipation of Drug Enforcement Administration rescheduling these combination products from Schedule III to Schedule II. Additional information is available in the Arizona State Board of Pharmacy's prescriptive authority chart available at *https://pharmacy.az.gov/naturopathic-prescriptive-authority.*

North Carolina Requires Epinephrine Auto-Injectors in Schools

All North Carolina public and public charter schools are now required to have a minimum of two epinephrine auto-injectors on hand, per a provision of the 2014 North Carolina budget bill. The provision went into effect on November 1, 2014.

North Carolina Board of Pharmacy staff has provided a guidance document for school systems and pharmacies concerning the requirement that answers a number of specific questions about implementation. The document may be downloaded at *www.ncbop.org/faqs/Pharmacist/GuidanceEpinephrineAutoInjectorStatuteDec2014.pdf.*

In early 2015, the Board was approaching the final stages of a rulemaking that, pursuant to a request from the state health director, would allow epinephrine auto-injectors for public schools to be dispensed by registered nurses who practice at local health departments. More information on this rulemaking is found in Item 2292 of the October 2014 *North Carolina Board of Pharmacy Newsletter* and, along with information about all rulemakings underway by the Board, at *www.ncbop.org/rulemakings.htm.*

nabp newsletter

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