newsletter

National Association of Boards of Pharmacy®

AWARE GET INFORMED. PRESCRIPTION DRUG SAFETY®

April 2013 / Volume 42 Number 4

aid to government
the profession
the public
1904 to 2013

Upcoming Events

April 10, 2013
Committee on Constitution and Bylaws Meeting

April 12, 2013
FPGEE Administration

April 25, 2013
PCOA Forum
NABP Headquarters

April 27, 2013
DEA National Prescription Drug Take-Back Day

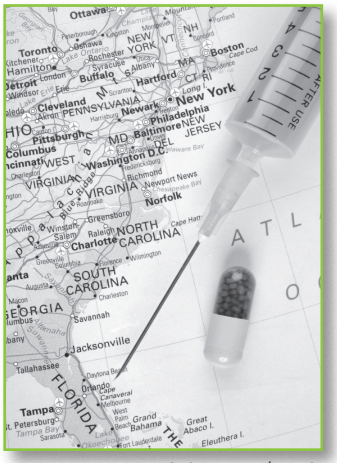
May 18-21, 2013
NABP 109th Annual Meeting
St Louis, MO

July 23-24, 2013
NABP Program Review and Training
NABP Headquarters

Compounding Pharmacy Information Sharing Network Available to Boards Soon

Data on Preparation of Patient-Specific Drugs and Non-Patient-Specific Drugs to Be Included

Following the tragic meningitis outbreak caused by contaminated injectable drugs compounded and distributed by the New England Compounding Center (NECC), several states implemented rounds of compounding pharmacy inspections, or conducted surveys of pharmacies, especially focusing on those engaged in sterile compounding. Utah and Massachusetts, for example, stepped up the frequency or initiated special rounds of compounding pharmacy inspections, while Texas surveyed pharmacies about compounding activity. And, as part of the NABP Compounding Action Plan, the Iowa Board of Pharmacy partnered with other states and NABP to begin conducting inspections of all nonresident pharmacies delivering compounded drugs into the state. An initial goal of the Iowa inspection program was to determine how many of the pharmacies were compounding drugs for individual patients pursuant to a prescription – that is, producing patient-specific drugs – and how many of the pharmacies were producing drug products without a prescription for distribution to clinics or hospitals – that is, producing non-patient-specific drugs. From a regulatory standpoint, in absence of such inspections, determining whether a facility is preparing patient-specific or non-patient-specific drugs is not always straightforward, and both state boards of pharmacy and Food and Drug Administration



©iStockphoto.com/gmutlu

(FDA) are challenged to answer the question of how to determine when a pharmacy identified as a drug compounding facility is actually engaged in manufacturing.

Findings from the first round of inspections conducted for Iowa include such data, along with additional demographic data

(continued on page 70)

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.

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

Carmen A. Catizone
Executive Director/ Secretary

Deborah Zak
Communications Manager

©2013 National Association of Boards of Pharmacy. All rights reserved. No part of this publication may be reproduced in any manner without the written permission of the executive director/ secretary of the National Association of Boards of Pharmacy.

Compounding Pharmacy

(continued from page 69)

that will help shape future inspection efforts and may be useful to boards of pharmacy in identifying other compounding-related regulatory issues. Further, these findings and additional data will be included in the national pharmacy information sharing network that will soon be available to all states electronically through NABP's secure portal.

Initial Inspection Results

Under the contract with the Iowa Board, from mid-December to mid-January, NABP surveyors completed inspections of seven pharmacies in five states – California, Florida, New Jersey, Texas, and Utah. Findings indicate that two of the pharmacies are FDA-registered facilities, however, neither have drug listings with FDA. One of the FDA-registered facilities has National Drug Code numbers for its products (prefilled syringes and outsourced hospital compounding).

Five of the seven pharmacies were determined by the surveys to distribute non-patient-specific sterile injectable drugs for "office use" and to institutions such as hospitals, surgery centers, and procedure centers, with four of these distributing non-patient-specific preservative-free sterile injectables. None of the pharmacies inspected possessed any documentation that authorizes the distribution of non-patient-specific drugs into interstate commerce.

Does FDA Manufacturer Registration Ensure Product Safety?

Is the pharmacy compounding patient-specific drugs or preparing non-patient-specific drug products? With the aim of addressing this question, one regulatory concept in place in many states, and under consideration by others, requires that entities producing non-patient-specific drugs should be registered with FDA as a manufacturer. The entity must also register with the state as a manufacturer. Some establishments possessing state pharmacy licenses have also obtained FDA manufacturing site registrations, creating confusion for regulators. Are they a pharmacy or a manufacturer?

The FDA registration requirement alone does not accomplish the goal of ensuring that drugs produced by such entities are consistently meeting appropriate standards of safety and efficacy. While entities meeting certain criteria must comply with the requirement to register with FDA as manufacturers, a facility inspection or other reviews are not required to obtain the registration. The Food and Drug Administration Amendments Act of 2007 (Public Law 110-85) requires that drug establishment registration and drug listing information be annually submitted to FDA electronically. While site registration provides the FDA with information to track firms for purposes such as scheduling inspections, it does not mean that drugs produced by that establishment have been reviewed and approved by FDA or that the firm complies with current Good Manufacturing Practices (cGMPs), key components to drug safety and effectiveness. Thus, requiring FDA registration on its own does not necessarily prevent another incident such as the meningitis outbreak caused by NECC products.

In contrast, drug products that are FDA approved have undergone a rigorous approval process and must be produced using cGMPs. FDA's drug approval process, designed to evaluate the safety and efficacy of the drug, may take several years as the drug maker's data is reviewed and clinical trials are conducted. The drug maker must also demonstrate that its manufacturing facility complies with cGMPs, which are updated by FDA as needed to keep pace with advancements in technology, and help to ensure the ability of a manufacturer to consistently reproduce a product meeting appropriate quality standards.

Compounded drugs do not undergo the FDA approval process, even if the pharmacy producing the drugs is also registered as a manufacturer. Further, it is important to note that while some FDA-registered entities producing non-patient-specific drugs may claim to follow cGMPs, this does not equate to the products being FDA approved. This clarification is important in scenarios such as when an FDA-registered facility is producing thousands of doses per day each month

for shipment into interstate commerce – the registration alone will not provide the safeguards to ensure that the drug products are consistently safe and effective.

Just as manufacturers approved by FDA to produce sterile drugs must follow cGMPs, pharmacies engaging in the practice of compounding sterile drugs must comply with state laws pertaining to sterile compounding. In many states the laws and regulations governing sterile compounding are based on or incorporate United States Pharmacopeia (USP) Chapter <797> Pharmaceutical Compounding – Sterile Preparations standards, with some states adopting regulations less strict than Chapter 797 standards, and some adopting Chapter 797 standards along with additional requirements.

The Chapter 797 standards were developed specifically for the compounding pharmacy engaged in preparing patient-specific sterile drugs. USP Chapter 797 standards were not designed for large-scale manufacture of a drug. USP indicates that "compounding is an integral part of pharmacy practice and is essential to the provision of health care." USP provides compounding standards and applicable monographs on formulation "to help define what constitutes good compounding practices and to provide general information to enhance the compounder's ability in the compounding facility to extemporaneously compound preparations that

©iStockphoto.com/kadmy

Just as manufacturers approved by FDA to produce sterile drugs must follow cGMPs, pharmacies engaging in the practice of compounding sterile drugs must comply with state laws pertaining to sterile compounding.

are of acceptable strength, quality, and purity." USP specifies that "[c]ompounding is different from manufacturing, which is guided by GMPs."

cGMPs were developed specifically for manufacturing of non-patient-specific FDA-approved products. FDA indicates that cGMPs "provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories." FDA states further that "[t]his formal system of controls at a pharmaceutical company . . . helps to prevent instances of contamination, mix-ups, deviations, failures, and errors" and "assures that drug products meet their quality standards." FDA also notes that cGMPs are minimum requirements and that many pharmaceutical manufacturers are already using systems that exceed these minimum standards.

When considering new or revised regulations for the practice of compounding, boards of pharmacy and other state agencies involved in regulating the practice of compounding may find it helpful to consider the distinctions between FDA manufacturer registration and compliance with cGMPs required for manufacturers producing FDA-approved drugs. Further, these statements from standard-setting organization USP and the FDA may also be helpful in distinguishing require-

(continued on page 80)

Executive Committee

Malcolm J. Broussard
Chairperson
One-year term

Michael A. Burleson
President
One-year term

Karen M. Ryle
President-elect
One-year term

Joseph L. Adams
Treasurer
One-year term

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

Edward G. McGinley
Member, District 2
Serving third year of a three-year term

Mark T. Conradi
Member, District 3
Serving second year of a three-year term

William John Cover
Member, District 4
Serving second year of a three-year term

Lloyd K. Jessen
Member, District 5
Serving third year of a three-year term

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

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

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

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

Subpoena Knows No Borders

By Dale J. Atkinson, JD

Advancements in technology increase the likelihood of licensees practicing across state and international lines. As has been emphasized in previous *Newsletter* articles, and in a feature article in this issue, physical presence is not necessarily a prerequisite to practice. That is, practitioners can use technology to render services within the scope of practice as defined without stepping foot within the jurisdiction where the patient is located. Practice without physical presence creates difficult legal and practical challenges for boards of pharmacy. The courts are currently, and will continue to grapple with jurisdictional issues involving what board and/or court has the authority to adjudicate administrative disputes. Further, the investigative processes will also be challenged regarding the gathering of relevant information to pursue administrative prosecution. Consider the following.

A physician (Licensee) is licensed in both Kansas and Missouri. In 2009, the Kansas State Board of Healing Arts (Board) opened an investigation of the Licensee based upon information that a patient filed a lawsuit alleging medical negligence, fraud, and misrepresentation. The lawsuit was filed in Missouri based upon the fact that the medical services were rendered in Missouri. The Board issued a subpoena to the Licensee requesting documents related to the medical treatment of the patient. The Board took the position that it had the authority to investigate the Licensee's practice and issue the subpoena because the Licensee holds a Kansas license and the allegations in the Missouri lawsuit constituted grounds for discipline under the Kansas Healing Arts Act.

The Licensee filed a petition in district court seeking a revocation of the subpoena arguing that the evidence sought was not relevant to a lawful investigation because the Board did not have the authority to investigate or discipline her based upon practice that occurred in Missouri. In response, the Board argued that the Licensee failed to exhaust her administrative remedies or was entitled to an interlocutory appeal. Under administrative law, litigants are required to exhaust the administrative appeals prior to pursuing litigation in state court. Further, an interlocutory appeal is a method for a litigant to have an important issue determined on appeal before the final disposition of the lower court proceedings.

The district court held that the Licensee was not required to exhaust her administrative remedies before seeking judicial determination of the validity of the subpoena and also held that the Board had the authority to investigate the Licensee's actions in Missouri. The court noted that the Licensee is licensed by the state of Kansas and was practicing medicine within the meaning of the Kansas Healing Arts Act. Thus, the court upheld the issuance of the subpoena and the Board's right to investigate the Missouri actions of the Licensee. The Licensee appealed.

On appeal, the Kansas Supreme Court noted that both parties appeared to have abandoned the issue of

whether the Licensee must exhaust her administrative remedies before appealing the matter to the courts. Rather than determining that such an issue is not ripe for review as being abandoned, the Kansas Supreme Court noted that it has a duty to question whether jurisdiction lies with the court and it must do so on its own initiative. The court requested briefs from the parties on the jurisdictional issue.

In its brief, the Board "reversed course" and argued that the appeal should be dismissed for lack of appellate jurisdiction based upon the Licensee's failure to exhaust her administrative remedies. The Licensee maintained her position that the applicable Kansas Judicial Review Act (KJRA) did not require her to exhaust her administrative remedies under these circumstances.

Ultimately, the Kansas Supreme Court held that it cannot reconcile the KJRA and the applicable statutes addressing exhaustion of administrative remedies. The court also reviewed the common law principles of exhaustion of remedies and found them to be inapplicable. Accordingly, the court using the statutory construction principles that the plain meaning and intent of the legislature must be considered, held that the exhaustion of remedies did not apply and that the Licensee was not required to internally appeal the validity of the subpoena before pursuing relief in district court.

Turning its attention to the merits of the Licensee's appeal, the court next addressed whether the Kansas Board had the authority to issue a subpoena seeking information regarding medical practice of a Missouri patient that took place in Missouri. The Licensee argued that the Board exceeded its scope of authority because her conduct in Missouri did not give rise to actions subject to discipline in Kansas. Conversely, the Board argued that multiple grounds for discipline existed under Kansas law for the acts alleged in the Missouri malpractice action.

A district court has the authority to revoke a subpoena if, in the court's opinion, "the evidence demanded does not relate to practices which may be grounds for disciplinary action." The Licensee argued that the Board has no authority to investigate or discipline her for acts related to treatment of a patient in Missouri. The Kansas Supreme Court disagreed with the Licensee.

The court noted that the operative issue is whether the Licensee was practicing under the Kansas Healing Arts Act when treating a patient in Missouri. It first held that the Licensee was indeed a licensed physician in Kansas, having been originally licensed in 1965 and continually renewed her authorization to practice since that year. The Licensee argued that she was only "incidentally licensed in Kansas because her primary practice is in Missouri." The court noted as "curious" the reference that the Licensee was only incidentally licensed in Kansas and cited that the only use of the term incidentally in the Kansas Healing Arts Act referred to persons licensed in another state when and while "incidentally called into this state in consultation with practitioners licensed in this state." The court interpreted this portion of the statute to refer to persons not licensed by Kansas, but called into the state to assist practitioners licensed in Kansas.

The court emphasized the public protection nature of the regulatory scheme and the intent to regulate the professional conduct of persons licensed to practice under Kansas law. It stated that such a public protection mission "does not diminish simply because the professional conduct occurred across state lines." The Licensee argued that the language of the Kansas Healing Arts Act was intended to address persons deemed to practice medicine in Kansas, rather than an encompassing interpretation of practice in any locale. The Licensee also argued that she was

(continued on page 80)

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

States, NABP Create Model Regulations Addressing Shared Remote Pharmacy Services Across Jurisdictions

Technology has spawned rapid innovation in all types of pharmacy practices and in the provision of pharmaceutical care to patients. In recent years, increasingly sophisticated technologies and carefully interconnected electronic systems have allowed such innovations as giving understaffed hospitals 24-hour virtual access to pharmacist medication review, or allowing community pharmacies opportunities for centralized functions. These newer processes and workflow models may include facilities, pharmacists, and pharmacy technicians in different locations that sometimes reach far across state lines.

In the midst of such large-scale adoption of new models, regulators seek to provide seamless protection of the public health. Their job is complicated by the fact that, while technology and commercial applications of new technologies move quickly, the legislative and rulemaking processes generally do not. Regulators may ask themselves, with many newer practices unaddressed by existing rules and regulations, and many comparatively recent regulations becoming quickly obsolete, how can the state boards of pharmacy continue to allow technological and practice innovation and increase patient access to pharmaceutical care, while still safeguarding the public health?

In 2012, NABP membership acknowledged this difficulty, and tasked the Association with addressing it. During the Association's 108th Annual Meeting, members passed Resolution 108-10-12, "Practice of Pharmacy in Virtual Environments Across Jurisdictions," which noted that "the growth of electronic data sharing, communication, and security has created the ability to practice pharmacy in virtual environments across jurisdictions and outside the walls of traditional pharmacies, and boards of pharmacy require leadership in developing compliance and safety processes to protect the patient, while embracing the changing face of pharmacy practice." The resolution then assigned NABP to "take a leadership role in creating model regulations and processes for mutual recognition to embrace improving technologies while protecting patients in the growing virtual practice of pharmacy across jurisdictions."

In response to this resolution, NABP is in the process of making revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*. A number of states have also begun to include broadly worded language in their regulations addressing shared pharmacy services across separate physical locations.

Long-Distance Pharmacy Services

Long-distance pharmacy services made possible by modern telecommunications technology have been gaining steam since 2001, when North Dakota and Texas each took steps to allow the use of telepharmacy in order to increase patients' access to medications and pharmaceutical care in previously underserved areas. Now often

called "shared services," pharmacy practice spanning distances (and, with increasing frequency, jurisdictions) tends to tackle one of two broad issues: increasing access to pharmacists and pharmacy services in underserved areas, and improving business practices to provide better patient care.

Increasing previously limited access to pharmacists is a particular concern in rural areas, where low patient volumes and limited resources, along with a shortage of pharmacists, has meant that many local hospitals, for example, may not be able to sustain full-time pharmacy staffing even during "normal" business hours, and also results in less coverage available for nights and weekends. Often this means no opportunity for a pharmacist medication review before a drug is administered to the patient, and a consequent increase in the possibility of harmful medication errors.

Advances in telepharmacy (or shared services) technology can allow pharmacists in a remote location with real-time, electronic access to a patient's health records and the hospital's pharmacy information and order systems to perform a medication review. In this model, providers may fax information to the pharmacist in the absence of integrated electronic systems. Video cameras can allow a pharmacist to remotely monitor which medication is physically removed from the pharmacy. One pilot project, undertaken by the University of California at Davis Health System, found that in six rural hospitals over a one-year period, remote medication review prevented 19% of patients enrolled in the pilot from potential harm resulting from medication errors. These early successes have not gone unnoticed; outside providers are increasingly offering such contracted remote pharmacist services to small hospitals or other health care institutions.

Community pharmacy is also using shared, remote pharmacy services and changing the way a prescription is handled. Pharmacy chains or groups may use a combination of central processing and central-fill models to fill prescriptions. For example, in the central processing model, labor-intensive tasks such as contacting a prescriber if a medication review turns up a drug interaction alert are moved to a central processing location, while a drug is physically filled at the place where the prescription originated. The central-fill model allows prescriptions to be processed and filled at a central location before the medications are routed to the relevant pharmacies for dispensing to the patient. For example, refills to be picked up the next day are sometimes processed using the central-fill model. In another example, at a large chain pharmacy, a prescription may be routed electronically to a remote location for medication review by a pharmacist who provides this service exclusively. The prescription might then go to a technician who physically fills the prescription under the video surveillance of a pharmacist in yet another location. In such scenarios bar codes and similar identifying technology assist the verification process.

The rapid increase in e-prescribing over the last several years has facilitated the increased use of shared services, as the act of prescribing electronically puts the process from the very beginning into the virtual realm. The e-prescribing network company Surescripts, which publishes an annual report tracking e-prescribing usage, estimated that, by the end of 2011, about 36% of prescriptions were being routed electronically – more than 570 million – up from 22% and 326 million just one

(continued on page 76)

Remote Pharmacy Services

(continued from page 75)

year prior. (E-prescribing became legal in all 50 states and the District of Columbia in 2007.)

New Regulatory Language

Under any of these systems, the pharmacists acting remotely may physically be, from a non-regulatory standpoint, almost anywhere. This fact poses problems primarily for regulators trying to ensure patient safety in a dispensing process that can involve personnel in several states: who has regulatory oversight of the various elements of the process to ensure that patient safety remains paramount, and how?

To answer this question, a number of state boards of pharmacy have begun to address remote prescription processing or shared services in greater or lesser specificity, from the definition of the term and the restrictions placed on it to the remote pharmacy's location. Georgia, for example, prohibits remote processing at any location "other than a retail pharmacy licensed in this State." Alaska requires "requesting" pharmacies participating in shared services to maintain a current in-state license, while "filling" pharmacies must either have a current in-state license or be registered by the state as an out-of-state pharmacy. In Oklahoma, remote processing pharmacies must hold an Oklahoma license specifically for that purpose – meeting a strict definition to qualify as such – but may be located anywhere within the continental United States.

NABP is developing new *Model Act* language that reflects the rapid change in technology, while ensuring boards have the tools to continue to protect public health. The changes address not only the 2012 Resolution, but also a recommendation from the Association's 2011-2012 Task Force on Pharmacy Practice Technology Systems. In its final report, the task force suggested the review and amendment of the *Model Act* "if necessary[,] utilizing existing 'shared services' concept language to replace technology-specific provisions . . . and to ensure that responsibility is placed on the pharmacist and pharmacy permit holder for resulting outcomes from the use of any technology systems." In making this recommendation, the task force noted that "it may be beneficial to incorporate less technology-specific definitions and provisions and remove those that have become antiquated" and that due to "technological advances in pharmacy practice and the trend for involvement of more than one pharmacist in the dispensing process that the 'shared services' concept . . . should replace all technology-specific automation language." The task force noted further that "the concept of shared services is more general and allows for broad categories of systems, is overarching, and can account for both operational and cognitive technology-supported functions."

While the new *Model Act* language was still undergoing the approval process at press time, it will likely share similarities with some of the broad language pioneered by states such as Arizona in addressing shared and virtual pharmacy practice. In the spirit of the task force recommendation, the language seeks to be clear while allowing enough flexibility to accommodate as-yet-unknown technological advances and corresponding shifts in work methods. At the same time, it seeks to place the responsibility for outcomes with the pharmacy and pharmacist, regardless of the methods and technologies they choose to use. Arizona's regulations, for example, along with those of a number of other states, specify such required elements as a shared electronic file "or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the Board's rules" (allowing flexibility for technology shifts) and a contract between two pharmacies (provided they do not have the same owner) outlining "the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules" (emphasizing responsibility).

Shared Pharmacy Services and CPPA

The concept of shared pharmacy in the community pharmacy setting has met with some criticism, with pharmacists worried about such issues as loss of jobs as they move from some of their traditional roles within the pharmacy, and high-stress working conditions – requirements to maintain an unrealistically fast, constant review of medication orders, for example. In theory, however, centralizing some tasks should allow pharmacists located in the community pharmacy to spend more of their time on more patient-centered activities like counseling, or offering higher-level patient services.

An increased focus on these activities also reflects the ideals expressed in the standards for the community pharmacy practice accreditation developed by the Center for Pharmacy Practice Accreditation (CPPA), a non-profit organization operated under the leadership of NABP, the American Pharmacists Association, and the American Society of Health-System Pharmacists to develop and implement programs for pharmacy practice site accreditation. The CPPA standards of care include three domains with one focused on patient care

(continued on page 80)

NABP Reports 2012 Year-End Clearinghouse Totals: 4,223 Disciplinary Actions Reported by State Boards of Pharmacy

NABP's 2012 year-end data results show a total of 4,223 disciplinary actions reported by the state boards of pharmacy to the NABP Clearinghouse. Of the 4,223 actions reported, 61% were actions taken against pharmacists and 39% were actions taken against pharmacy technicians.

In 2012, administrative or publicly available fines/monetary penalties accounted for the highest percentage of disciplinary actions taken against pharmacists and pharmacy technicians with an overall high of 16.7%.

Probation of license had an overall percentage of 16%, and the miscellaneous category, which consists of several smaller categories, came in with the third largest percentage with 11.2%. (See Figure A.)

Of all the actions taken in 2012, 18.5% of actions were taken due to a violation of federal or state statutes, regulations, or rules. In addition, 16.8% of actions taken were due to those categories summed up in the miscellaneous category, and 11.6% of actions were based on disciplinary actions related to diversion of controlled substances. (See Figure B.)

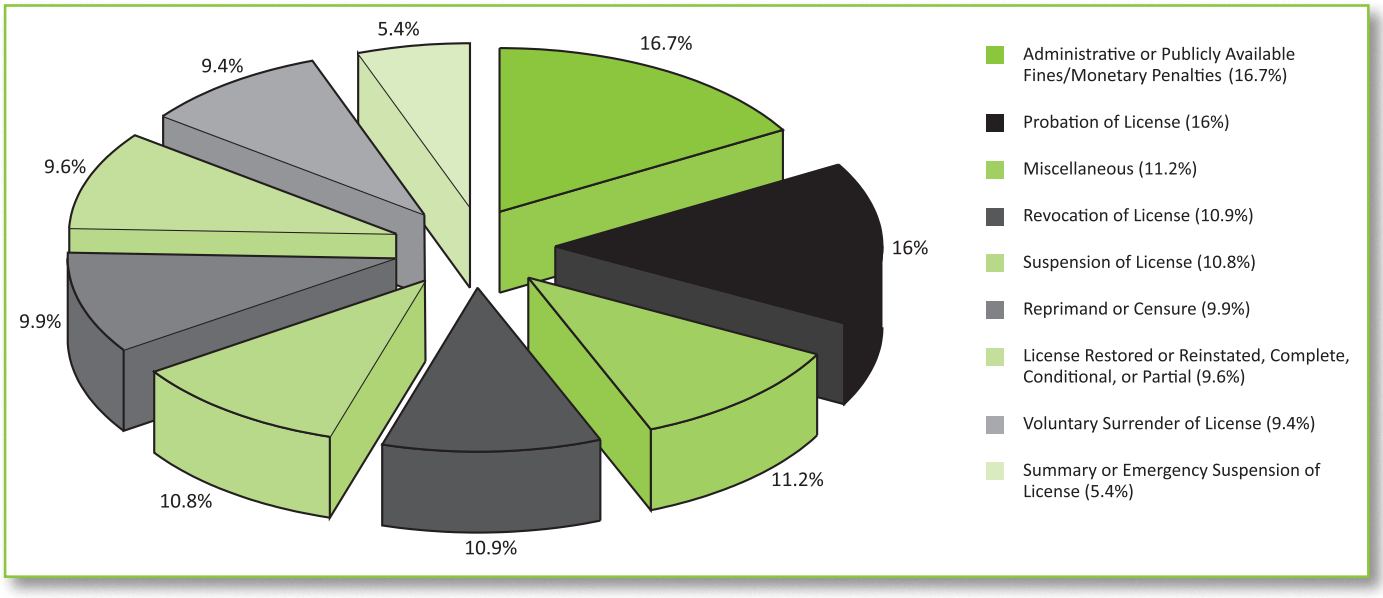
Due to the recent New England Compounding Center tragedy, NABP expects to see an influx of actions reported to the NABP Clearinghouse during 2013. From December 1, 2012 to mid-January 2013, there have been 260 actions against facilities reported to the NABP Clearinghouse. These numbers might also affect the number of actions taken against pharmacists and pharmacy technicians in 2013 as the state boards of pharmacy work diligently to strengthen inspections and regulations for compounding pharmacies.

The Clearinghouse is regularly updated to serve as a comprehensive resource for the boards of pharmacy. Housing a tremendous amount of disciplinary data provided by the boards, the Clearinghouse is an important resource for the license transfer process as it tracks everything from the actions taken against pharmacists and pharmacy technicians to the basis for these actions. In addition, reporting to the Clearinghouse is required by the NABP Constitution and Bylaws. NABP also offers its services as a reporting agent for the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank (HIPDB).

In May 2012, NABP launched a reporting tool that enables the boards to conveniently report disciplinary actions for pharmacists, pharmacy technicians, and pharmacy interns through a secure Web portal. The reporting tool has assisted

(continued on page 78)

Figure A: Disciplinary Actions Reported in 2012



*The miscellaneous category includes denial of initial license; denial of license renewal; extension of previous licensure action; interim action; license restoration or reinstatement denied; limitation or restriction on license; modification of previous licensure action; other licensure action – not classified; summary or emergency limitation or restriction on license; and reduction of previous licensure action.

2012 Clearinghouse Totals

(continued from page 77)

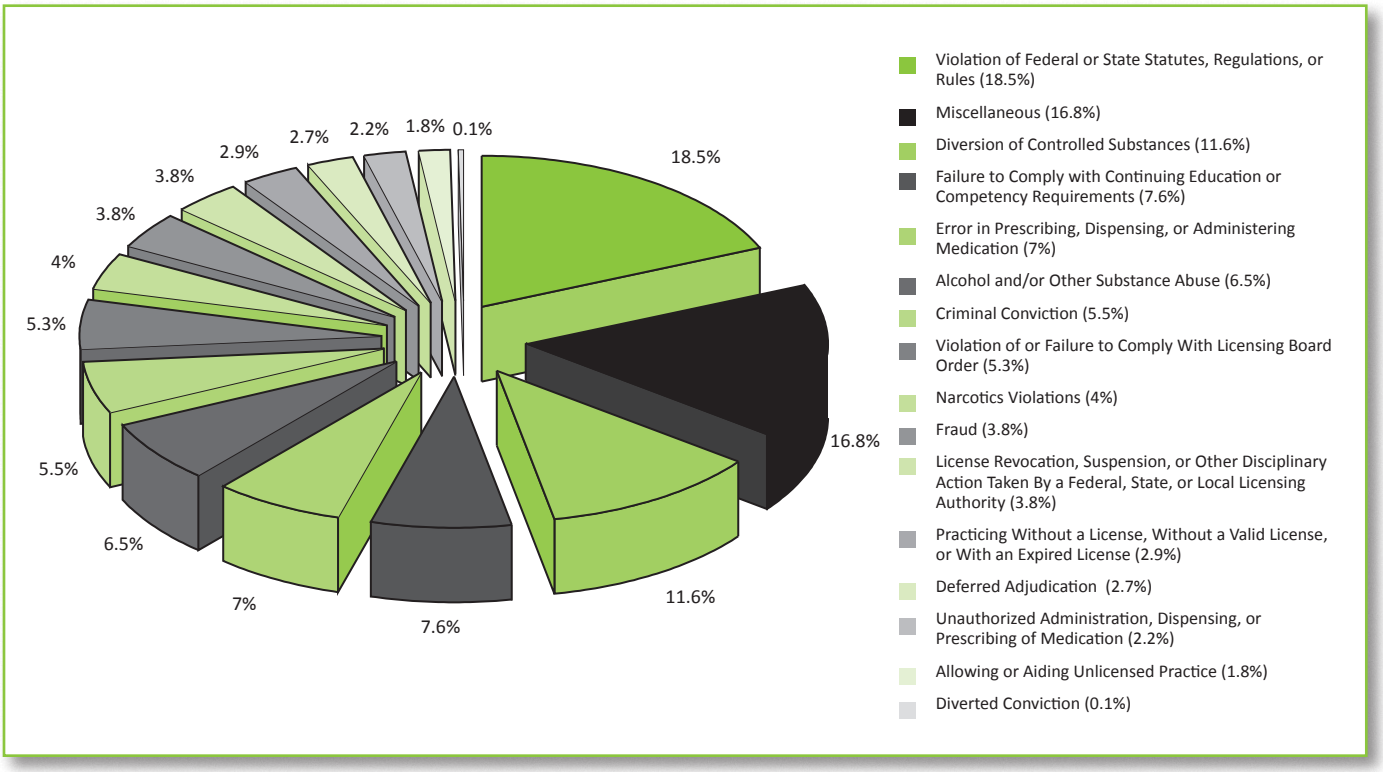
the boards in meeting the requirements set forth by the United States Department of Health and Human Services, Health Resources and Services Administration, Division of Practitioner Data Banks. Boards that have designated NABP as their reporting agent for HIPDB can utilize the reporting tool to transmit the disciplinary data directly to the federal data banks.

To further assist the boards in reporting actions against licensees and to enhance the system's usability, NABP will be revamping its Clearinghouse this month to enable real-time reporting among the state boards of pharmacy. Utilizing the NABP e-Profile ID, boards reporting disciplinary actions to the Clearinghouse will be able to notify and share in real time with other states when action has been taken against a licensee.

Currently, 32 boards of pharmacy have designated NABP as their HIPDB reporting agent; however, all boards of pharmacy are encouraged to utilize the online tool to report pharmacy disciplinary actions to the Clearinghouse regardless of whether NABP is their reporting agent.

Additional information about the NABP Clearinghouse and designating NABP as a reporting agent is available at *www.nabp.net/programs/member-services/nabp-clearinghouse.*

Figure B: Basis for Disciplinary Actions Reported in 2012



*The miscellaneous category includes conduct evidencing ethical unfitness; conduct evidencing moral unfitness; disruptive conduct; failure to consult or delay in seeking consultation with supervisor/proctor; failure to disclose; failure to pay child support/delinquent child support; filing false reports or falsifying records; immediate threat to health or safety; improper or inadequate supervision or delegation; incompetence; malpractice; mental disorder; misappropriation of patient property; misrepresentation of credentials; negligence; nolo contendere plea; other – not classified; other unprofessional conduct; patient abandonment; practicing beyond the scope of practice; sexual misconduct; submitting false claims; substandard or inadequate skill level; substandard or inadequate care; unable to practice safely; and unable to practice safely by reason of psychological impairment or mental disorder.

NABP Seeks Volunteers for Review Committees

NABP is seeking volunteers to serve on the Association's three examination review committees including the North American Pharmacist Licensure Examination® (NAPLEX®), the Multistate Pharmacy Jurisprudence Examination® (MPJE®), and the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). Volunteers are also needed for the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

If chosen, volunteers will write, edit, and assess potential questions for the competency assessment programs, as well as assist in establishing passing standards. Previous item writing experience in the program of interest is highly recommended and preferred.

Ideal candidates for the NAPLEX Review Committee are educators, regulators, and practitioners from all areas of practice who have previous experience as NAPLEX item writers.

The MPJE Review Committee has openings for volunteers knowledgeable with state and federal jurisprudence requirements. Participation on this review committee is limited to individuals who reside or practice in states that participate in the MPJE. Though not a requirement, board of pharmacy affiliation is beneficial and would be helpful to the committee.

The FPGEE Review Committee requires representation from individuals in academia who teach in areas of basic biomedical sciences; pharmaceutical sciences; social, behavioral, and administrative sciences; or clinical sciences. Previous experience in writing examination questions for the FPGEE is preferred for this committee.

In addition, volunteers are needed to serve as item writers for the PCOA. Requirements for PCOA item writers are individuals in academia who teach in areas of basic biomedical sciences; pharmaceutical sciences; social, behavioral, and administrative sciences; or clinical sciences. Previous experience in writing examination questions is preferred.

Participation in these review committees typically requires a commitment of two to four meetings per year with all travel and meal expenses covered by NABP.

Those interested in serving may submit a letter of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone, via mail to NABP Headquarters; e-mail to exec-office@nabp.net; or fax to 847/391-4502.

NABP Announces the 2013-2014 NAPLEX Review Committee

NABP is pleased to announce the members of the 2013-2014 North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee, introducing two 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, which, in essence, determine the question pool.

The NAPLEX Review Committee members (listed below) began their terms on February 1, 2013.

- Marie Abate, West Virginia University
- Jennifer Beall, Samford University
- Christopher Betz, Sullivan University
- Pauline Cawley,* Pacific University
- Michael Cockerham, University of Louisiana – Monroe
- Mark Decerbo, Roseman University of Health Sciences
- Betty Dong, University of California – San Francisco
- Darla Gallo, pharmacist, Philadelphia, PA
- W. Franklin Gilmore, professor emeritus, Montana Tech of The University of Montana
- Robert P. Henderson, Samford University
- William A. Hopkins, Jr, pharmacist, Big Canoe, GA
- Tom M. Houchens, pharmacist, London, KY
- Arthur I. Jacknowitz, professor emeritus, West Virginia University
- William Kehoe, Jr, University of the Pacific
- Susan C. Lutz, pharmacist, Altoona, IA
- David W. Newton, Shenandoah University
- Stephen M. Ouellette, pharmacist, Oakland, ME
- Roy Parish, University of Louisiana – Monroe
- Benjamin Prewitt,* pharmacist, Lebanon, OH
- David B. Roll, professor emeritus, University of Utah
- Theresa Salazar, pharmacist, Indianapolis, IN
- Eric F. Schneider, University of Waterloo
- Cynthia Sieck, pharmacist, Vancouver, WA
- John L. Szarek, The Commonwealth Medical College
- Neal F. Walker, pharmacist, Hibbing, MN
- Siu-Fun Wong, Loma Linda University

*Denotes new members

Compounding Pharmacy

(continued from page 71)

ments for compounding pharmacies from cGMPs followed by manufacturers.

Forthcoming results of the Iowa inspection program and other data to be included in the national pharmacy information sharing network being developed by NABP may also assist boards of pharmacy in determining whether licensees are preparing patient-specific or non-patient-specific drugs, and assist in addressing other regulatory matters.

Inspections Continue, Sharing Network Under Development

The Iowa Board originally contracted with NABP to complete inspections by June 2013, and will extend the contract so that all pharmacies providing compounding services are inspected, as well as nonresident pharmacies that do not engage in compounding.

NABP believes that the list of nonresident pharmacies provided by the Iowa Board represents many of the large-scale compounding operations across the country. Continuing toward its goal of inspecting over 600 pharmacies by the end of the year as part of the Iowa inspection program, NABP initiated a second round of inspections of nonresident pharmacies in February. In addition, surveyors, many already knowledgeable in sterile compounding, will receive comprehensive training in sterile compounding to better equip them for planned inspections of facilities engaged in this practice.

The national pharmacy information sharing network under development by NABP will include data resulting from these inspections, as well as other relevant information submitted by boards of pharmacy. Providing a means for boards of pharmacy to share this information should assist in developing, implementing, and enforcing regulations for the practice of compounding. NABP will continue to provide updates to assist its member boards in taking actions to help ensure the safety of compounded drug products for the protection of public health.

Legal Briefs

(continued from page 73)

"exempt" from the Kansas law to the extent she practiced outside its borders.

The Kansas Supreme Court noted that no geographic limitation as to practice is contained anywhere in the Kansas act. Further, the court noted that 18 separate exemptions are contained within the act and that the Licensee concedes that she does not fall within any of the delineated exemptions. The Kansas Supreme Court noted that the Kansas Healing Arts Act specifically states that every act falling within the scope of practice but not specifically exempted "shall constitute the practice thereof."

Finally, the Licensee argued that the grounds for discipline in the Kansas Healing Arts Act, among others, refers to the authority of the Board to discipline a licensee based upon the final disciplinary actions of another jurisdiction and that no such final action has occurred. But, the court noted that limiting discipline in Kansas to final disciplinary action of another state does not prohibit Kansas from investigating alleged wrongdoing.

Based on the above, the Kansas Supreme Court upheld the validity of the subpoena issued by the Board for the production of medical records related to treatment by a Kansas licensee on a patient in Missouri.

This opinion answers some very interesting and potentially difficult questions related to the breadth of authority of a regulatory board seeking to investigate action of a licensee that took place outside the borders of the licensing state. The court engaged in a thorough analysis of the issues and concluded that the public protection mission of the practice act extends beyond the patients of Kansas but, perhaps, to all patients, regardless of location.

Ryser v. State of Kansas; Kansas Board of Healing Arts, 284 P. 3d 337, 2012 Kan. LEXIS 465 (KS 2012)

Remote Pharmacy Services

(continued from page 76)

and patient counseling expecting that the pharmacy practice "develops, implements, and oversees patient-centered services focused on improving patient medication use, health, and wellness."

Since their origins as groundbreaking telepharmacy programs just over 10 years ago, shared pharmacy services have held out the potential for increased access to medical care and improved outcomes for patients. But the rapid pace of technological innovation and the ensuing shift in practice methods, along with the removal of proximity constraints in processing medication orders, has created new complications for regulators seeking to protect the public health. NABP's forthcoming *Model Act* update aims to assist the boards of pharmacy in building the necessary flexibility into their regulatory language to cope with these changes, now and in the future.

PCOA Data Continues to Demonstrate Progression in Students' Scores, Successfully Measure Student Growth

Over the past five years, NABP has remained committed to assisting the schools and colleges with their review assessment of their pharmacy curricula. Launched in April 2008, the Pharmacy Curriculum Outcomes Assessment® (PCOA®) was developed after stakeholders and schools and colleges of pharmacy expressed the need for a national assessment that would provide an external measure of student performance as a tool for curricular evaluation. Now, celebrating its fifth anniversary, the PCOA is still the only independent, objective, and national assessment available that enables schools and colleges to assess their curriculum, measure their students' knowledge, and compare their results to other schools and colleges throughout the United States.

Assisting the Schools and Colleges

As part of the schools' or colleges' commitment to quality improvement, the PCOA may be used to help evaluate if curricula are meeting the desired outcomes of their doctor of pharmacy programs. Utilizing the PCOA, schools and colleges can measure the overall performance of pharmacy students and compare their scores to a representative national sample. The PCOA may also be used as a tool to provide feedback on the strengths and weaknesses of students and track scores from year to year to show each student's growth. In addition, the PCOA can assist the schools and colleges by providing documentation of improvement in student performance after their curriculum has been modified or updated.

Of additional value, the PCOA may assist the schools and colleges in maintaining compliance with the Accreditation Council for Pharmacy Education (ACPE) standards as it provides an objective, psychometrically sound, comprehensive assessment that allows for comparisons with peer institutions. ACPE's latest standards provide an additional focus on competencies, outcomes, and the need for assessment and evaluation, and the PCOA can serve as a component of this evaluation plan.

The PCOA also provides schools and colleges with score data that can be used in research studies. Academic proficiency (eg, grade point average or completion of the PharmD program), other assessments such as national Pharmacy College Admission Test scores, and future North American Pharmacist Licensure Examination® (NAPLEX®) scores can be evaluated along with the PCOA to provide insight to performance measures. It is important to note, however, that the PCOA does not measure the same information as the NAPLEX. Although there is some overlap on 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.

Construct Validity

There is compelling evidence that PCOA scores provide reliable and valid information about the abilities and knowledge of participating students.

Data obtained from 2009 to 2012 substantiate the claim that the PCOA is a valid measure of the construct of interest (knowledge in US pharmacy school curricula) by demonstrating a step progression of knowledge as students advance in the professional curriculum. The concept that examinees with higher scores have more knowledge and ability than examinees with lower scores is supported when comparing scores from P1 students through P4 students. (See Table A.)

Content Validity

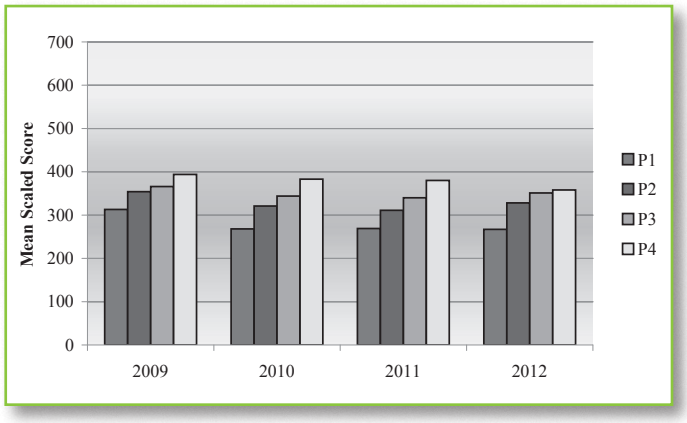
Inter-scale correlations among the PCOA's four content areas: basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences demonstrate that scores in all areas are positively correlated with one another – suggesting that the examination is measuring a uni-dimensional construct. Additionally, each content area maintains its own uniqueness and provides information given the area score increases from P1 to P4 years. (See Table B.)

The content validity argument for the PCOA is also strengthened given

(continued on page 82)

Table A.

Data from 2009 to 2012 indicates that there is a progression of student scores across program years P1 through P4.



PCOA Data Trends

(continued from page 81)

the assessment's rigorous and representative content development process. The design, development, administration, and scoring of the PCOA aligns with US pharmacy curricula and also aligns with professional standards for test development and psychometrics used in education and high-stakes test development. The assessment's content is developed and revised by US pharmacy school faculty, practitioners, and other pharmacy education specialists. These subject matter experts are screened through 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 test questions and examination forms are written and reviewed by subject matter experts from more than 60 accredited colleges of pharmacy.

Reliability

The PCOA's reliability measure represents the consistency of scores across administrations. This statistic describes the extent to which all items in a test are related. The higher the reliability measure, the less random error contributes to an individual's score and thus the more confidence we have in the scores. Each year of administration, the PCOA's reliability measure meets professional testing industry standards for high stakes examinations such as the NAPLEX or the Multistate Pharmacy Jurisprudence Examination®.

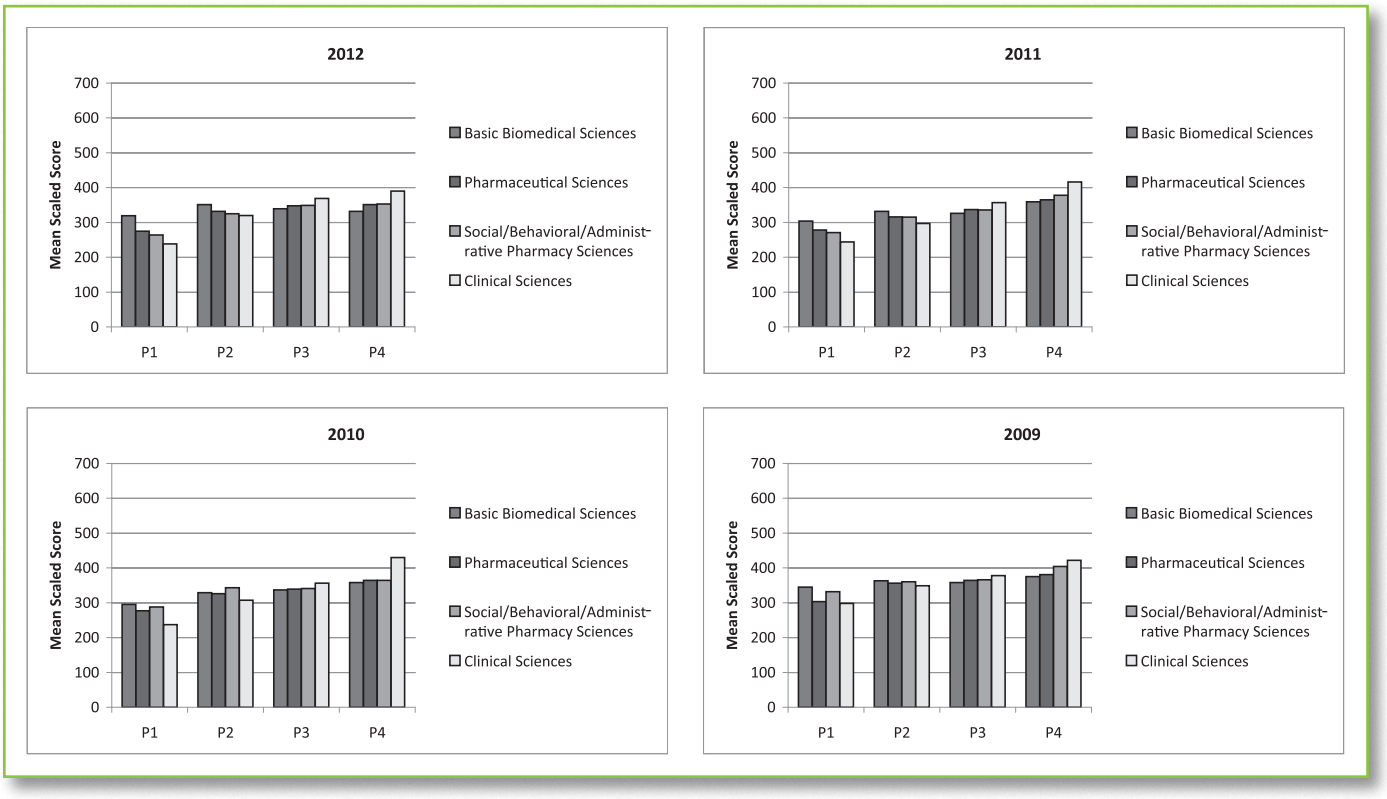
As in 2012, NABP will host a forum on April 25, 2013, to continue its efforts in cultivating a communicative, educational, and collegial environment for current PCOA users, prospective users, stakeholders, and developers to convene and share their own perspectives and experiences with the assessment.

NABP also plans to participate in a panel discussion at the American Association of Colleges of Pharmacy's Annual Meeting in July 2013, where they will discuss the PCOA.

The next available testing window for the 2013 PCOA is September 23 to October 12, 2013. Registration for this testing window ends June 25, 2013. Twenty-seven schools participated in the January/February PCOA administration. More information about the PCOA may be found at *www.nabp.net/programs/assessment/pcoa.*

Table B.

Data from 2009 to 2012 indicates a commonality among content areas, but that each content area is unique to a certain extent.



Pre-NAPLEX and Pre-FPGEE Mark 10 Years as an Asset to Test Preparation for Candidates Seeking Licensure

First launched in 2003, the Pre-NAPLEX® and Pre-FPGEE® have given candidates the opportunity to "preview" the North American Pharmacist Licensure Examination® (NAPLEX®) and the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). These are the only practice examinations written and developed by NABP. They contain actual questions that previously appeared on the NAPLEX and FPGEE, and are based on the same blueprint as the actual examinations. By taking these practice examinations, candidates are provided with information on their performance under pre-testing conditions when answering a subset of test questions similar to those that may be included on the NAPLEX and FPGEE.

The Pre-NAPLEX is intended to benefit candidates who are preparing for the NAPLEX. The Pre-NAPLEX is 70 minutes in length and contains 50 questions. Once the Pre-NAPLEX is begun, it must be completed in its entirety. Candidates may not review questions or change answers during the exam once an answer choice is confirmed, as in the NAPLEX. Candidates may take the Pre-NAPLEX two times.

The Pre-FPGEE is 85 minutes in length and contains 66 questions. The Pre-FPGEE is intended to benefit FPGEE candidates who are preparing for the FPGEE. Candidates may review and change answers any time during the exam, similar to the FPGEE. Candidates may only take each Pre-FPGEE test form once; however, a new form is available approximately four weeks before each FPGEE administration. Candidates must complete the Pre-FPGEE in order to receive a score.

Candidates taking the Pre-NAPLEX and Pre-FPGEE should allow an additional 15 to 20 minutes to complete the registration process and the exit survey. Each practice examination is scored in similar fashion as the NAPLEX and FPGEE. Upon completion of the practice examination, candidates will be given a scaled score that can be printed for their own records, and will not be released to anyone other than the candidate. NABP does not claim that a strong performance on the Pre-NAPLEX or Pre-FPGEE predicts passing the NAPLEX or FPGEE.

Candidates may register online and pay via any major credit card through the NABP Web site. The Pre-NAPLEX and Pre-FPGEE are $50 each per attempt. Once a candidate registers and pays for the practice examination, it must be taken within seven days. After the seventh day, the practice exam will expire and a new one must be purchased. Candidates may take the practice examinations at any time on any day, and anywhere there is an Internet connection, through the NABP-hosted server. Visit *www.nabp.net/programs* and log in to your NABP e-Profile to register for and take the Pre-NAPLEX or Pre-FPGEE.

Pre-NAPLEX Vouchers Available

While students may purchase the Pre-NAPLEX individually, some schools and colleges of pharmacy may find it beneficial to purchase the Pre-NAPLEX for distribution to their students. NABP offers a Pre-NAPLEX voucher program for schools and colleges of pharmacy, as well as pharmacy associations. By purchasing vouchers in bulk, schools and colleges of pharmacy have the advantage of administering the Pre-NAPLEX in a controlled testing environment.

To redeem their vouchers, students may register for the Pre-NAPLEX on the NABP Web site and enter their voucher code. Once the voucher is redeemed, the practice examination must be taken within seven days. Vouchers expire two years from the date of purchase.

Discounts are available for purchases of 100 or more vouchers. For more information, contact the Competency Assessment Department at NABP_Comp_Assess@nabp.net or 847/391-4406.

Newly Accredited Vet-VIPPS Facility

The following veterinary Internet pharmacy was accredited through the NABP Veterinary-Verified Internet Pharmacy Practice Sites℠ (Vet-VIPPS®) program:

Animal Pharm, LLC, dba PetRx2go
www.petrx2go.com

A full listing of the accredited Vet-VIPPS sites is available on the NABP Web site at *www.nabp.net*.

Deadline Approaching to Designate Official Voting Delegates

The deadline for active member boards to designate official voting delegates and alternate voting delegates for the 109th Annual Meeting is **Thursday, April 18, 2013.**

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 18 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 also encouraged to submit their signed Official Delegate Certificates.

Executive officers of the boards may submit their signed Official Delegate Certificates to Lisa Braddy, Executive Office coordinator, at NABP Headquarters via fax at 847/391-4500 or may scan and e-mail the certificates to exec-office@nabp.net.

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

109th Annual Meeting Travel Grant Opportunities Still Available

Annual Meeting travel grant opportunities are still available to active member boards of pharmacy interested in attending the 109th Annual Meeting to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO. One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board's administrative officer.

In years past, the travel grant was provided only for voting delegates. Although that restriction no longer applies, active member boards of pharmacy still must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

The Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for needed 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 109th 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 Lisa Braddy. Executive Office coordinator, at NABP Headquarters or via fax at 847/391-4500. NABP requests that applications be submitted prior to the Annual Meeting. All applicants will be informed of whether or not they have qualified for the grant.

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

Newly Accredited VAWD Facilities

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

Fisher Clinical Services, Inc, dba Fisher Clinical Services
Breinigsville, PA

Jacobson Warehousing Company, Inc
Delano, PA

Medline Industries, Inc
Shepherdsville, KY

UPS Supply Chain Solutions, Inc
Suwanee, GA

VWR International, LLC
Visalia, CA

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

Exciting, Timely Topics to Offer Attendees Up to Nine Contact Hours of CPE Credit at NABP 109th Annual Meeting

The NABP 109th Annual Meeting, "State Boards of Pharmacy and NABP – Gateway to Shared Responsibility and Success," to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO, offers attendees the chance to earn up to 9 contact hours (0.9 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 18

Pre-Meeting CPE

The Compounding/ Manufacturing Debate: When Is a Duck Not a Duck?

During this special pre-meeting CPE panel session, federal and state regulators and compounding experts will discuss the perplexities surrounding the issue of compounding pharmacies acting as manufacturers and the resultant and ongoing regulatory challenges facing the boards of pharmacy. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit.

Sunday, May 19

Joint CPE

Educational Poster Session – Sharing Responsibility for Public Protection

Continuing an annual favorite, this CPE session will offer the boards of pharmacy and schools and colleges of pharmacy the unique opportunity to present various poster displays as they relate to this year's Poster Session theme, "Sharing Responsibility for Public Protection." CPE is earned through interactive participation with presenters for one hour during the three and one-half hour offering and by completing a post-session test. Participants will earn 1 contact hour (0.1 CEU) of CPE credit.

Joint CPE

gTLD and LegitScript Investigations Update

During this joint CPE session, meeting attendees will hear an update regarding enforcement successes, including what registrars, search engines, credit card companies, and others are doing to shut down rogue sites. In addition, the issue of generic Top-Level Domains (gTLD) will be discussed, including NABP's application to obtain the .PHARMACY gTLD and the current strategy for keeping the rogue players out of the game. Participants will earn 1 contact hour (0.1 CEU) of CPE credit.

Monday, May 20

Joint CPE

Veterinary Pharmacy Issues: Identifying Illegal Practices and Distinguishing Supply Chain Variations

This session's discussion will center around what knowledge is necessary regarding drug therapy and pharmacokinetics in veterinary medicine and why a lack of such knowledge may place our animal counterparts at risk. Attendees will also learn the differences between the two drug supply chains, including how and why the veterinary drug supply chain is legally allowed to be separate and vary from the human drug supply chain. Participants will earn 2 contact hours (0.2 CEUs) of CPE credit.

Tuesday, May 21

Executive Officer and Board Member CPE

Virtual Pharmacy Practice and Wholesale Distribution – Out of Thin Air

A recent NABP task force tackled issues on virtual manufacturing and some alarming trends were unveiled. Attendees will learn about how some virtuals fly under the enforcement radar and what changes are necessary to protect the public by making them visible and ensuring their compliance. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Compliance Officer CPE

Pill Mills, Non-Therapeutic Drug Use, and Prescription Drug Monitoring: What to Look for During Investigations

Prescription drug monitoring programs, along with other advanced technology, provide boards of pharmacy and their compliance officers better tools with which to conduct pharmacy investigations and detect cases of diversion and abuse. During this CPE session, experienced regulators will provide attendees proven methods on using these and other tools when investigating pill mills and non-therapeutic drug use. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Joint CPE

Are Biosimilars the Same as Generics? Point-Counterpoint

Biosimilars are becoming a hot topic with the upcoming implementation of the Biologics Price Competition and Innovation Act of 2009. A panel of government and industry experts will provide session attendees with in-depth information on biologics and biosimilars, including the pros and cons of interchangeability and what regulatory hurdles need to be cleared. Participants will earn 1.5 contact hours (0.15 CEUs) of CPE credit.

Additional information about the 109th Annual Meeting is available at *www.nabp.net/meetings.*

Meeting Program

May 18-21, 2013 Hyatt Regency St Louis at the Arch St Louis, MO

Saturday, May 18, 2013

9 AM - 7 PM
Registration/Information Desk Open

2 - 4 PM
Pre-Meeting CPE
The Compounding/Manufacturing Debate: When Is a Duck Not a Duck?
ACPE #205-000-13-001-L03-P
(0.2 CEUs – 2 contact hours)

5 - 6 PM
Annual Meeting and District Meeting Orientation

7 - 10 PM
President's Welcome Reception
Honoring NABP President
Michael A. Burleson, RPh
Dinner will be served
Dress: business casual

Sunday, May 19, 2013

6:30 AM - 5 PM
Registration/Information Desk Open

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

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

8 - 11:30 AM
Joint CPE
Educational Poster Session – Sharing Responsibility for Public Protection
ACPE #205-000-13-002-L04-P
(0.1 CEU – 1 contact hour)

Noon - 3:15 PM
First Business Session
Presiding: Michael A. Burleson, RPh, NABP President

- Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/ Secretary
- Presentation of Colors
- National Anthem
- Keynote Address
  Sponsored by Humana Pharmacy Solutions
  Chef Jeff Henderson
- Call to Order
- Greetings from the Host State
  Missouri Board of Pharmacy
- Recognition of Sponsors
- Report of the Executive Committee
  Malcolm J. Broussard, RPh, Chairperson, NABP Executive Committee
- President's Address
  Michael A. Burleson, RPh, NABP President
- Report of the Treasurer
  Joseph L. Adams, 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
gTLD and LegitScript Investigations Update
ACPE #205-000-13-003-L03-P
(0.1 CEU – 1 contact hour)

Monday, May 20, 2013

7 AM - 2 PM
Registration/Information Desk Open

7 - 8:15 AM
NABP/USP Breakfast
Sponsored by United States Pharmacopeial Convention

8:15 - 10:15 AM
Joint CPE
Veterinary Pharmacy Issues: Identifying Illegal Practices and Distinguishing Supply Chain Variations
ACPE #205-000-13-004-L03-P
(0.2 CEUs – 2 contact hours)

10:30 AM - noon
Second Business Session
Presiding: Michael A. Burleson, 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
  Karen M. Ryle, MS, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  - First Reading of Resolutions
- Report of the Committee on Constitution and Bylaws
  Jeannine G. Dickerhofe, MS, RPh, Chairperson, Committee on Constitution and Bylaws
  - Presentation of Proposed Amendments to the Constitution and Bylaws
- Candidate Speeches for Open Executive Committee Officer and Member Positions

Noon - 12:30 PM
Informal Member/Candidate Discussion

1:30 - 5:30 PM
Optional Tour
Gateway to St Louis
Reservation required.

Tuesday, May 21, 2013

7:30 AM - 4:15 PM
Registration/Information Desk Open

7:45 - 8:45 AM
NABP Breakfast

8:45 - 10:15 AM
Executive Officer and Board Member CPE
Virtual Pharmacy Practice and Wholesale Distribution – Out of Thin Air
ACPE #205-000-13-005-L03-P
(0.15 CEUs – 1.5 contact hours)

8:45 - 10:15 AM
Compliance Officer CPE
Pill Mills, Non-Therapeutic Drug Use, and Prescription Drug Monitoring: What to Look for During Investigations
ACPE #205-000-13-006-L03-P
(0.15 CEUs – 1.5 contact hours)

10:30 AM - noon
Joint CPE
Are Biosimilars the Same as Generics? Point-Counterpoint
ACPE #205-000-13-007-L05-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: Michael A. Burleson, RPh, NABP President

- Election of 2013-2014 Executive Committee Officers and Members
- Remarks of the Incoming President
  Karen M. Ryle, MS, RPh, NABP President-elect
- Installation of 2013-2014 Executive Committee Officers and Members
- Final Report of the Committee on Constitution and Bylaws
  Jeannine G. Dickerhofe, MS, RPh, Chairperson, Committee on Constitution and Bylaws
  - Discuss and Vote on Proposed Amendments to the Constitution and Bylaws
- Final Report of the Committee on Resolutions
  Karen M. Ryle, MS, RPh, NABP President-elect and Chairperson, Committee on Resolutions
  - Discuss and Vote on Resolutions
- Invitation to the 2014 Annual Meeting in Phoenix, AZ
  Thomas Van Hassel, RPh, President, Arizona State Board of Pharmacy

5:45 - 6:45 PM
Awards Dinner Reception

7 - 11 PM
Annual Awards Dinner
Presiding: Karen M. Ryle, MS, RPh, 2013-2014 NABP President

- Presentation to 2013 Honorary President
- Presentation to Michael A. Burleson, RPh, 2013-2014 Chairperson, NABP Executive Committee
- Presentation of the 2013 Fred T. Mahaffey Award
- Presentation of the 2013 Henry Cade Memorial Award
- Presentation of the 2013 John F. Atkinson Service Award
- Presentation of the 2013 Lester E. Hosto Distinguished Service Award

Dress: semiformal

Note: The 109th Annual Meeting schedule is subject to change.

NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). ACPE Provider Number: 205. 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 for each session are required to receive CPE credit and a Statement of Continuing Pharmacy Education 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.

Register Online Today for the 109th Annual Meeting at NABP.net

Early registration rates are available for the NABP 109th Annual Meeting, "State Boards of Pharmacy and NABP – Gateway to Shared Responsibility and Success," to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO. Attendees are encouraged to register early to receive the reduced registration rates. In order to receive the early registration rate, attendees must register **on or before April 8, 2013.** Registration is available in the Meetings section of the NABP Web site at *www.nabp.net/meetings*.

NABP offers attendees three payment options:

1. Mailing in the payment
2. Using a credit card (American Express, MasterCard, or Visa)
3. Paying in St Louis

To maintain the accuracy of attendee information and streamline the registration process, all registration will be handled electronically. Attendees who do not have access to a computer may contact the NABP Customer Service Department at 847/391-4406. More information about the 109th Annual Meeting is available in the Meetings section of the NABP Web site at *www.nabp.net/meetings*.

AWARXE Online PSA Campaign Encourages Participation in Sixth National DEA Take-Back Day

Program Continues to Deliver Local Presentations

The AWARXE® Consumer Protection Program has embarked on a second social media awareness campaign to encourage consumer participation in the Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day to take place April 27, 2013. This is the sixth DEA Take-Back Day since the events began in October 2010, and provides consumers in every state numerous sites for safe, legal disposal of unwanted, unneeded, and expired prescription drugs – including controlled substances. The first five take-back day events brought in 2 million pounds of unwanted prescription medications in total, with the last date bringing in 488,396 pounds on its own, showing the continued need for the drug collection days.

The AWARXE campaign, through online public service announcements (PSAs) and a social media press release, stresses the importance of using opportunities such as DEA Take-Back Days to rid the home of unneeded medications to prevent misuse, abuse, and diversion. With over 50% of prescription medicine abusers obtaining the drugs from friends and family, drug disposal plays a key role in prevention. In fact, of 12th-grade students who abused prescription narcotics in 2012, over 67% were given the drugs by a friend or relative, and 22% took the drugs from a friend or relative without asking.

Through April 27, 2013, an AWARXE audio PSA airing on Pandora.com raises awareness about the dangers when medications in the home fall into the wrong hands and provides information about the DEA Take-Back Day. In addition, banners displaying on both Pandora.com and Yahoo.com raise awareness and link back to *www.AWARERx.org* so that consumers can learn more about the importance of securely storing needed medications and safely disposing of unneeded prescription drugs. These PSAs will potentially reach millions of Internet users with the AWARXE Web site just a click away. Pandora.com has 50 million unique visitors per month and Yahoo .com, 160 million unique visitors per month and a large portion of visitors to both Web sites include moms in the "sandwich generation," a key audience for the AWARXE message since they are often providing caregiving for their parents as well as their children.

AWARXE also continues to educate at the local level by providing flyers and other materials to awareness events, and also by delivering presentations to students, seniors, civic groups, and health care organizations. AWARXE provided handouts on safe drug disposal methods to Madison Block, a Washington State University (WSU) pharmacy student, who distributed them at an awareness week for all WSU students.

An AWARXE presentation on prescription drug abuse dangers and the importance of secure storage and safe disposal was delivered to the staff of Rainbow Hospice & Palliative Care, Mount Prospect, IL, on March 19, 2013, and a similar presentation will be delivered to the Kiwanis Club of Streamwood, Schaumburg, IL, on April 2, 2013.

AWARXE slideshow presentations are available for board of pharmacy members and staff who seek to educate about prescription drug abuse dangers at schools, community events, or health organizations. The three slide shows available present the latest data from government reports on the prescription drug abuse epidemic and information on the importance of secure medication storage and safe disposal, and are tailored for the specific audiences: middle school and high school students, seniors and members of community organizations, and health care providers. The slideshows also include talking points. For more information or to obtain a slideshow, you may send an e-mail to AWARERx@NABP.NET.

Sixth DEA National Prescription Drug Take-Back Day

The next Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day will take place **Saturday, April 27, 2013, from 10 AM to 2 PM.** This will be the sixth event coordinated by DEA to help consumers safely dispose of unused, unneeded, and expired prescription medications, including controlled substances.

North Carolina Compounding Working Group

The North Carolina Board of Pharmacy has created, empaneled, and charged a Pharmacy Compounding Working Group to conduct a comprehensive review of all aspects of compounding pharmacy regulation including (1) whether and to what extent changes are needed in either or both of the North Carolina Pharmacy Practice Act and Board of Pharmacy rules governing compounding pharmacy; (2) whether and to what extent United States Pharmacopeia Chapter 797 standards should be specifically incorporated into state law; (3) whether and to what extent North Carolina law should mandate or recognize any form of "accreditation" for compounding pharmacies; (4) whether and to what extent changes are needed in Board investigator training or inspection methods with respect to compounding pharmacies; and (5) what particular issues, if any, with respect to out-of-state compounding pharmacies, require different or additional regulatory approaches. Each of these broad topics will encompass numerous subsidiary issues. The working group will provide a report and recommendation to the full Board on these issues.

Five-Year Anniversary of the Arizona Board CSPMP

The Arizona State Board of Pharmacy's Controlled Substances Prescription Monitoring Program (CSPMP) started collecting data from dispensers of Schedule II, III, and IV controlled substance prescriptions in October 2008, and has been available for use by medical practitioners and pharmacists since December 2008. Medical practitioners who are registered with the CSPMP as required by law may request access to the CSPMP database to look up their own patients' prescription information in order to better treat or evaluate their patients. Pharmacists who are licensed may also request access in order to make more informed decisions about whether or not to dispense a particular controlled substance prescription. Perhaps of equal importance to pharmacists, the CSPMP provides a quick way to comply with the "corresponding liability" clause in Drug Enforcement Administration (DEA) Regulation 1306.05 (f), which can be found in the Code of Federal Regulations.

On October 22, 2012, the process for requesting access to the CSPMP was changed to an online and paperless process. The Board provided instructions for medical practitioners and pharmacists, including information about a required training course, in its January 2013 *Newsletter*. The Board also provided instructions for medical practitioners and pharmacists who are not licensed in Arizona to request access online.

Louisiana Board of Pharmacy PMP Regulatory Project

The Louisiana Board of Pharmacy has provided a status update on the process for rulemaking related to the state's PMP. Louisiana's Regulatory Project 2012-10 ~ Prescription Monitoring Program includes several amendments to Chapter 29 of the Louisiana Board's rules, all intended to implement the provisions of Acts 144 and 488 of the 2010 Legislature as well as Act 352 of the 2012 Legislature. The proposed amendments include (1) additional organization representatives on the PMP Advisory Council; (2) the requirement for dispensers to report prescription transaction data as soon as possible and no later than seven days after the dispensing date; (3) the modification of

(continued on page 90)

Around the Association

Executive Officer Changes

- **Larry Loring, RPh,** now serves as executive director/chief inspector of the New Mexico Board of Pharmacy. Prior to this position, Loring served as acting executive director/chief inspector of the New Mexico Board of Pharmacy.

Board Member Appointments

- **Buddy Bunch, RPh,** has been appointed a member of the Alabama State Board of Pharmacy. Bunch's appointment will expire December 31, 2017.
- **Sandra Zaragoza, RPh,** has been appointed a member of the Delaware State Board of Pharmacy. Zaragoza's appointment will expire October 25, 2015.
- **King Milne, RPh,** has been appointed a member of the Vermont Board of Pharmacy. Milne's appointment will expire December 31, 2017.
- **James Arisman** has been appointed a public member of the Vermont Board of Pharmacy. Arisman's appointment will expire December 31, 2017.

Board Member Reappointments

- **Joli Martini, RPh,** has been reappointed a member of the Delaware State Board of Pharmacy. Martini's appointment will expire October 25, 2015.

(continued on page 90)

State Board News

(continued from page 89)

required data elements to include suffix numbers of DEA registration numbers where applicable, the use of National Provider Identifier numbers where applicable, and additional data elements for veterinary prescriptions; (4) permission for the Louisiana PMP to participate in a national network to share PMP data with similar programs in other states; and (5) permission for prescribers to make inquiries not only for their patients but also to verify their own prescribing records. The Board published its Notice of Intent on July 20, 2012, and held a public hearing to receive comments on August 27, 2012. The Board considered those comments during its December 12, 2012 meeting and has decided to move forward with the remainder of the rulemaking process.

Minnesota Pharmacy Technician Training Requirement

Effective January 1, 2014, the Minnesota Board of Pharmacy will not renew the registration of a pharmacy technician who was initially registered after January 1, 2013, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual has completed a pharmacy technician training program. The Board detailed the types of training that will be acceptable in its January 2013 *Newsletter*, available at *www.nabp.net/system/redactor_assets/documents/111/MN012013.pdf*. The Board also described how its annual audit of technicians will be conducted. Additional information about these and other requirements related to pharmacy technicians can be found on the Board's Web site at *www.pharmacy.state.mn.us/pharmtec.htm*.

Washington State Certified Pharmacy Tech CE Requirement

Beginning with 2014 renewals, all active certified pharmacy technicians in Washington must attest to completing 10 hours of continuing education (CE) every year.

The Washington State Board of Pharmacy notes that the requirement to complete 10 hours every year was equivalent to the national certification requirement. The national requirement changed and the Washington State standard is currently not equivalent. Washington State certification and national certification are not the same certification. National certification requires 10 hours of CE every two years. Washington State requires 10 hours of CE every year. Pharmacy technicians must complete their 10 hours during the year between their 2013 and 2014 renewal. The Board also provides information about the types of CE required in its January *Newsletter*, available at *www.nabp.net/system/redactor_assets/documents/118/WA012013.pdf*.

Newly Approved e-Advertiser

The following entity was accredited through the NABP e-Advertiser Approval℠ Program:

Quidsi, Inc
www.wag.com

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

Around the Association

(continued from page 89)

- **Howard Simon, RPh,** has been reappointed a member of the Delaware State Board of Pharmacy. Simon's appointment will expire November 1, 2013.

Board Officer Changes

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

- **Charles "Kenny" Sanders, Jr, RPh,** President
- **Mark T. Conradi, JD, RPh,** Vice President
- **Dan McConaghy, RPh,** Treasurer

The Massachusetts Board of Registration in Pharmacy has elected the following officer to the Board:

- **James T. DeVita, RPh,** President

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

- **Laura Schwartzwald, RPh,** President
- **Stuart "Stu" Williams, JD,** Vice President

The West Virginia Board of Pharmacy has elected the following officers to the Board:

- **Lydia Main, RPh,** President
- **Carl Hedrick, Jr, RPh,** Vice President

FDA Issues New Guidelines for Sleep Aids With Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

ISMP Launches Program to Track Vaccine Errors

The Institute for Safe Medication Practices (ISMP) has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org.*

Study Examines EHR-Related Errors

In a new study analyzing electronic health record (EHR)-related patient safety events, the majority of events involved medication errors. Medication errors accounted for 81% of the events analyzed for the report and included wrong -dose, -drug, -time, -patient, and -route errors, or omitted dose errors. Complications of procedures, treatments, or tests accounted for 13% of the errors. The study examined various causes such as human error, system capabilities, configuration of systems, and use of dual workflow (paper and EHR). The study "The Role of the Electronic Health Record in Patient Safety Events," is available on the Pennsylvania Patient Safety Advisory Web site, *www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2012/Dec;9(4)/Pages/113.aspx.*

FDA Warns About Drug Products from Foreign Suppliers

In December 2012, FDA alerted more than 350 medical practices across the country that they may have received unapproved medications, including unapproved versions of Botox®, from a foreign supplier. FDA sent a letter warning the practices that these medications may be counterfeit, contaminated, ineffective, and/or unsafe because they may have been improperly stored and transported. FDA requested that medical practices stop administering the unapproved versions of Botox and any other products they have received from foreign suppliers owned and operated by Canada Drugs and known under the following names: Quality Specialty Products, A+ Health Supplies, QP Medical, Bridgewater Medical, or Clinical Care. FDA stressed that many, if not all, of the products sold and distributed by these suppliers have not been approved by FDA, and that the safety and efficacy of the products cannot be confirmed. Further, in a statement about the warning letters, FDA urges the health care community to examine its purchasing practices to make sure that products are purchased directly from the manufacturer or from state-licensed wholesale drug distributors in the United States. The text of the letter and a list of the medical practices that received it are provided in an FDA statement available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm.*

nabp newsletter

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

First Class
U.S. POSTAGE
PAID
Permit #583
Schaumburg, IL 60173

Pharmacists and Technicians Encouraged to Register for CPE Monitor

As a reminder, all pharmacists and pharmacy technicians who have not already registered for CPE Monitor® are encouraged to do so. In January, all Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) providers were required to integrate CPE Monitor into their systems. Pharmacists and pharmacy technicians will now need to provide an NABP e-Profile ID number and date of birth (MMDD) in order for their ACPE-accredited CPE credit to be accurately processed.

To avoid missing out on valuable CPE credit, individuals can obtain their e-Profile ID by visiting *www.MyCPEmonitor.net,* creating an e-Profile, and registering for CPE Monitor. To ensure that the CPE Monitor portion of the e-Profile is fully activated and ready to process CPE credit, an individual must record at least one license, registration, or certification number into his or her e-Profile.

As of press time, more than:

- 2,524,852 CPE activity records were stored in the CPE Monitor system
- 235,708 pharmacists have created e-Profiles
- 144,383 pharmacy technicians have created e-Profiles

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers. Through CPE Monitor, individuals are able to electronically view and track their CPE credits from ACPE-accredited providers. In addition, it is anticipated that by mid-2013, the boards of pharmacy will have the ability to monitor their licensees' compliance directly through the service.