



newsletter

National Association of Boards of Pharmacy®



October 2013 / Volume 42 Number 9

aid to government
the profession
the public
1904 to 2013

Task Force to Examine Regulation of Pharmacy Benefit Managers

Upcoming Events

October 14-15, 2013
Task Force on Pharmacy Licensure Standards
NABP Headquarters

October 17-19, 2013
NABP/AACP Districts 1 & 2 Meeting
Bar Harbor, ME

October 22-23, 2013
Task Force on the Regulation of Pharmacy Benefit Managers
NABP Headquarters

October 26, 2013
DEA National Prescription Drug Take-Back Day

November 6-8, 2013
NABP/AACP District 4 Meeting
Alsip, IL

December 3-4, 2013
Interactive Compliance Officer and Legal Counsel Forum
Northbrook, IL

Pharmacy benefit managers, or PBMs, have become very influential in the delivery of prescription drugs. Patients who receive drug benefits as a part of their health care coverage likely have those benefits administered through a PBM, and the activities of these companies have expanded. PBM clients include health plans, self-insured employers, union-sponsored plans, and state and federal governments (for programs such as Medicare Part D, Medicaid, and the Federal Employees Health Benefits Program). All told, according to the national association that represents PBMs, the Pharmaceutical Care Management Association, PBMs administer prescription drug plans for more than 210 million patients in the United States. In 2011, an estimated 3.8 billion

retail prescriptions were filled in the US – about 12 per person. With Americans estimated to spend more than \$271 billion annually on their prescription medications, and with analysts predicting that this number will rise as the 2010 Patient Protection and Affordable Care Act allows millions of currently uninsured individuals to enroll in private health care coverage or qualify for expanded state Medicaid programs, the regulation of PBMs has become an area of concern for state boards of pharmacy and consumer protection groups.

Recognizing these concerns, and noting that PBM regulation extends beyond individual jurisdictions and therefore requires communication and cooperation among the states, NABP member boards at the Association's



©iStockphoto.com/DNY59

109th Annual Meeting in May 2013 approved a resolution charging the Association with convening a task force to assess the current state of PBM-oriented regulations and related collaboration among states. The task force will also review the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*, with an eye toward ensuring that it contains language that can act as a comprehensive and cur-

(continued on page 182)

In This Issue. . . .

Interactive Forum:
Upcoming NABP Interactive Forum Presents Opportunity for Dialogue and Networking Among Compliance Officers, Legal Counsel

183

Legal Briefs:
132,265 Bye Byes

184

Association News:
President Ryle Appoints Members to Serve on 2013-2014 Standing Committees and Two Single-Issue Task Forces

187

Association News:
Four States Pilot New Generation of PMP Software Developed by NABP to Meet Administrator and User Needs

191

Association News:
Nominees Sought for Association's 2014 Awards to Be Presented at the 110th Annual Meeting in Phoenix, AZ

195

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.

PBM Task Force

(continued from page 181)

rent guideline for states to use in developing appropriate PBM regulations.

PBMs see their mission as increasing patients' access to safe, effective, and affordable prescription drugs, and are often credited with having helped to mitigate climbing prescription drug costs. Since their beginnings in the 1970s and 1980s, PBMs have developed an increasingly large list of strategies designed to reduce medication costs for their clients. Depending on the company, these strategies include:

- negotiating discounts and rebates from manufacturers,
- negotiating discounts with pharmacies,
- creating formularies,
- encouraging substitution of generics for brand-name drugs,
- utilizing mail-service pharmacies,
- promoting electronic prescribing,
- creating/managing pharmacy networks,
- requiring clinical prior authorization and step therapy,
- performing drug utilization review,
- promoting consumer and physician education,
- offering medication therapy management and disease state management programs, and
- administering patient medication adherence programs.

As PBMs have expanded in scope, pharmacy regulators have noted that the companies increasingly engage in acts that may fall under the “practice of pharmacy” and that directly affect patient health and safety. Yet most states’ pharmacy regulations do not address PBMs. Because of PBMs’ health insurance role, states have thus far generally regulated them through state insurance commissions.

A Complex Field

The PBM field is a complicated one: While some PBMs are privately owned and operated, others are subsidiaries of managed care plans, major chain drug stores, and other retail outlets. They engage in complex and varied negotiations with manufacturers as well as pharmacies, using complex and changing pricing calculations. As noted above, they are involved in many activities beyond claim processing, including becoming increasingly involved in areas such as disease state management and specialty pharmacies.

Regulation involving PBMs is likewise complex. Inconsistent and varying regulations – many states do not even specifically address PBMs – can lead to uncertainty. “Many aspects of our businesses are regulated by federal and state laws and regulations,” Express Scripts Holding Company noted in its 2012 Form 10-K filing with the US Securities and Exchange Commission. Express Scripts also notes, “We

believe we are operating our business in substantial compliance with all existing legal requirements material to the operation of our businesses. There are, however, significant uncertainties involving the application of many of these legal requirements to our business.”

Controversies and Legislation

As of mid-2013, about 29 states were regulating PBMs, 19 state legislatures were considering PBM-related legislation, and three PBM-related bills were pending in the US Congress.

As lobbyists in the health care and pharmaceutical industries, PBMs have become a source of controversy, and much of the introduced and enacted legislation addressing the companies reflects that fact. Critics charge PBMs with, among other actions, engaging in abusive and inconsistent audit practices that punish pharmacies for minor technical errors and operating in a non-transparent manner, such that plan managers may not know if negotiated discounts and rebates are reaching their plan members. Some critics claim that PBMs force patients to obtain their medications through mail-order pharmacies, even without additional savings to the consumer, and potentially generating large amounts of unused, wasted medications. For example, when a patient receives a 90-day

(continued on page 186)

Upcoming NABP Interactive Forum Presents Opportunity for Dialogue and Networking Among Compliance Officers, Legal Counsel

As part of the 2013 NABP Interactive Forum series themed “Creating New Tools to Maintain and Enhance Board Authority,” NABP will be hosting a forum December 3-4, 2013, tailored specifically to board of pharmacy compliance officers and legal counsel. As with the September 2013 forum held for board of pharmacy executive officers, the NABP Interactive Compliance Officer and Legal Counsel Forum will offer opportunities for dialogue, presentations, and networking. A forum for board members is scheduled to be held in fall 2014.

The forums were first announced in 2010 at the NABP 106th Annual Meeting, as part of an initiative to provide additional support and resources to the member boards of pharmacy. With the success of the first five forums and the eagerness of the board staff to reconvene with their peers, the series returns this year to continue a partnership to protect public health through collaboration.

The Interactive Compliance Officer and Legal Counsel Forum invites each executive officer to select one compliance officer from his or her board to attend the forum at no charge. New this year, each executive officer may also invite one attorney who serves as the board’s legal counsel to par-

ticipate in the forum. Travel, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting.

The Interactive Compliance Officer and Legal Counsel Forum will take place over two, half-day sessions. During the forum, attendees will have the chance to meet with their peers to discuss regulatory trends and challenges faced by their boards. In addition, the meeting will include presentations on timely and

relevant topics developed directly from suggestions submitted by attendees in advance of the meeting. The forum will include breakout sessions for compliance officers and legal counsel so that they may discuss timely issues specific to challenges they encounter as they perform their respective duties.

Formal invitations as well as meeting details will be forthcoming. The meeting will be held at the Hilton Northbrook in Northbrook, IL. ☎



Upcoming PARE Testing Window: December 2-13, 2013

Member boards of pharmacy are encouraged to take advantage of the next available Pharmacist Assessment for Remediation EvaluationSM (PARESM) testing window set for **December 2-13, 2013**.

To pre-register an individual for PARE, boards of pharmacy may use the NABP Clearinghouse or they may contact the NABP Competency Assessment Department at NABP_comp_assess@nabp.net.

PARE was created to assist the boards as part of their decision-making process in cases of remediation or brief departures from practice. Future PARE testing windows for 2014 will be available the following dates:

- January 20-31, 2014
- April 1-12, 2014
- July 15-26, 2014
- October 7-18, 2014

More information about PARE may be found on the NABP Web site at www.nabp.net/programs/assessment/pare. ☎

Executive Committee

Michael A. Burleson
Chairperson
One-year term

Karen M. Ryle
President
One-year term

Joseph L. Adams
President-elect
One-year term

Edward G. McGinley
Treasurer
One-year term

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

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

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

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

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

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

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

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

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

132,265 Bye Byes

By Dale J. Atkinson, JD

On occasion, civil and criminal judicial decisions maintain relevance to the regulatory community and are of interest to boards of pharmacy. Prescribers and pharmacists are empowered to exercise professional judgment and must be held accountable to an applicable standard under the circumstances. Boards of pharmacy and boards of medicine must not only be empowered to administratively address persons abusing the prescribing and dispensing of drugs, but must also dedicate the resources for enforcing such authority. The sanctions and penalties imposed by boards may provide a basis for deterring future activity. In addition, law enforcement authorities have significant powers to investigate, prosecute, and punish wrongdoers through criminal proceedings, as well as civil forfeiture actions. Consider the following.

In 2008, a pharmacist was arrested after filling written prescriptions presented by an undercover law enforcement authority. Based upon the prescriptions, the pharmacist dispensed 5,310 tablets of hydrocodone and 3,600 tablets of Xanax® from his pharmacy and charged \$3,920. The pharmacist also requested an \$80 tip from the officer. Later estimates identified the street value of the hydrocodone and Xanax at more than \$45,000.

The police had set up a surveillance operation of

the pharmacy and arrested a man and a woman driving a vehicle with Louisiana license plates. They had entered the pharmacy with two empty duffel bags and exited 15 minutes later with the duffel bags full. The police conducted a traffic stop and searched the vehicle finding thousands of tablets of hydrocodone and Xanax along with approximately \$4,000 in cash. The suspects were arrested.

The surveillance results prompted law enforcement authorities to set up a sting operation. Police obtained

from a licensed physician 25 prescriptions for 25 different people. The prescriptions were for hydrocodone, Xanax (or both), along with medications that were not controlled substances. According to authorities, abusers of the prescription process often include non-controlled substances to avoid detection by Drug Enforcement Administration.

On the day of the sting, a confidential informant accompanied an officer into the pharmacy and introduced the officer as a friend. The officer presented the 25 prescriptions and a photocopy of an identification card for each of the 25 patients. The pharmacist refused to fill the prescriptions that did not list a medication besides hydrocodone and Xanax. The pharmacist provided the officer with a list of “other” medications “he typically used when filling prescriptions for controlled substances.” The officer left the pharmacy while the other prescriptions were being filled and returned stuffing the prescriptions into a duffel bag. The officer paid the pharmacist \$3,920 and an \$80 tip. Further, and when asked about future transactions, the pharmacist told the officer to come twice per week and to make sure to have the “prescriptions in order.”

The pharmacist was arrested immediately after the transaction. Officers testi-

fied that the pharmacist did not record the transaction, did not have a cash register, did not have any billing records, was disorganized, and had little medicine on the shelves. Further, the pharmacist consented to allow his home to be searched where officers found \$39,710 in envelopes, 2,700 tablets of hydrocodone, and 720 tablets of Xanax in unmarked vials. The pharmacist admitted that the money was from the pharmacy but stated he was going through a divorce and did not want his spouse to have access to the money.

Police also found a suitcase with the pharmacist's name on it containing \$92,555. Although the suitcase contained the pharmacist's medical identification card, the pharmacist told officers that it belonged to a Nigerian businessman who was out of town. However, in the three years following the pharmacist's arrest and seizure, no claim was made for the monies.

The state filed a civil forfeiture proceeding against the \$132,265 in cash found in the pharmacist's home. At the time of the civil proceedings, the criminal charges were still pending. After the hearing, the trial court entered 28 findings of fact, including, among many others, the results from the surveillance and sting operations and the reference to future transactions. The court also entered 11

conclusions of law, notably that the pharmacist has an affirmative duty to only fill prescriptions issued for a legitimate medical purpose and in the course of professional practice and that the state proved that it was more probable than not that the seized property "was intended for use in, or derived from, a violation of the offenses enumerated in the foreclosure statute."

Based upon a finding that the monies seized were gained from the commission of a felony under state law, the court found such funds were to be forfeited to the state of Texas (State). The pharmacist appealed the matter to the Court of Appeals.

The Court of Appeals first reviewed the criminal code section that authorizes the forfeiture of contraband gained from the commission of any felony under the Controlled Substances Act. It also noted that forfeiture proceedings are civil in nature. To prevail in a forfeiture proceeding, the State must satisfy a two-part test. First, the State must show probable cause or "a reasonable belief that 'a substantial connection exists between the property to be forfeited and the criminal activity.'" The link or nexus establishes the probable cause that provides seizure and forfeiture authority.

Second, the State must prove by a preponderance of the evidence that the

seized property is contraband and, thus, subject to forfeiture. As in this current case, where there is no direct evidence showing the seized property is the "fruit of the commission of the statutorily enumerated felonies," the State must present sufficient circumstantial evidence that "does more than raise a mere surmise or suspicion regarding the source of the currency." Notably, the State is not required to exclude every other possibility by which the currency might have been acquired.

On appeal, the pharmacist argued that the State failed to prove that he committed a felony by dispensing a controlled substance without a valid medical purpose. The court noted that the record showed that the pharmacist dispensed large amounts of controlled substances under suspicious circumstances allowing an inference of a lack of a valid medical purpose. Viewing the evidence in a light most favorable to the lower court verdict, the Court of Appeals found that reasonable and fair-minded people could conclude that the pharmacist violated the applicable law prohibiting the dispensing of controlled substances without a valid medical purpose.

Next, the pharmacist argued that evidence did not support that the \$39,710 found in envelopes and the \$92,555 found in

(continued on page 192)



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

PBM Task Force

(continued from page 182)

supply of a medication before being stabilized on that drug, unused medication may result.

Earlier this year, Oregon’s governor signed into law legislation addressing several of these complaints. The new law establishes audit standards, provides increased transparency into generic drug reimbursement, and requires PBMs to register with the state insurance division. Kentucky’s Legislature also passed a bill requiring greater transparency. Those board of pharmacy-monitored laws and regulations already on the books that address PBMs often seek to promote fair audit practices, including those in Alabama, Florida (as related to Medicaid), Minnesota, North Dakota, Oklahoma, Vermont, and Mississippi. Although NABP’s *Model Act* lists PBMs among those entities that should be licensed by the state board of pharmacy (along with pharmacists, pharmacies, wholesalers, manufacturers, and distributors), most state boards of pharmacy do not have extensive oversight over PBMs. Georgia stands out in that it requires “every pharmacy benefit manager providing services or benefits in this state which constitutes the practice of pharmacy” to “be licensed to practice as a pharmacy in this state . . .” Mississippi, too, is unusual in that its legislature

transferred significant PBM regulation to the state board of pharmacy.

Pharmacy regulators, as reflected in the resolution passed at NABP’s 109th Annual Meeting, view the situation objectively, and are seeking to regulate PBMs in the interest of protecting the public health.

On the other side of the debate, critics of many proposed (and enacted) regulations argue that, while much of the legislation may be well-intentioned, unintended side effects of restricting PBM activities such as forming limited pharmacy networks, pushing the use of mail-order pharmacies, establishing restrictive drug formularies, negotiating lower dispensing fees, and rigorously combatting fraud (in part through audits and delayed payments) only increase overall health care costs while not improving patient outcomes. Moreover, they claim that some of the legislation is intended primarily to protect entities that might be in contention with PBMs, such as community pharmacists, and give them a competitive advantage. They criticize a few states’ move to place PBM regulatory authority with the state board of pharmacy, arguing that, because pharmacy boards are largely made up

of pharmacists – who may have a contentious relationship with PBMs – conflicts of interest may occur.

Pharmacy regulators, as reflected in the resolution passed at NABP’s 109th Annual Meeting, view the situation objectively, and are seeking to regulate PBMs in the interest of protecting the public health. NABP’s *Model Act* includes in its definition of the “Practice of Pharmacy”:

the interpretation, evaluation, and implementation of Medical Orders; the Dispensing of Prescription Drug Orders; participation in Drug and Device selection; Drug Administration; Drug Utilization Review (DUR); the Practice of Telepharmacy within and across state lines; Drug or Drug-related research; the provision of Patient Counseling; the provision of those acts or services necessary to

provide Pharmacist Care in all areas of patient care, including Primary Care, Medication Therapy Management, Collaborative Pharmacy Practice . . .

Generally, entities that engage in these activities would need to be licensed by the relevant state board of pharmacy.

The Task Force on the Regulation of Pharmacy Benefit Managers is scheduled to meet October 22-23, 2013, to review the existing state laws and regulations dealing with PBMs, identify PBM activities that might fall under the definition of the practice of pharmacy, and, if necessary, recommend relevant changes to the language of the *Model Act*. After it has been approved by the NABP Executive Committee, the task force’s report will be available in the Members section of the NABP Web site. ☺

Receive Free, Weekly Pharmacy News: Sign-Up for NABP e-News Today!

Looking for breaking news and time-sensitive information relating to pharmacy legislation, regulations, and competency? Sign-up to receive *NABP e-News!*



NABP e-News is a free, weekly electronic newsletter that delivers timely information on policy issues and pharmacy practice standards directly to your e-mail.

To subscribe, visit the News section on the NABP Web site at www.nabp.net/news and click the subscribe button located along the top right of the page titled “Sign Up to Receive NABP E-News.”

Questions? Contact custserv@nabp.net. ☺

President Ryle Appoints Members to Serve on 2013-2014 Standing Committees and Two Single-Issue Task Forces

NABP provides guidance on current topics of interest to the state boards of pharmacy through the commissioning of single-issue task forces. When an issue arises that requires special expertise or a commitment of time and funds, a task force is appointed to address an explicit charge and to report its findings to the Executive Committee. When final, the task force reports are posted on the NABP Web site. This year, NABP has commissioned two single-issue task forces pertaining to the following topics:

1. Pharmacy licensure standards
2. Regulation of pharmacy benefit managers (PBMs)

NABP President Karen M. Ryle, MS, RPh, has finalized her appointments for the following task forces and standing committees for the 2013-2014 year.

2013-2014 Task Forces

The **Task Force on Pharmacy Licensure Standards** is scheduled to meet October 14-15, 2013, at NABP Headquarters. The development of this task force stems in part from the request made by NABP member boards for the Association to create a means of providing a uniform licensing process

to assist the boards as they inspect resident and nonresident pharmacies, as well as ensure the safety of compounded drug products. To assist in this effort, NABP has begun to develop the Verified Pharmacy Program™ (VPP™), an electronic resource to facilitate the sharing of pharmacy licensure and related information among the states. VPP will store licensee data and inspection report components in a uniform format. The system will be particularly beneficial when considering applications for licensure from nonresident pharmacies. Currently, boards must make licensing decisions about nonresident pharmacies with incomplete or outdated information. Challenges contributing to this situation include differing laws and regulations as well as differing levels of resources from board to board.

Along with the development of VPP, the Association established the Task Force on Pharmacy Licensure Standards to work toward a uniform inspection form that would assist states with the inspection of resident and nonresident pharmacies.

The task force is charged with the following objectives:

1. Review existing state pharmacy inspection forms;

2. Review relevant language from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*;
3. Compile requirements that are consistent across the states with the possible purpose of structuring a uniform inspection form that may assist states with the inspection of resident and nonresident pharmacies; and
4. Recommend amendments, if necessary, to the *Model Act*, to address pharmacy licensure standards.

Chairperson of this task force is Joanne Trifone, RPh, member, Massachusetts Board of Registration in Pharmacy.

Individuals appointed to serve as members include:

- Gayle Cotchen, MBA, PharmD, RPh, Pennsylvania
- Mark Hardy, PharmD, RPh, North Dakota
- Virginia “Giny” Herold, MS, California
- Donna Horn, DPh, RPh, Massachusetts
- Doug Lang, RPh, Missouri
- Stephanie McAntee, CPhT, Wyoming
- Michael Podgurski, RPh, Pennsylvania
- Ken Saunders, PharmD, RP, TTS, Nebraska
- Cody Wiberg, PharmD, MS, RPh, Minnesota

- Charles Young, RPh, CFE, Massachusetts
The Executive Committee liaison is William John Cover, RPh.

The **Task Force on the Regulation of Pharmacy Benefit Managers** is scheduled to meet October 22-23, 2013, at NABP Headquarters. The task force came about in response to Resolution 109-3-13, passed at the NABP 109th Annual Meeting. The resolution acknowledges that the regulation of PBMs extends beyond individual state jurisdictions and requires communication and cooperation among the state boards of pharmacy. In addition, the resolution indicates the need to determine the status of PBM regulations in the states to provide a cohesive strategy for revising and reviewing the *Model Act*. Thus, NABP member boards agreed that the Association should assess the current state of PBM-related regulations and related collaborative efforts among the states – and President Ryle has established the task force to undertake this effort.

The task force is charged with the following objectives:

1. Review existing current state laws and regulations addressing the regulation of PBMs;
2. Identify activities in which PBMs engage that may be construed to fall under the defini-

(continued on page 188)

Committees, Task Forces

(continued from page 187)

tion of the practice of pharmacy; and

3. Review and, if necessary, recommend amending the *Model Act* to address appropriate regulation of PBMs.

Chairperson of this task force is Patricia Donato, RPh, member, New York State Board of Pharmacy.

Individuals appointed to serve as members include:

- Buford Abeldt, Sr, RPh, Texas
- Julia Eaton, RPh, Vermont
- Susan Kedron, JD, Texas
- Cathy Lew, RPh, Oregon
- LuGina Mendez-Harper, PharmD, RPh, New Mexico
- Jeffrey Mesaros, PharmD, JD, RPh, Florida
- Steve Parker, Mississippi
- Richard Palombo, DPh, RPh, New Jersey
- Laura Schwartzwald, RPh, Minnesota
- Brenda Warren, DPh, CHC, Tennessee
- Cindy Warriner, RPh, Virginia
- Stuart Williams, JD, Minnesota

Don Johnson, RPh, of Colorado, will serve as an alternate. The Executive Committee liaison is Hal Wand, MBA, RPh.

2013-2014 Standing Committees

As authorized by the NABP Constitution and

Bylaws, the Association's standing committees annually perform specific responsibilities that are essential to the success of NABP's programs. Once a committee has explored its assigned issues, the members submit recommendations or resolutions to the NABP Executive Committee for consideration.

The **Committee on Law Enforcement/Legislation** will meet on January 21-22, 2014, at NABP Headquarters. The committee is charged with the following tasks:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists.
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association.
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Michael Moné, JD, RPh, member, Ohio State Board of Pharmacy, is the committee chairperson. Committee members include:

- Jody Allen, PharmD, RPh, FASHP, Virginia

- Patricia D'Antonio, MS, MBA, RPh, CGP, District of Columbia
- Susan DelMonico, JD, RPh, Rhode Island
- Catherine Hanna, PharmD, RPh, Kentucky
- Caroline Juran, RPh, Virginia
- Chris Humberson, RPh, Washington
- Dennis McAllister, RPh, FASHP, Arizona
- Alice Mendoza, RPh, Texas
- Penny Reher, RPh, Oregon
- Charles Wetherbee, JD, Texas
- Phyllis Stine, BS, Texas, will serve as an alternate. The Executive Committee liaison is Susan Ksiazek, RPh.

The **Committee on Constitution and Bylaws** will meet in April 2014. The charge of this com-

mittee, as defined by the NABP Constitution and Bylaws, is to review proposed amendments to the Constitution and Bylaws, suggest changes where appropriate, and issue a recommendation for each proposed amendment.

Gay Dodson, RPh, executive director, Texas State Board of Pharmacy, is the committee chairperson. Committee members include:

- Lenna Israbian-Jamgochian, PharmD, RPh, Maryland
- Kevin Mitchell, RPh, Ohio
- Patricia Smeelink, RPh, Michigan
- Joyce Tipton, MBA, RPh, FASHP, Texas
- Nona Rosas, CPhT, of Arizona will serve as an alternate. The Executive Committee liaison is Gary Dewhirst, RPh. ☺

Errata

The article "NABP *Model Act* Amended to Address Shared Service Concept, Medication Reuse Programs, and Internet Pharmacy Safety," published in the September 2013 *NABP Newsletter*, erroneously attributed to the Task Force on Pharmacy Practice Technology Systems recommended revisions to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* regarding language noting that – as relates to multi-jurisdictional shared services – the responsibility shall be placed on the pharmacist-in-charge to possess licenses in those states in which shared services are being performed. To clarify, this revision to the *Model Act* was included by the Committee on Law Enforcement/Legislation. NABP regrets any confusion this error may have caused. ☹

Task Force Convenes to Update TOEFL iBT Passing Standards

The TOEFL iBT Standard Setting Task Force convened at NABP Headquarters on July 9-10, 2013, to discuss and review the passing standards for the Test of English as a Foreign Language (TOEFL) Internet-based Test (iBT) to update the requirement for English language proficiency necessary for foreign pharmacy graduates to safely practice in the United States. The TOEFL iBT, provided by the Educational Testing Service, is the sole English language proficiency examination accepted for new candidates seeking Foreign Pharmacy Graduate Examination Committee™ Certification based on four components: reading, listening, speaking, and writing. ③



Pictured from left to right: Edith G. Goodmaster, Connecticut Commission of Pharmacy; Marian Crandall, Educational Testing Service (ETS); Catherine Moore, ETS; Kenneth R. Wells, RPh, Oregon State Board of Pharmacy; Susan Nissan, ETS; Linda Kott, PharmD, RPh, Osco Drug; Anne Policastri, PharmD, MBA, FKSH, University of Kentucky College of Pharmacy; Thomas F.X. Bender, Jr, RPh, New Jersey State Board of Pharmacy; Jeanne Malloy, ETS; and Eileen Tyson, ETS. Not pictured: Lawrence H. "Larry" Mokhiber, MS, RPh, New York State Board of Pharmacy served as chair.

Review Committee Members Discuss Items on the FPGEE



Members of the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) Review Committee gathered at NABP Headquarters in August 2013. This group of dedicated volunteers contributes their time and expertise to review and verify the examination questions and assist with the development of new questions. Pictured left to right: Philip Proteau, PhD, Oregon State University College of Pharmacy, and Carolyn Friel, PhD, RPh, Massachusetts College of Pharmacy and Health Sciences, discuss the FPGEE's item pool.

nabp newsletter

NABP Seeks Individuals to Serve on ACE to Help Safeguard the Integrity and Validity of Examinations

NABP is currently accepting letters of interest from individuals wishing to serve on the NABP Advisory Committee on Examinations (ACE). Established by NABP in 1912, this standing committee was created to safeguard the integrity and validity of NABP examinations.

ACE typically convenes three to four times per year to oversee the development and administration of all NABP examination and certification programs. In ad-

dition, ACE considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

To be considered for ACE, an individual must hold an active, unrestricted pharmacist license in any state or territory of the United States and meet at least one of the following:

- be a member or administrative officer of an active member board of pharmacy;

- have served within the last five years as a member or administrative officer of an active member board of pharmacy;
- be a practicing pharmacist; or
- serve as pharmacy school faculty.

Open positions on ACE are determined by the current composition of the committee and in accordance with NABP policy. Each ACE appointment is for a three-year term beginning June 1, 2014.

Interested individuals are asked to submit a written statement of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Drive, Mount Prospect, IL 60056 or exec-office@nabp.net no later than December 31, 2013.

Please contact the NABP Competency Assessment Department at NABP_comp_assess@nabp.net with any questions regarding ACE. ☎



2013-2014 ACE Members Convene at NABP Headquarters

On August 8, 2013, the Advisory Committee on Examinations (ACE) convened at NABP Headquarters to oversee the development and administration of the Association's examination and certification programs. Pictured above from left to right: Mark D. Johnston, RPh, NABP Executive Committee liaison; Tom Houchens, RPh, FASCP, Laurel Housing, Inc; Carl W. Aron, RPh, member, Louisiana Board of Pharmacy; David C. Young, PharmD, member, Utah Board of Pharmacy; Neal F. Walker, RPh, University Medical Center – Mesabi; Sara St Angelo, PharmD, RPh, member, Indiana Board of Pharmacy; Kay L. Hanson, RPh, Minnesota Board of Pharmacy; John D. Taylor, RPh, Florida Department of Health; and Michael Duteau, RPh, member, New York State Board of Pharmacy. Not pictured: David Todd Bess, PharmD, RPh, BCPS, University of Tennessee Health Science Center College of Pharmacy and Dale Eric Wurster, Jr, PhD, University of Iowa College of Pharmacy.



Newly Approved e-Advertiser

The following entity was accredited through the NABP e-Advertiser Approval^{CM} Program:

King Kullen Grocery Co, Inc
www.kingkullen.com

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

Four States Pilot New Generation of PMP Software Developed by NABP to Meet Administrator and User Needs

Stemming from the success of the NABP PMP InterConnect® program, NABP has begun to develop and test a new, comprehensive prescription monitoring program (PMP) software system, created to meet state needs as expressed by PMP administrators. This new generation of PMP software, called PMP AWAR_XE™, is designed to provide greater flexibility and more services than the PMP software systems currently on the market, and is intended to work seamlessly with NABP InterConnect.

Software Features

PMP AWAR_XE offers many features and functions to assist state PMP administrators and provide a better experience for requestors. Administrators have the benefit of overseeing a streamlined online registration process and assigning role-based permissions to various types of users. To assist PMP staff with this task, one of the many benefits to the new software is that standard software can be configured to meet state-specific needs. For example, the state PMP administrators themselves have the ability to include and revise a form to register users and provide additional information. The users are then able to directly upload the completed form to be sent back to the adminis-

trators to complete their registration. The states can also modify required fields without having to wait for a vendor to do so. As an additional benefit, the software is engineered to connect with NABP InterConnect without the need for additional coding. Administrators will also be able to generate audit, compliance, diversion prevention, and statistical reports when needed. In addition, the new software allows the state PMP administrator to brand the PMP by adjusting the settings for color scheme, contact information, agency address and phone, and upload the state's PMP logo.

Requestors will also benefit from the new software and its security features. In many states, the registration process will be easier and faster. The user will need to provide personal information such as name, date of birth, and employer information, as well as information related to his or her role within the PMP system in order to receive unique login credentials. The system will also provide a venue for messaging among administrators, requestors, and data submitters.

For those submitting PMP data, particularly for chain pharmacies, PMP AWAR_XE makes the process of data submittal easier by receiving multistate data in a single submission.

Finally, as an additional benefit, when enhancements to the software are made, all participating states will receive updated software. All enhancements will be designed based on input from those states using the software.

States Pilot Software

To ensure the software meets the needs of PMPs, four states have agreed to assist NABP with testing the new software – Idaho, Kansas, Mississippi, and

Nevada. Kansas was the first state to test the new software with a pilot launch date of July 2013. The Kansas pilot was a success and yielded several insights that will be applied to the pilot in the next state, Mississippi, which will launch the software in early October 2013. Idaho and Nevada will follow. In addition, NABP plans to identify a fifth state to deploy the software as part of the pilot. With the assistance of Ap-

(continued on page 192)

PMP Interconnect Participation Expands; 16 States Now Sharing Data



NABP PMP InterConnect® participation continues to expand

- with Tennessee's prescription monitoring program (PMP) now live as of August 2013. As of press time,
- Authorized users in 16 states are sharing data through the NABP InterConnect, which enables the secure interstate transfer of PMP data among participating states: Arizona, Colorado, Connecticut, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, New Mexico, North Dakota, Ohio, South Carolina, South Dakota, Tennessee, and Virginia.
 - Nine additional states have signed memorandums of understanding (MOU) to participate in NABP InterConnect.
 - Four states have MOUs under review.
 - It is anticipated that approximately 30 states will either be connected to or working toward a connection to NABP InterConnect in 2013. Since launching, the NABP InterConnect has processed more than 2 million requests, with an average total wait time of 7.8 seconds for a consolidated multistate PMP report.

The most up-to-date information about state PMP participation is available in the NABP PMP InterConnect map, available at www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect. 

nabp newsletter

PMP Software

(continued from page 191)

priss, Inc, NABP’s vendor that developed and hosts NABP InterConnect, NABP is working to apply additional improvements to the

software for the upcoming pilots.

NABP is currently providing the new software free of charge to the aforementioned four participating states; however, it is the ultimate goal to make this soft-

ware available to all states at no cost in the future.

During the PMP Steering Committee’s August 1-2, 2013 meeting at NABP Headquarters, Appriss, Inc, provided the states with a demonstration of the new

software, and Kansas was present to share information on their launch.

More information about the PMP software, including state pilots, will be available in future issues of this *Newsletter*. ⑩

Legal Briefs

(continued from page 185)

the suitcase were contraband. When determining whether currency is contraband, the courts look at multiple factors. They include:

- 1. the proximity of the money to the drugs and evidence of drug trafficking;

- 2. evidence that the money was previously in contact with drugs;
- 3. suspicious activity consistent with drug trafficking;
- 4. the amount of money at issue; and
- 5. the presence of expert testimony indicating that there was probable cause linking the money to the criminal activity.

The court concluded that the uncontradicted evidence of all the circumstances supports the lower court conclusion that the currency was contraband. Thus, the court rejected the arguments of the pharmacist and affirmed the forfeiture ruling.

Pharmacists and prescribers must abide by and be held accountable to professional standards. Such account-

ability can be adjudicated through administrative, civil, and criminal processes. As illustrated, civil forfeiture proceedings can, under certain circumstances, provide a basis for prohibiting wrongdoers from profiting off their illegal activities.

\$132,265.00 in U.S. Currency v. State of Texas, 2013 Tex. App. LEXIS 7121 (Tx. App. Ct. 2013) ⑩



Newly Accredited VAWD Facilities

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

Associated Pharmacies, Inc,
dba API
Memphis, TN

BluPax Pharmaceuticals, LLC,
dba BluPax Pharma
Edison, NJ

Dixon Shane, LLC, dba R & S Northeast, LLC
Fountain Run, KY

Calvin Scott & Company, Inc
Albuquerque, NM

Qualanex, LLC
Gurnee, IL

A full listing of more than 550 accredited VAWD facilities is available on the NABP Web site at www.nabp.net. ⑩



Newly Accredited DMEPOS Facilities

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

Allcare Discount Pharmacy Inc
Chicago, IL

Bliss Drugs, Inc
Sunnyside, NY

A full listing of the nearly 550 accredited DMEPOS companies representing nearly 27,500 facilities is available on the NABP Web site at www.nabp.net. ⑩

NABP Records 1,028 Actions in Clearinghouse During Second Quarter; System Now Tracking Actions Taken on Facilities

As the state boards of pharmacy work diligently to strengthen regulations and inspection protocols for compounding pharmacies, the NABP Clearinghouse reporting capabilities have been expanded to enable tracking of the number of actions taken against facilities. The system continues to track actions against other licensees and is able to provide a broad picture of the scope of actions being reported by the state boards.

During the second quarter of 2013, the state boards of pharmacy reported a total of 1,028 disciplinary actions to the NABP Clearinghouse, including actions taken against

pharmacists, pharmacy technicians, pharmacy interns, pharmacies, wholesalers, manufacturers, and other licensees. Of the 1,028 actions taken in second quarter:

- 478 actions or 46% were taken on pharmacists;
- 290 actions or 28% were taken on pharmacies;
- 216 actions or 21% were taken on pharmacy technicians;
- 19 actions or approximately 2% were taken on pharmacy interns;
- 16 actions or nearly 2% were taken on wholesalers and manufacturers; and
- 9 actions or 1% were taken against other licenses,

including mail-order pharmacies, controlled substance licenses, and durable medical equipment licenses.

Of all the actions reported in the second quarter to the NABP Clearinghouse, publicly available fines/monetary penalties accounted for the most actions reported comprising 257, or 25% of the total 1,028 actions. Following this category, probation of license was the second most reported action with 160, or 15.6%, of the actions reported. The third most common action reported to the Clearinghouse is the miscellaneous category, which includes a number

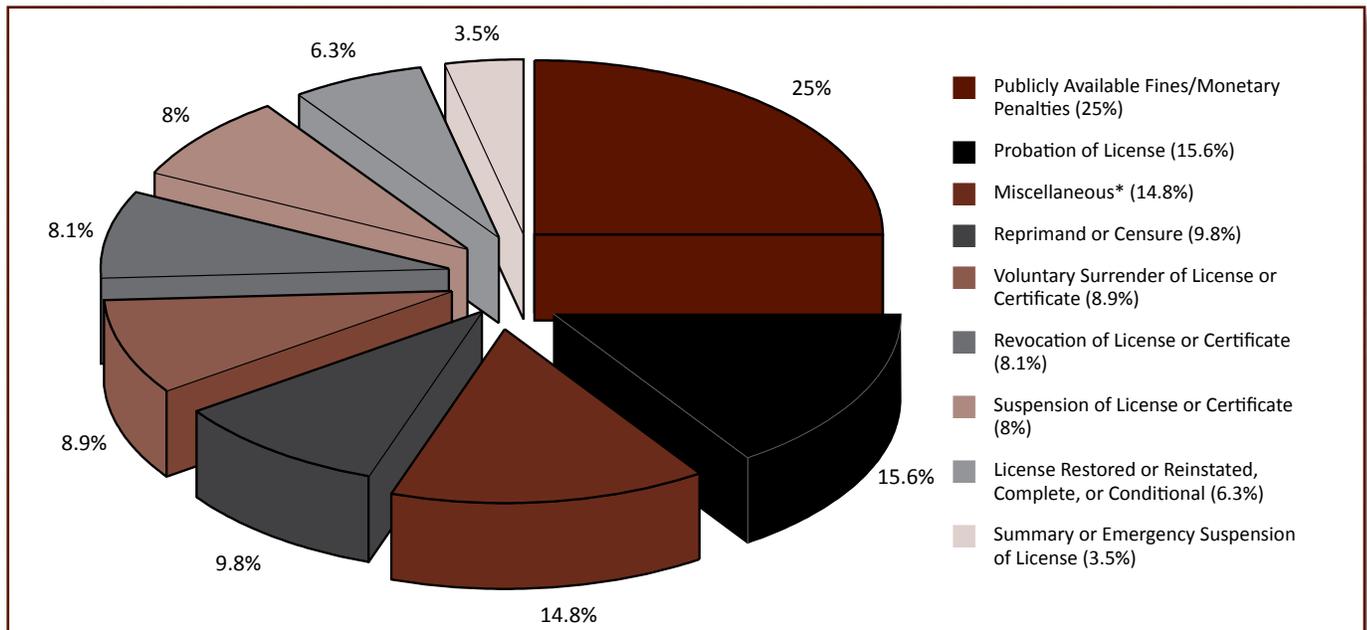
of smaller categories, with 152 or 14.8% of the actions falling in this category.

Finally, the action categories reprimand or censure and voluntary surrender of license or certificate accounted for 9.8% (101) and 8.9% (92) of the total records, respectively. (See Figure A for a full breakdown of the actions taken during second quarter 2013.)

The state boards of pharmacy also report the basis for all actions taken to the Clearinghouse. In second quarter, 264 or 25% of the actions were taken on the basis of issues included in the

(continued on page 194)

Figure A: Disciplinary Actions Reported in Second Quarter 2013



*The miscellaneous category includes civil money penalty; conditional, provisional, or probationary license or certificate; denial of initial license; denial of license renewal; directed in-service training; directed plan of correction; 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; reduction of previous licensure action; summary or emergency action; and summary or emergency limitation or restriction on license.

Clearinghouse

(continued from page 193)

miscellaneous category, such as deferred adjudication, drug screening violations, and failure to comply with patient consultation requirements.

Following this category are actions taken due to violation of federal or state statutes, regulations, or rules, comprising 18.7% (197) of the basis for action. Another 11.5% (121) of the actions reported during the second quarter were taken on the basis of diversion of controlled substances. (See Figure B for a full breakdown of the basis for actions taken during second quarter 2013.)

As an essential component to maintaining the integrity of the licensure transfer program among the states, reporting to the NABP Clearinghouse is required by the NABP Constitution and Bylaws. Currently 32 boards of pharmacy have also designated NABP as their Healthcare Integrity and Protection Data Bank (HIPDB) reporting agent; however, all boards of pharmacy are encouraged to utilize the online tool to report pharmacy disciplinary actions to the NABP Clearinghouse regardless of whether NABP is their reporting agent.

The NABP Clearinghouse, which is accessed through

the Board e-Profile Connect, 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 actions taken against pharmacists and pharmacy technicians, to the basis for these actions.

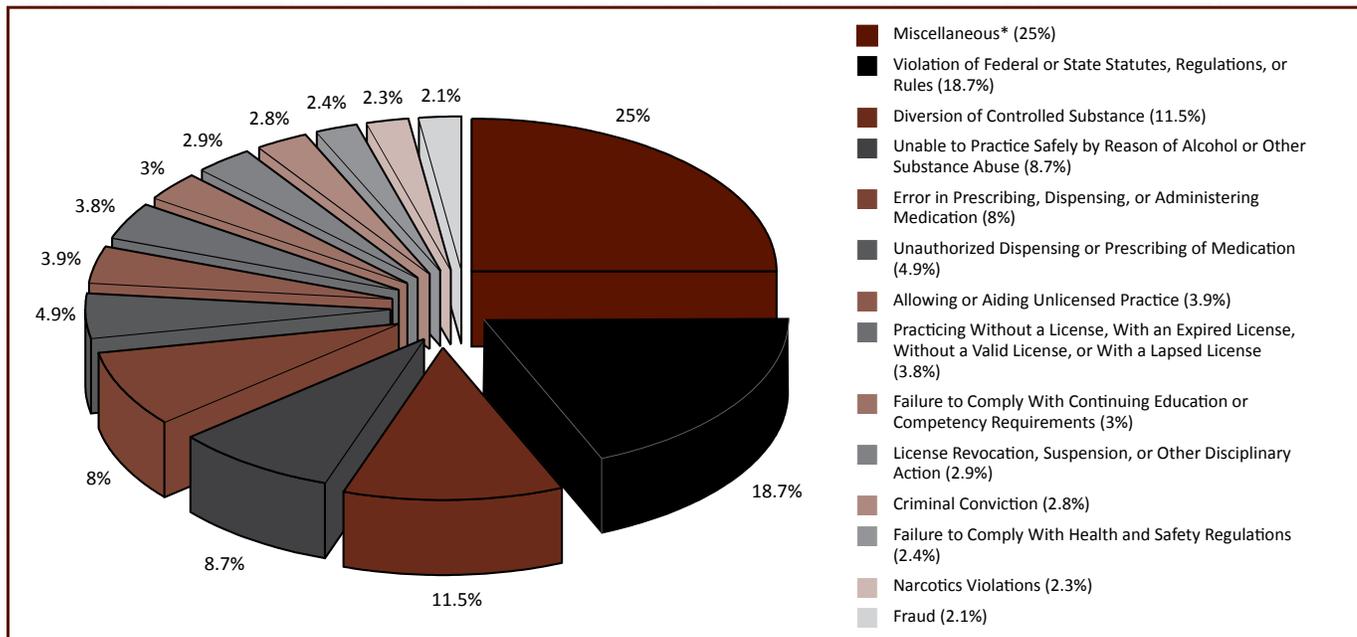
To further assist the state boards of pharmacy with reporting actions taken against licensees and to enhance the system's usability, the NABP Clearinghouse also enables real-time reporting among the state

boards. Utilizing Board e-Profile Connect, boards reporting disciplinary information to the Clearinghouse are able to notify and share in real time with other states when actions have been taken against a licensee.

Boards of pharmacy that wish to request search queries of the NABP Clearinghouse data may do so by contacting the NABP Licensure Programs Department. NABP is able to provide the boards of pharmacy with specified reports whenever needed. For example, if a board would like to review data for a specific reported action, such as diversion

(continued on page 199)

Figure B: Basis for Disciplinary Actions Reported in Second Quarter 2013



*The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; default on health education loan or scholarship obligations; deferred adjudication; drug screening violation; failure to comply with patient consultation requirements; failure to consult or delay in seeking consultation with supervisor/proctor; failure to cooperate with board investigation; failure to disclose; failure to maintain adequate or accurate records; failure to maintain equipment/missing or inadequate equipment; failure to maintain records; failure to meet licensing board reporting requirements; failure to obtain informed consent; immediate threat to health or safety; improper or inadequate supervision or delegation; inadequate or improper infection control practices; inadequate security for controlled substances; incompetence; mental disorder; negligence; nolo contendere plea; operating beyond scope of license; other – not classified; practicing beyond the scope of practice; unable to practice safely; unable to practice safely due to psychological impairment or mental disorder; unprofessional conduct; and violation of or failure to comply with licensing board order.

Nominees Sought for Association's 2014 Awards to Be Presented at the 110th Annual Meeting in Phoenix, AZ

NABP is currently accepting 2014 award nominations for individuals that represent and further the Association's mission of protecting the public health. The 2014 awards will be presented during the 110th Annual Meeting, to be held May 17-20, 2014, at the Sheraton Phoenix Downtown Hotel in Phoenix, AZ.

Nominations are currently being accepted for the following awards: 2014 Lester E. Hosto Distinguished Service Award (DSA), 2014 NABP Honorary President, 2014 Fred T. Mahaffey Award, and 2014 John F. Atkinson Service Award.

Lester E. Hosto DSA

This award is the highest honor bestowed by the Association. Originally known as the Distinguished Service Award, it was renamed by NABP to serve as a memorial to the 1990-1991 NABP President Lester E. Hosto, whose motivating presence in the practice of pharmacy was recognized by practitioners of his state, pharmacy leaders across the nation, and former United States President Bill Clinton.

The Lester E. Hosto DSA recognizes those individuals whose efforts to protect the public health greatly furthered the goals and objectives of NABP. Any individual who meets these criteria may be nominated for the DSA, regardless of his or her member affiliation with NABP.

Honorary President

Nominees who will be considered for the position of honorary president must meet the following criteria:

- service on one or more NABP committee or task force;
- participation in NABP/American Association of Colleges of Pharmacy District Meetings and NABP Annual Meetings;
- exemplary services for, or on behalf of, NABP;
- strong commitment to NABP, the mission of the Association to protect the public health, and the practice of pharmacy; and
- affiliation (either current or past) as a board member or as an administrative officer of an active or associate member board.

Individuals submitting nominations for the Honorary President must be an active or associate member board.

Fred T. Mahaffey Award

This award was named after the late NABP Executive Director Emeritus Fred T. Mahaffey, who held the executive director position from 1962 to 1987. His leadership and contributions to NABP, state boards of pharmacy, and the protection of the public health were significant and established NABP as one of the leading pharmacy organizations. The award recognizes a board(s)

of pharmacy that has made substantial contributions to the regulation of the practice of pharmacy over the past year.

Boards considered for this award must have contributed to protecting the public health and welfare through the enforcement of state and federal laws and regulations, and to the advancement of NABP goals and objectives as specified in the Association's Constitution and Bylaws.

John F. Atkinson Service Award

Recipients of the John F. Atkinson Service Award are individuals who have provided NABP with exemplary service in protecting the public health and have shown significant involvement with the Association related to pharmacy law and compliance. This award was named in honor of former NABP general counsel John F. Atkinson who served the Association for more than 40 years.

How to Submit Nomination

Individuals interested in submitting a nomination are asked to fill out and complete a nomination form, which may be accessed by visiting the Meetings section on the NABP Web site at www.nabp.net/meetings. Directions for electronic submission are provided on the online form or nomination forms may be mailed to the NABP Executive Director/Secretary Car-

men A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056.

Nominations for these awards must be received at NABP Headquarters no later than **December 31, 2013**. The NABP Executive Committee will review the nominations and select the honorary president and award recipients.

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

Henry Cade Memorial Award

In addition to the aforementioned awards, the Henry Cade Memorial Award will also be presented during the Annual Meeting. The NABP Executive Committee selects a recipient(s) for this award who has supported the goals and objectives of the Association and the state boards of pharmacy to protect the public health and advanced the safety and integrity of the distribution and dispensing of medications. *Nominations are not accepted for this award.*

The Henry Cade Memorial Award is named in honor of the late Henry Cade, who served as NABP president from 1987 to 1988. Tireless in his efforts on behalf of NABP and the Illinois Division of Professional Regulation – State Board of Pharmacy, Cade was also a long time pharmacy practitioner. 



AWAR_xE Encourages Consumer Participation in October 2013 DEA Prescription Drug Take-Back Day

The AWAR_xE® Consumer Protection Program continues to encourage consumers to get involved in the fight against prescription drug abuse by disposing of unneeded medications, particularly unused controlled substance prescription drugs, at Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day events. The next DEA Take-Back Day event is Saturday, October 26, 2013, and AWAR_xE has alerted consumers to this unique opportunity for safe, secure drug disposal through its various communication channels.

The bi-weekly *AWAR_xE Prescription Drug Safety News* has included reminders and notified consumers when the DEA Take-Back Day locator became available. The AWAR_xE Web site also reminds visitors to participate in the event and will include a link to the collection site locator.

AWAR_xE Facebook posts continue to include updates on permanent drug drop boxes, as well as information on the DEA Take-Back Day. Facebook posts have featured memes, a combination of a concise message and an eye-catching image, to engage users and prompt them to look for more in-

formation on the AWAR_xE Web site.

Studies continue to show that over 50% of those abusing medications get them from family and friends for free. In some cases individuals may take prescription drugs from the medicine cabinet of a parent or grandparents, or a friend or friend's family. Disposing of unneeded medications helps prevent them from falling into the hands of those who may misuse or abuse them.

AWAR_xE also continues to raise awareness about the importance of securely storing needed medications to prevent abuse, and also to protect children and pets from poisoning due to accidental ingestion.

NABP also continues to share information about the DEA Take-Back Day and other prescription drug safety topics with community groups in Illinois including the following:

- Bloomingdale Neighborhood Watch Meeting
Bloomingdale, IL
September 18, 2013
 - Lions Club of Elk Grove Village
Elk Grove, IL
October 16, 2013
- AWAR_xE also participated in the Stop Overdose

IL – Awareness Day Rally and Vigil at Roosevelt University, Schaumburg, IL, on August 24, 2013. The event was hosted by Roosevelt University's Illinois Consortium on Drug Policy and served as a platform for attendees to learn about drug overdose prevention and to connect with those who lost loved ones to drug overdose.

A recent Substance Abuse and Mental Health Services Administration study indicates that 80% of people who recently began using heroin initiated drug abuse with prescription painkillers. In response to

this trend, AWAR_xE staff participated in the rally to share prescription drug abuse prevention information, and to network with other programs in order to raise awareness about AWAR_xE resources.

If you are interested in delivering an AWAR_xE presentation at a board-related event or community organization event, AWAR_xE flyers, presentations, and giveaways, such as bookmarks, are available for distribution. For more information, please contact AWAR_xE by sending an e-mail to AWARERX@NABP.NET. ☺

Got Drugs?
If unneeded prescriptions are crowding your medicine cabinet, DEA has a solution.
National Prescription Drug Take-Back Day
October 26, 2013

DEA to Hold Its Seventh National Prescription Drug Take-Back Day: October 26, 2013

The next Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day will take place **Saturday, October 26, 2013, from 10 AM to 2 PM**. This will be the seventh annual event coordinated by DEA to help consumers safely dispose of unused, unneeded, and expired prescription medications, including controlled substances. For more information, including where to find a collection site in your area, visit the DEA Web site at www.dea.gov.

FDA Alerts Consumers and Providers of Potential Acetaminophen Risks

Through the use of blog posts, videos, and numerous consumer resources, Food and Drug Administration (FDA) is alerting consumers about the potential risk of rare but serious skin reactions associated with the use of acetaminophen as well as the need to be mindful of the amount of acetaminophen they take to prevent overdose and potential liver damage.

In an effort to prevent overdose and liver damage, FDA reminds consumers to check their medication labels, both on prescription and over-the-counter (OTC) products, to know when they contain acetaminophen and how much medicine they contain. In addition, FDA advises consumers to do the following:

- Avoid taking two medications that contain acetaminophen
- Track how much acetaminophen they take and how long they should wait before taking another dose
- Know when and when not to take acetaminophen
- Read the directions on children’s medications to determine if the medication is appropriate and how much to administer to a child

An additional risk associated with the use of acetaminophen is the potential

for rare but serious skin reactions. Symptoms of the three serious skin reactions include rash, blisters, and widespread damage of the surfaces of the skin. In an August 2013 Consumer Update, FDA announced that it will soon require a warning on medicine labels for all prescription medicines containing acetaminophen, and will work with manufacturers to add warnings to OTC medicines with acetaminophen.

FDA has emphasized that these skin reactions to acetaminophen are extremely rare and that these rare reactions should be viewed within the context of millions who, over generations, have used and benefited from acetaminophen. FDA will continue to monitor the issue and provide consumer updates. More information about these allergic skin reactions may be found at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Additional consumer information on acetaminophen safety may be found in a July 2013 FDA blog post at <http://blogs.fda.gov/fdavoices/index.php/2013/07/fda-reminds-consumers-to-always-use-acetaminophen-safely/>, or in the Drugs section on the FDA Web site at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/SafeUseofOver-the-CounterPainRelieversandFeverReducers/ucm164977.htm.

Two Compounded Sterile Drugs Recalled After FDA Inspection

Park Pharmacy & Compounding Center of Irvine, CA, voluntarily recalled two lots of compounded sterile preparations after an FDA inspection raised concerns about the accuracy and reliability of testing methods used to assess sterility in the laboratory. The recalled products are:

- Methylcobalamin 5 mg/ml 30 ml Amber Vials, Lot #06132013@1, Expiration: 12/10/2013
- Multitrace-5 Concentrate 10 ml Amber Vials, Lot #05212013@20, Expiration: 11/17/2013

The products were dispensed to patients and distributed to physician offices by prescription in June and July 2013 in California, Florida, New Mexico, and Indiana. As of press time, no adverse events associated with the use of these products have been reported, and there has been no confirmation of lack of sterility. Customers who are affected by the recall may contact the company at 949/551-7195 or by e-mail at info@parkrx.com to ask questions, or to arrange for the return of any unused products. Adverse reactions may also be reported to FDA’s MedWatch Adverse Event Reporting Program.

Overdose Deaths Rising Among Women, CDC Warns

The Centers for Disease Control and Prevention (CDC) reported that ap-

proximately 18 women die every day from an overdose of prescription pain medication. CDC also reported that the number of deaths related to prescription painkiller overdose increased more sharply among women than among men from 1999 to 2010. Over this time period, prescription painkiller overdose deaths among women increased more than 400% compared with a 265% increase among men.

CDC also indicates that for “every woman who dies of a prescription painkiller overdose, 30 go to the emergency department for painkiller misuse or abuse.”

CDC suggests that health care providers can help fight this trend by recognizing that women are at risk of prescription painkiller overdose, following guidelines for responsible prescribing, and using prescription monitoring programs to “identify patients who may be improperly obtaining or using prescription painkillers and other drugs.” More information is available in the July 2013 *Vital Signs*, available at www.cdc.gov/vitalsigns/PrescriptionPainkillerOverdoses/index.html and in a CDC July 2013 press release at www.cdc.gov/media/releases/2013/p0702-drug-overdose.html.

NABPLAW Online Now Available Via Mobile Devices

To celebrate the 20th anniversary of NABPLAW® Online, NABP has announced that the

(continued on page 198)

Around the Association

Executive Officer Changes

- **Norene Lind** is now serving as board manager of the Michigan Board of Pharmacy and 23 other health professional boards, replacing Rae Ramsdell. Prior to this position, she served as the administrative rules manager for the State Office of Administrative Hearings and Rules. Lind also serves as the secretariat of the Michigan Driver and Traffic Safety Education Association.
- **Reginald Dilliard, DPh**, is now serving as executive director of the Tennessee Board of Pharmacy replacing Terry Grinder, DPh, who served as interim executive director. Prior to this position, he worked as a pharmacy manager for Walgreens. Dilliard also served as a member of the Tennessee Board of

Pharmacy, serving as president in 2006, and vice president in 2005. From 2005 to 2008, Dilliard served on the NABP Executive Committee representing District 3. Dilliard received his bachelor of science degree in pharmacy from The University of Tennessee Health Science Center.

Board Member Appointments

- **Darren Kennedy, RPh**, has been appointed a member of the Arizona State Board of Pharmacy. Kennedy's appointment will expire January 15, 2018.
- **Wesley Hunter, RPh**, has been appointed a member of the Colorado State Board of Pharmacy. Hunter's appointment will expire July 1, 2017.
- **Cheri Pugh** has been appointed a public member of the Kansas State Board of Pharmacy. Pugh's appointment will expire April 30, 2017.
- **Sigsbee Duck, MD, RPh**, has been appointed a member of the Wyoming

State Board of Pharmacy. Duck's appointment will expire March 1, 2017.

Board Member Reappointments

- **Rebecca Gillespie, PharmD**, has been reappointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Gillespie's appointment will expire June 30, 2017.
- **Christopher Barry, RPh**, has been reappointed a member of the Washington State Board of Pharmacy. Barry's appointment will expire January 19, 2017.
- **Stephanie McAntee, CPhT**, has been reappointed an ex officio member of the Wyoming State Board of Pharmacy. McAntee's appointment will expire March 1, 2019.
- **Charles Smith, MA**, has been reappointed a public member of the Wyoming State Board of Pharmacy. Smith's appointment will expire March 1, 2019.

Board Officer Changes

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

- **Thomas F.X. Bender, Jr, RPh**, President
- **Richard Palombo, DPh, RPh**, Vice President

The South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy has elected the following officers to the Board:

- **Addison Livingston, PharmD**, Chairperson
- **Robert Hubbard, RPh**, Vice Chairperson

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

- **Jody Allen, PharmD**, Chairperson
- **Ellen Shinaberry, PharmD**, Vice Chairperson

The Washington State Board of Pharmacy has elected the following officer to the Board:

- **Elizabeth Jensen, PharmD**, Vice Chairperson 

Professional Affairs Update

(continued from page 197)

comprehensive national database of state pharmacy laws and regulations now supports mobile devices to increase accessibility

to subscribers. The new mobile device support is being provided at no additional cost to subscribers.

The **NABPLAW** Online mobile device support:

- Automatically detects the source of the browser, whether it is

a desktop, mobile, or a tablet device, and directs users to the appropriate mobile template after logging in.

- Optimizes space with a slightly rearranged toolbar to accommodate smaller screens.

- Includes all toolbar functions except Print.

More information about **NABPLAW** Online is available in the Programs section of the NABP Web site at www.nabp.net/programs/member-services/nabplaw. 

New Jersey Modifies Compounding Regulations to Align With USP Standards

The New Jersey State Board of Pharmacy recently modified its regulations related to the compounding of sterile and nonsterile preparations in retail and institutional pharmacies. The regulation (N.J.A.C. 13:39-11) was amended to divide the subchapter into sterile compounding and nonsterile compounding, and also brings the regulations into agreement with practice standards established by the United States Pharmacopeia (USP) General Chapter 797 “Pharmaceutical Compounding of Sterile Preparations” and USP General Chapter 795 “Pharmaceutical Compounding of Nonsterile Preparations.” The Board will continue to summarize critical changes in the new regulation in its quarterly *Newsletter*. The Board summarized amendments related to cleanroom requirements in its July 2013 *Newsletter*, available at www.nabp.net/system/redactor_assets/documents/586/NJ072013.pdf. To view the regulation in its entirety visit www.njconsumeraffairs.gov/pharm/phar_rules.htm and select Pharmacy Regulations.

New Oklahoma Law Prohibits Refills of Hydrocodone Products

Effective November 1, 2013, prescriptions for any medication containing hydrocodone may not be refilled in the state of Oklahoma. This new law also applies to prescriptions that are written prior to November 1. The Oklahoma State Board of Pharmacy notes that prescription transfers are considered to be a refill of a preexisting prescription and are also not allowed. However, partial fills would be permitted (eg, a prescription is written prior for a quantity of 100 but the patient only wants to purchase 20 at a time). Documentation for partial fills would be required in accordance with Oklahoma regulations. Hydrocodone combination medications are still classified as Schedule III products and may be phoned in. Mid-level practitioners (nurse practitioners, physician assistants, etc) may continue to prescribe hydrocodone combination medications at this time.

SD PDMP Makes Enhancements to Increase Efficiency

The South Dakota Prescription Drug Monitoring Program (SD PDMP) is mov-

ing forward with making enhancements that are scheduled to increase the efficiency and ease of use of the system. This past summer, the South Dakota State Board of Pharmacy began sending alerts to practitioners and pharmacies regarding patients who have breached a threshold of six practitioners and six pharmacies in a 90-day time period. The Board is also planning survey activities to obtain user feedback on the system. A grant has been written to focus on integration of SD PDMP data into the workflow of a South Dakota health system.

As of March 2013, South Dakota began data sharing PDMP data with other states through the NABP PMP InterConnect®. Practitioners may now run “multistate” queries to obtain data on their patients who may have ties to other states.

More information about the SD PDMP is available on the South Dakota State Board of Pharmacy’s Web site at <http://doh.sd.gov/boards/pharmacy/pdmp.aspx>.

Washington Law Allows Prescription Drug Donation

Washington law was amended to allow for the donation of prescription

drugs or supplies by any health care practitioner, pharmacist, medical facility, drug manufacturer, or drug wholesaler to a participating pharmacy. Under certain conditions, a participating pharmacy may redistribute the donated prescription drugs and supplies without compensation or expectation of compensation to another pharmacy, pharmacist, or prescribing practitioner for use pursuant to the program. Medications and supplies donated shall be provided to uninsured or low income individuals at or below 200% of the federal poverty level or to others if an uninsured or low income person cannot be identified. A pharmacist is responsible to ascertain that the prescription drug is in the original and sealed tamper-evident packaging or, if opened, that it is contained within a unit-dose packaging. Additionally, the prescription expiration date must be more than six months after the date it was donated, the prescription must not contain any medications recalled by the manufacturer, and the prescription drug must meet the criteria of rules set forth by the Washington Department of Health. Ⓢ

Clearinghouse

(continued from page 194)

of controlled substances, reported by the boards during a certain timespan, NABP

can provide the report upon request. Reports detailing all actions by a board or all bases for actions during a certain time period can also be provided. Boards may request

a report by calling 847/391-4406 or sending an e-mail to Clearinghouse@nabp.net.

More information on reporting to the NABP Clearinghouse, as well as

designating NABP as a reporting agent for HIPDB, is available on the NABP Web site at www.nabp.net/programs/member-services/nabp-clearinghouse. Ⓢ



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