



newsletter

National Association of Boards of Pharmacy®



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aid to government
the profession
the public
1904 to 2012

Regulators Review Reverse Distribution Process to Prevent Diversion, Environmental Hazards

Upcoming Events

January 24-25, 2012
Task Force to Review and Recommend Revisions to the Controlled Substances Act
NABP Headquarters

January 23-February 4, 2012
PCOA Administration

February 29, 2012
Committee on Law Enforcement/Legislation Meeting
NABP Headquarters

March 6-7, 2012
Task Force on Internet Pharmacy Practice Standards
NABP Headquarters

April 2012
Committee on Constitution and Bylaws Meeting

April 19, 2012
FPGEE Administration

Regulators have renewed focus on the reverse distribution process in the context of a national prescription drug abuse epidemic, which creates a market for diverted drugs, and national concerns for the safety of drinking water and other environmental issues related to pharmaceutical disposal. For over a decade, reverse distributors have provided a service to pharmacies by processing unused drug inventory – either for return to the manufacturer for credit, or for safe disposal – while also helping to protect public health by maintaining compliance with federal and state laws and regulations. The federal regulatory bodies that oversee the reverse distribution process are the same regulatory bodies that govern pharmaceutical waste management: Drug En-

forcement Administration (DEA), the Environmental Protection Agency (EPA), Department of Transportation, and Occupational Safety and Health Administration.

While federal laws requiring registration of reverse distributors have helped to secure the drugs they process, as with the distribution supply chain, the reverse distribution process can be vulnerable to diversion. In addition, not all entities needing to process or dispose of unused controlled substance (CS) pharmaceuticals are able to do so. For example, long-term care facilities (LTCFs) cannot use reverse distributors for CS disposal under the current DEA regulations. Further, EPA stresses that numerous pharmaceutical compounds have been detected “at discernable con-



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centrations in our nation’s rivers, lakes, streams, and drinking water,” raising the question of how hazardous pharmaceutical waste should be regulated for safe disposal and EPA mandates.

Even as notice of new federal regulations is imminent from EPA and anticipated from DEA within 2012, state regulators, including boards of pharmacy, may want to consider the following:

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Reverse Distribution

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- What requirements are needed to ensure that drug products travel securely through the reverse distribution process?
- How is reverse distribution regulated in various states? Which states require licensure for reverse distributors? Do any states recognize Verified-Accredited Wholesale Distributors® (VAWD®) for reverse distributors?
- What are the environmental concerns, or other state-specific concerns, regarding drugs returned for destruction, including those deemed to be hazardous waste?

Mitigating Diversion

Generally, the process of reverse distribution begins with a retail or hospital pharmacy sending unused drug inventory, including overstocked and expired prescription medications, to the reverse distributor. The reverse distributor processes the items and either sends them to the manufacturer for credit, or disposes of the products in compliance with all federal and local regulations. The pharmacy receives reports from the reverse distributor documenting the items returned to manufacturer, or proof of destruction, as applicable.

In May 2005, DEA published the final rule to

regulate this process: “Definition and Registration of Reverse Distributors.”

The rule established reverse distributors as a new category of registration and regulates the “standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances to illegal purposes.” As stated in the DEA final rule, requirements for a reverse distributor include, but are not necessarily limited to:

These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances to illegal purposes.” As stated in the DEA final rule, requirements for a reverse distributor include, but are not necessarily limited to:

- meeting federal standards for physical security controls;
- completing and maintaining records that include periodic inventories and records of all CS received, destroyed, or returned to the original, registered manufacturers for two years. Further, receipt and accountability methods and records used to ensure the establishment of effective controls against diversion must be described;
- meeting requirements for completing order forms for all Schedule I and II items prior to their transfer to the reverse distributor. Only after the order form has been received by the reverse distributor may the controlled substances be transferred;

- submitting reports as required under the Automation of Reports and Consolidated Orders System.

In addition to DEA requirements, reverse distribution applicants must obtain the appropriate state and federal approvals for CS and disposal activities.

State Laws

As reported in the 2012 NABP *Survey of Pharmacy Law*, at least 34 states have laws or regulations pertaining to the disposal of medications, including some laws specific to reverse distributors.

In the *Survey*, Vermont reported that entities must use approved reverse distributors, and Virginia indicated that the pharmacist-in-charge may dispose of unwanted drugs by “one of the following procedures: (1) Transfer the drugs to another person or entity authorized to possess or provide for proper disposal of such drugs; or (2) Destroy the drugs by burning in an incinerator in compliance with all applicable local, state, and federal laws and regulations. If Schedule II through Schedule V drugs are to be destroyed, additional procedures apply.”

Some states require that reverse distributors become licensed by the board of pharmacy, as either a manufacturer, wholesale distributor, or drug outlet. In Idaho, for example, reverse distributors are required to obtain registration through the Idaho State Board of

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2012-2013 NABP Executive Committee Nominees Announced; Elections to Take Place During Upcoming 108th Annual Meeting

The new 2012-2013 NABP Executive Committee officers and members will be elected in May 2012 during the 108th Annual Meeting in Philadelphia, PA. Open officer positions include president-elect and treasurer.

The treasurer serves a one-year term, while the individual selected as president-elect makes a three-year commitment to the Association. Following one year as president-elect, he or she serves one year as the NABP president before assuming the responsibilities of chairperson of the Executive Committee for a final year.

Individuals interested in running for an open officer position must submit written notification including a letter of intent, the expiration date for their term on the active member board, and a resume or curriculum vitae to the NABP executive director/secretary at least 45 days prior to the Annual Meeting's First Business Session (**by April 5**).

Currently, NABP has received the following nominations for the open officer positions.

President-elect (one-year term)

- Karen M. Ryle, MS, RPh, Massachusetts Board of Registration in Pharmacy

Treasurer (one-year term)

- Joseph L. Adams, RPh, Louisiana Board of Pharmacy

- Michael A. Moné, RPh, JD, Ohio State Board of Pharmacy

Nominations for open member positions on the NABP Executive Committee were accepted during the business sessions of the NABP district meetings.

As of press time, the following nominations have been accepted for the two Executive Committee member positions.

District 6 (three-year term)

- John Clay Kirtley, PharmD, Arkansas State Board of Pharmacy
- Jeanne D. Waggener, RPh, Texas State Board of Pharmacy

District 7 (three-year term)

- Ronald J. Klein, RPh, Montana Board of Pharmacy

Additional Nominations

In addition to the nominations made by the districts for the open district member positions, individuals may seek to become a candidate by providing written notice to the NABP executive director/secretary. The written notice must include a letter of intent, the expiration date for their term on the active member board, and a resume or curriculum vitae, and must be submitted after the relevant district meeting, but received no

later than 45 days prior to the Annual Meeting's First Business Session (**by April 5**), as stated in Article IV, Section 3(c)(ii) of the NABP Constitution and Bylaws. Only those individuals who have been determined by NABP to meet all qualifications for the open member position will be placed on the ballot.

Qualifications and Voting Procedures

District member and officer nominees must meet the following criteria:

- The individual must be an affiliated member (administrative officer or board member) of the Association serving on a board of pharmacy of an active member state at the time of nomination and election.
- The individual must not, in addition to his or her board of pharmacy activities, currently serve as an officer, official, or board or staff member for any national or state pharmacy organization.
- The individual must not have a conflict of interest with the purpose, mission statement, and operation of NABP.

During the First Business Session of the Annual Meeting on Sunday, May 20, NABP President Malcolm J. Broussard, RPh, will announce the

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Executive Committee

William T. Winsley
Chairperson
One-year term

Malcolm J. Broussard
President
One-year term

Michael A. Burleson
President-elect
One-year term

Karen M. Ryle
Treasurer
One-year term

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

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

Mark T. Conrad
Member, District 3
Serving first year of a three-year term

William J. Cover
Member, District 4
Serving first year of a three-year term

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

Joseph L. "Joe" Adams
Member, District 6
Serving third year of a three-year term

Cathryn J. Lew
Member, District 7
Serving third year of a three-year term

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

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

Boards Are Employers Too

By Dale J. Atkinson, JD

Sometimes lost in the regulatory issues discussed in the *NABP Newsletter Legal Briefs* is the fact that boards of pharmacy are employers, in addition to acting as the state agency created and empowered to regulate the practice through enforcement of the practice act. Acting as an employer, boards and executive directors/administrators must be cognizant of the legal aspects of employment decisions and the potential to be named as a defendant in litigation. Of course, issues related to immunity may come into play. Consider the following.

An employee of the Mississippi Board of Pharmacy was hired as an administrative assistant IV in 2003. Thereafter, she was promoted to administrative assistant VII. Her duties included matters customary to administrative work such as application processing, issuing licenses, filing, and telephone responsibilities. In June 2006, the executive director of the Board began interviewing candidates for the position of bureau director II. After an initial dispute over the administrative assistant's eligibility for the position, it was determined that the employee did qualify and she applied for the position. The executive director did not interview the employee for the position, but interviewed two other applicants. Both such applicants were white, one male and one female. Eventually, the

executive director offered the position to the white male candidate.

The employee (referred to as Plaintiff) filed a discrimination charge with the Equal Employment Opportunity Commission (EEOC) in July 2006. After filing the EEOC charge, the Plaintiff was demoted and was unable to take advantage of certain benefits related to "comp time" and compressed schedules. Based upon this demotion and lost benefits, the Plaintiff filed two additional charges with the EEOC alleging retaliation. In March 2008, she left the employ of the Board to work for another state agency. In April 2007, the Plaintiff filed litigation in state court in Mississippi against the Board and executive director (collectively referred to as Defendants) alleging discrimination, retaliation,

and civil violations under state law, including alleged violations of the state whistleblowers laws. The Plaintiff sought punitive damages based upon these claims. The Defendants had the lawsuit removed to federal court in May 2007 and thereafter filed a motion for summary judgment. Summary judgment is a motion that alleges that there are no issues of material fact in dispute and allows a court to determine, without the need for a trial, matters of law.

After addressing when summary judgment is appropriate, the court turned its attention to the various claims of the Plaintiff. First, it is alleged that the Defendants engaged in race discrimination and retaliation under Title VII of the Civil Rights Act, which prohibits employment discrimination based upon race, color, religion, sex, and national origin. The initial legal inquiry when addressing such a complaint is whether the Board and/or executive director are deemed an "employer" as defined under Title VII. To be an employer under Title VII, the Defendant must have "fifteen or more employees" during the time period alleged in the complaint. During the time period in question, the Board had nine employees.

However, the court also addressed the issue of whether the Board mem-

bers could be counted as determining the number of employees. By affidavit, it was determined that the seven Board members serve as volunteers, receive no salary, and maintain independent employment outside their service rendered to the Board. As noted by the court, jurisprudence and arguments offered by the Defendants support a finding that the Board is not an employer as defined by Title VII of the federal law. In addition, the court found that if the Board is not an employer as defined, its executive director cannot be an employer. In this conclusion, the court did outline the fact that under certain circumstances, an individual supervisor may be held liable as an “employer.” As a result, neither the Board nor the executive director were found to be an employer under Title VII.

The Plaintiff also alleged race discrimination under federal law, specifically 42 USC, Section 1981. Section 1981 prohibits race discrimination in making and enforcing private contracts. The court quickly disposed of this allegation determining that there is no private right of action under Section 1981 against a public employer. Thus, the Defendants were entitled to summary judgment on the Section 1981 claim.

Next, the Plaintiff argued for relief under 42

USC, Section 1983. Section 1983 prohibits discrimination by covered employers on the basis of race, color, religion, sex, and national origin. Again, the court noted that states and state subdivisions are protected by the Eleventh Amendment to the United States Constitution, which provides states with sovereign immunity and limits the authority of federal courts to hear lawsuits brought against state governments by its own residents, residents of another state, residents of a foreign country, and governments of a foreign country. Accordingly, the Section 1983 claim of Plaintiff against the Board was subject to summary judgment.

Further, and related to the Section 1983 claim against the executive director, the court held that the virtues of qualified immunity protect the state employee under delineated circumstances. Indeed, the Plaintiff bears the burden of overcoming the defense of qualified immunity and to do so must show a violation of a clearly established law, and show that the executive director’s conduct was not “objectively reasonable.” Citing previous precedence, the court noted that state employee acts are reasonable unless “all reasonable officials in the defendant’s circumstances would have then known that defendant’s conduct

violated the United States Constitution. . .” Based upon the Plaintiff’s lack of response to this requirement in addressing the executive director’s motion for summary judgment, the court dismissed the Section 1983 claim.

The court next addressed the state law claims of outrage and intentional infliction of emotional distress. Under Mississippi law, to support a claim for intentional infliction of emotional distress the Plaintiff must show that the Defendant’s conduct was “so outrageous in character, and so extreme in degree as to go beyond all possible bounds of decency, and to be regarded as atrocious, and utterly intolerable in a civilized community.” Again, citing the lack of evidence produced by the Plaintiff, the court held the facts do not give rise to the level of outrageous conduct necessary to support the tort claims of outrage and intentional infliction of emotional distress.

Addressing the state law claim of negligent infliction of emotional distress, the court quickly ruled that such a claim was barred by the Worker’s Compensation statutes, which provide an exclusive remedy for negligence claims by employees against their employers.

Finally, regarding the state whistleblower claims, the court outlined the ap-
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Attorney Dale J. Atkinson is a partner in the law firm of Atkinson & Atkinson, outside counsel for NABP.

Executive Committee Nominees

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open Executive Committee officer and member positions. The president will also announce any additional nominations of those candidates who have submitted the required materials to run for office by the specified deadlines and have been qualified by NABP. The final ballot for the Executive Committee will include those individuals nominated at the district meetings, as well as those candidates announced

during the First Business Session.

During the Annual Meeting, time will be designated for candidate speeches and/or speeches given on the candidates' behalf for open Executive Committee officer and member positions. Individuals giving candidate speeches must be affiliated members of NABP, and a maximum of two speeches may be given for each candidate, including the candidate's own speech. Individuals giving speeches must limit their remarks to two minutes.

Voting will take place during the Final Business

Session on Tuesday, May 22. Candidates, whether running opposed or unopposed, must receive a majority of the delegate votes present in order to be elected to office. If more than two candidates are slated for office, the candidate(s) receiving the fewest votes will be eliminated from subsequent ballots. The results of the election will be announced immediately and an installation ceremony will be conducted for the new officers and members of the 2012-2013 Executive Committee. Terms commence immediately

following the Annual Meeting.

More information about the procedures for nominating and electing Executive Committee officers and members is available in Article IV, Section 3(b) and 3(c) of the NABP Constitution and Bylaws.

Updates to the list of nominations will be posted in the Meetings section of the NABP Web site at www.nabp.net/meetings.

More information on the 108th Annual Meeting is available on pages 12-16. Ⓞ

Legal Briefs

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plicable law. The whistleblower statutes protect an employee from retaliation when they report improper government action to a state investigative body, which includes the Attorney General, the State Auditor, the Mississippi Ethics Commission, any district attorney in the state, and various other delineated entities in Mississippi. The whistleblower statutes do not apply to employees who do not report alleged employer

misconduct to one or more of these state entities. In the current matter, the Plaintiff produced no evidence whatsoever that she reported such conduct to an identified state entity. Thus, the claims under the whistleblower statutes were also subject to summary judgment in favor of the Defendants. Based upon the dismissal of all claims, the court dismissed any notion of punitive damages and held in favor of the Defendants on its motion for summary judgment.

This case presents a tidy overview of the application of federal principles

related to allegations of discrimination. Boards of pharmacy must remember that they act as employers as well as regulators of the practice of pharmacy and that personnel actions may result in allegations of wrongdoing. Board members are encouraged to ask to what degree they are involved in employment decisions and to what degree they **should** be involved.

Claiborne v Mississippi Board of Pharmacy, 2011 US Dist. LEXIS 93849 (US District Ct. MS 2011) Ⓞ



Newly Approved e-Advertiser

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

Catlin Enterprises, Inc dba Withdrawal-Ease
www.withdrawal-ease.com

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

FPGEC and FPGEE Celebrate Three Decades of Service

Celebrating its 30th anniversary, the Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) was founded to provide state boards of pharmacy with a standardized uniform examination to assist them in evaluating academic credentials of graduates from foreign pharmacy schools while ensuring that the standards of pharmacy practice are maintained.

In November 1981, the NABP Committee on Law Enforcement/Legislation recommended that the Association prepare an examination by which foreign pharmacy school graduates could demonstrate the equivalency of their education to that of graduates of United States undergraduate programs. This recommendation initiated the process for developing the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®); however, discussions related to foreign-educated pharmacists practicing in the US date back as far as 1921. As an increasing number of foreign-educated pharmacists began entering the US through New York and Florida around 1972, the question of who should be allowed to practice became more prevalent.

Establishing the Program

In 1977, Martin I. Blake of Illinois reported to NABP that his state permitted graduates of foreign schools and colleges of pharmacy

to take its licensure examination provided the pharmacists' credentials were deemed acceptable and a two-year apprenticeship was completed. Blake went a step further and asked for the development of a national evaluative examination to assess academic background equivalency, a request seconded by then NABP President Frank E. Kunkel.

In 1982, Resolution 78-8: Equivalency Examination, was passed during the NABP 78th Annual Meeting resolving "that the NABP in convention assembled, direct the Executive Committee to take the necessary steps to fund, develop, and produce such an educational equivalency examination by December 1983 for use by participating states." Moving quickly, in August 1982 the original FPGEC was established as the Foreign Pharmacy Graduate Examination Commission. Soon after, the commission negotiated with the American College Testing (ACT) Program to assist in the development of the FPGEE. The first examination was administered in a paper-and-pencil format at three different test sites on April 1, 1984, and since then, has been administered more than 40,900 times. The commission was eventually transformed into a committee, now known as the FPGEC, and in 1993 NABP transferred the FPGEE from ACT to the Association's in-house staff to allow for increased efficiency in the



management of the program. Since 1984, more than 33,300 applicants have participated in the FPGEC Certification program.

The FPGEE was first introduced in a computerized format in 2000. Computerized testing was reintroduced in 2009 at over 200 testing centers throughout the continental US. In addition, candidates have the opportunity to take the Pre-FPGEE®, a Web-based practice examination developed and administered by NABP. The Pre-FPGEE utilizes questions that have previously appeared on the FPGEE and provides candidates with a preview of the FPGEE testing experience.

Maintaining Program Integrity

Since it was established, NABP continues to evaluate the FPGEC program and the FPGEE to ensure that they evolve appropriately and are in line with current US pharmacy education standards. During the 90s, the FPGEC added the Test of Spoken English (TSE) as a requirement for certification in addition to the already required Test of English as a Foreign Language (TOEFL), later updating the program to require the TOEFL iBT (Internet-based Test). Ad-

ditionally, in accordance with recommended testing industry standards regarding the review and updating of examinations, the FPGEE competency statements and blueprint continue to undergo evaluation at least every five years. The latest update will be effective beginning with the April 19, 2012 administration. (See the November-December 2011 *NABP Newsletter* for more detail.)

To ensure that FPGEC candidates are allotted a sufficient amount of time to complete their certifications, in 2005 NABP eliminated the two-year time limit for candidates to take the TOEFL and TSE for FPGEC Certification. In addition, one year later the Association began a partnership with the Educational Credential Evaluators, Inc, to assist in expediting the review of candidates' educational credentials.

More recently, NABP passed a new FPGEC policy that limits the number of times a candidate may sit for the FPGEE. Effective January 1, 2012, all FPGEC candidates will be allowed a maximum of five attempts to pass the FPGEE. FPGEC candidates who have already met or exceeded this limitation

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Reverse Distribution

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Pharmacy as drug outlets, including obtaining CS registration, if receiving CS.

As a means to help protect the public from the threat of counterfeit drugs infiltrating the United States medication supply, the NABP VAWD® program verifies suppliers' compliance with state and federal laws for wholesale distributors. Some reverse distributors may seek VAWD accreditation to comply with state regulations that require VAWD for state licensure. Such state laws can help to ensure the security of the reverse distribution process. According to the 2012 NABP Survey, 20 states now recognize the VAWD program.

Disposal of Surplus CS Drugs by LTCFs

In testimony presented to the US Senate Special Committee on Aging, June 30, 2010, Mary L. Hendrickson, PharmD, MBA, RAC, director of quality & regulatory affairs, Capital Returns, Inc, stated that she has witnessed the "surplus of unused medications in long-term care facilities as well as witnessed the destruction method utilized by these facilities." She indicated that "many facilities have limited resources to destroy products like controlled substances" and that they are "frequently not familiar with the best standards of practice or

environmental regulations for discarding pharmaceuticals. As a result many of these products are destroyed by flushing them down the drain or toilet."

The DEA reports that one comment received in response to the interim final rule for reverse distributors highlighted the need for regulations that allow LTCFs to return or dispose of unused controlled substances using the services of a reverse distributor. "The commenter stated that its studies have shown that a majority of long term care facilities and nursing homes are improperly accounting for and disposing of their controlled substances, indicating that sewage is a primary means of disposal and that EPA has concluded that improper disposal results in contamination."

In the public comments section of the final rule on reverse distributors, DEA reiterated that because "LTCFs are not registrants they may not transfer controlled substances to either the pharmacy from which they came or to a reverse distributor, or any other registrant for disposal." Instead, DEA regulations require that LTCFs "dispose of the excess controlled substances directly." DEA's position is intended to maintain the security of the closed system of distribution, and DEA advises that, "In cases where long term care facilities must dispose of controlled substances, they should follow the guidelines within their

State for disposing of the drugs and maintain appropriate documentation of the disposal."

The Report of the NABP Task Force to Review and Recommend Revisions to the Controlled Substances Act, states that DEA has indicated that a separate rule is pending relating to LTCFs and the developing regulations to implement the Secure and Responsible Drug Disposal Act of 2010. The Task Force, which met January 25-26, 2011, recommended that NABP comment appropriately when the Notice of Rulemaking is published.

Addressing Environmental Concerns

Because the reverse distribution process generates waste, it is also regulated by the EPA. In addition, some states regulate hazardous pharmaceutical waste with stricter requirements overseen by their state environmental protection agencies. For example, the Minnesota Pollution Control Agency (MPCA) studied the issue and determined that the majority of the drugs sent to reverse distributors in its state are destroyed or disposed of, not reused, making them subject to the Minnesota Hazardous Waste Rules. The MPCA concluded that "the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals" and allows pharmacies

to manage unused drugs through this process as long as they are in compliance with additional requirements implemented by MPCA. Specifically, the pharmacy or entity using a reverse distributor service for disposal management must:

- obtain a Hazardous Waste Identification Number;
- ensure that the reverse distributor is licensed by the Minnesota Board of Pharmacy as a pharmaceutical manufacturer or wholesaler, and has a DEA registration number if CS will be handled; and
- meet specified requirements for shipping, documentation, and record keeping.

The regulation also specifies, consistent with DEA rules, that the entity may not accept or ship for reverse distribution any wastes that were accepted from households or another waste generator.

The Wisconsin Department of Natural Resources (WDNR) takes a different approach, and places the responsibility for proper destruction of hazardous waste with the reverse distributor. WDNR interprets that because the unused pharmaceutical product is considered to have value, it is not regulated as a waste, and WDNR cautions pharmacies that "Only pharmaceuticals that are eligible for credit should be sent

to the reverse distributor. Reverse distributors are not waste management facilities and are not allowed to accept waste or waste-like materials, such as partial packages, compounded IVs, broken or spilled materials, patient's personal medications or samples from pharmaceutical representatives."

Instead, WDNR indicates that "Products that are never eligible for credits must be properly managed as a waste, and not sent to a reverse distributor." Further, the WDNR states that "Reverse distributors must properly manage any hazardous waste that is generated as part of their business activities" and must follow Wisconsin hazardous waste rule requirements.

Similarly, the Virginia Department of Environmental Quality (DEQ) indicates that there is no Virginia-specific guidance on reverse distribution of pharmaceuticals, but that the process should not be used instead of proper hazardous waste management. The Virginia DEQ advises that the process "does not generally apply

to used, spent, damaged, contaminated or degraded materials or products."

Both Kansas and Iowa encourage use of an appropriate reverse distributor. As reported in the March 2011 *Kansas State Board of Pharmacy Newsletter*, "the Kansas Department of Health and Environment (KDHE) issued guidance relating to the disposal of non-controlled substance pharmaceuticals and the potential for surface and groundwater contamination." KDHE indicates that reverse distribution is the most desirable disposal method, while incineration and disposal in trash are less desirable methods. The Board reminded pharmacists that "If a pharmacy wishes to dispose of controlled substances from its own stock, it may transfer them to a DEA-registered reverse distributor," and that the "pharmacy must maintain a record of distribution that includes the drug name, dosage form, strength, quantity, and date transferred."

The Iowa Pharmacy Association (IPA) provides information for processing

unused drugs as hazardous waste versus processing the drugs for potential credit. The IPA notes that some reverse distributors only destroy unused medications or hazardous medications and supplies, while others have the required permits to process unused drugs for return to the manufacturer, and provides guidelines to assist pharmacies in selecting an appropriate reverse distributor.

New rules proposed by EPA in 2008 are intended to facilitate environmentally safe disposal of hazardous pharmaceutical waste by generators such as hospitals and pharmacies. The proposed rule would allow these entities to manage the waste as "handlers," as opposed to "generators," of universal wastes, with the intent of creating a more streamlined system for disposal of hazardous pharmaceutical waste. As part of the proposed amendment to the EPA Universal Waste Rule, reverse distributors could become universal waste handlers and accept universal waste for purposes of consolidation. "Under this scenario,"

notes EPA, "reverse distributors may accept both pharmaceutical universal waste and unused and 'creditable' pharmaceutical products from health care facilities, but, due to requirements under current DEA regulations, reverse distributors may not accept controlled substances from consumers or other persons who are not registered with DEA."

Currently, EPA is reviewing comments on security issues related to the transport and management of pharmaceutical wastes and the agency does not have a projected date for the finalization of the rule.

Regulations on the Horizon

Once EPA publishes the final rule, it must be adopted by states before pharmaceutical wastes can be managed under the rule, as noted by EPA. It is anticipated that proposed rules related to CS disposal and LTCFs will be published for comment by DEA in 2012. NABP will continue to provide updates as they become available.®



Newly Accredited VAWD Facilities

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

AmerisourceBergen Drug Corporation
Glen Allen, VA
Roanoke, TX

Owens & Minor Distribution, Inc
Denver, CO
Raleigh, NC
Tinley Park, IL

A full listing of more than 485 accredited VAWD facilities is available on the NABP Web site at www.nabp.net.®

nabp newsletter

NABP PMP InterConnect Successfully Meets 2011 Development Timeline; More States to Go Live in Early 2012

Successful implementation of the NABP PMP InterConnectSM continues, with eight additional states scheduled to make NABP InterConnect available to prescription monitoring program (PMP) users in early 2012, for a total of 11 live states. PMPs in Ohio, Indiana, and Virginia had implemented use of the NABP InterConnect by September 2011. And, as of press time, PMPs in Arizona, Connecticut, Kansas, Michigan, New Mexico, North Dakota, South Carolina, and West Virginia plan to go live by first quarter 2012.

In the first 100 days since launch the NABP InterConnect has processed 39,346 requests among Indiana, Ohio and Virginia. The average hub response/processing time for those

requests was under one second and the average PMP response time for those requests was approximately 13 seconds. In total, using NABP InterConnect, authorized users of the PMPs only waited an average of under 15 seconds for a consolidated multistate PMP report.

Two additional states have executed a memorandum of understanding (MOU) with NABP to participate in the NABP InterConnect: Mississippi and Utah.

The following PMPs intend to sign on to use the NABP InterConnect and have MOUs under review: Delaware, Louisiana, Montana, Nevada, North Carolina, Rhode Island, and South Dakota.

It is anticipated that approximately 30 states will be sharing



data using the NABP InterConnect in 2012.

The NABP PMP InterConnect fact sheet provides information about the background, development, governance, and funding of NABP InterConnect and also presents a timeline highlighting key accomplishments in the development and implementation of the system beginning with the initiation of the development process in January 2011.

The fact sheet and additional information are available in the NABP PMP InterConnect section of the NABP Web site at www.nabp.net/programs. ©

CPE Monitor Provider Pilot Approaching Completion; Additional ACPE-Accredited CPE Providers to Transition to Service Soon

The CPE MonitorTM provider pilot is nearing completion with great success. The Accreditation Council for Pharmacy Education (ACPE) has worked with NABP and 42 ACPE-accredited continuing pharmacy education (CPE) providers to test the system's ability to upload and transmit licensees' CPE data. It is expected that the pilot will conclude at the end of 2011.

By early 2012, several additional accredited providers are anticipated to begin transitioning their

systems to CPE Monitor. Pharmacists and technicians will be required to provide their NABP e-Profile ID, plus their birth date (MMDD) to participating providers in order to receive credit for completed CPE. As a secure, central system, CPE Monitor will assist licensees by maintaining and tracking all ACPE-accredited CPE units.

The majority of the ACPE-accredited providers are projected to have completed the integration of CPE Monitor into their

systems by July 2012. All providers will be required to transmit their CPE data in this manner by December 31, 2012, in order to continue to issue ACPE-accredited CPE units.

Since the initial launch of the CPE Monitor service in March, more than 93,100 pharmacists and 36,500 pharmacy technicians have set up their NABP e-Profiles to prepare for the shift to electronic tracking of all ACPE-accredited CPE units. NABP strongly encourages all pharmacists and pharmacy techni-



cians to set up their NABP e-Profiles now so that they are prepared once providers begin requiring the NABP e-Profile ID. This will assist in eliminating any delays in the processing and tracking of CPE data.

Licensees may obtain additional information and set up their e-Profiles at www.MyCPEmonitor.net. ©

NABP Establishes PARE to Aid Boards of Pharmacy in Pharmacist Remediation Evaluation; Pilot Underway Soon

When a pharmacist's ability to practice is questioned, it is left to the state board of pharmacy to determine whether that pharmacist is able to continue practicing competently and safely. The boards have indicated that there is a need for an assessment that would assist in this decision-making process. In response, NABP has developed the Pharmacist Assessment for Remediation Evaluation (PARE), a multidimensional assessment that will provide the boards with a statistical element when determining conditional pharmacist practice issues.

Soon to be in the pilot stages, PARE will be administered to a representative sampling of boards of pharmacy from all eight NABP districts. Feedback garnered from the pilot will be utilized in the next phases of assessment development

and will contribute to the enhancement of PARE to ensure it meets the boards' needs. It is with the boards' assistance that NABP will be able to finalize implementation of PARE, which is anticipated for the first or second quarter of 2012.

PARE can act as an aid in instances when a board is questioning a pharmacist's adherence to pharmacy practice standards. More specifically, boards may wish to use the assessment when considering cases such as reinstatement of a pharmacist's license after a brief departure from the practice or other ramifications related to disciplinary actions.

As a computer-based assessment, PARE is anticipated to take approximately five to six hours to complete and will cost \$250 per administration. It consists of 210 test items, which are composed of

three distinct content domains broken down into subdomains. These items were created by a group of subject matter experts with input and approval by the NABP Executive Committee. Each participating board will determine how the assessment will be administered, whether in the board office, in a proctored environment, or elsewhere.

The content domains consist of:

1. The Practice of Pharmacy and Medication Safety (50%)
 - a. Safe and effective preparation and dispensing of medications
 - b. Prevention of medication errors
 - c. Continuous quality improvement
2. Pharmacist Care (25%)
 - a. Patient assessment, clinical pharmacology, therapeutics

- b. Drug information
- c. Promotion of wellness and public health
3. Professional Ethics/Pharmacist Judgment (25%)
 - a. Professional ethics
 - b. Decision/actions affecting patient care
 - c. Code of ethics, professional behavior

Each section of the assessment will be scored separately to allow the boards the option of focusing on a pharmacist's performance in specific areas or utilizing the results from the entire assessment. Pharmacists will need to take the assessment in its entirety in order to receive a score.

Questions regarding PARE may be directed to the NABP Competency Assessment Department via e-mail at NABP_comp_assess@nabp.net. 

FPGEC and FPGEE Celebrate 30 Years

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before January 1, 2012, will be allowed one final attempt at passing the FPGEE. Candidates who do not pass the FPGEE on the fifth or final allowed attempt will not be able to reapply to the FPGEC Certification Program and their file will be closed. These conditional limits on the number of times a candidate may take an examination are consistent with professional standards and practices of peer institutions to NABP.

Also effective January 1, 2012, the new policy sets shelf-life parameters for candidates' FPGEE scores. FPGEE scores will be valid for a period of five years from the examination date, after which the score will expire. It has been demonstrated that test scores become obsolete over time, no longer reflecting the current abilities and knowledge of the test taker. Candidates who do not complete the FPGEC Certification process within the five years of sitting for the examination will be required to retake the FPGEE if they wish to pursue certi-

fication. Current candidates whose FPGEE scores are five or more years old, and whose program file is still open, will have until December 31, 2012, to complete the requirements for certification.

NABP will continue make enhancements to the FPGEC Certification Program as necessary to uphold the integrity of the program.

Additional information on FPGEC and the FPGEE is available in the Programs section of the NABP Web site at www.nabp.net/programs. 

Boards of Pharmacy Invited to Philly, “City of Liberty,” for NABP 108th Annual Meeting

NABP invites its members and other pharmacy stakeholders to experience the historical “City of Brotherly Love” during the Association’s 108th Annual Meeting in Philadelphia, PA. Known as the birthplace of freedom, Philadelphia affords an ideal setting for this year’s Annual Meeting, “State Boards of Pharmacy and NABP – *Empowering Liberty with Knowledge and Responsibility.*” After participating in important business sessions and timely continuing pharmacy education sessions, attendees will have the chance to explore the many landmarks of our nation’s history scattered throughout Philadelphia, where the past blends with a modern landscape. The Annual Meeting will be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel.

Europeans first arrived in the area now known as Philadelphia in the early 1600s. Originally inhabited by native Americans who called themselves the Lenni-Lenape, the land in the Philadelphia area was eventually granted to William Penn, an English Quaker, by Charles II of England as payment for a debt. Penn developed his colony in hopes that it would be a place where people of any religion could practice their beliefs freely, and to this day, Philly remains a city based on freedom of expression.

The rural town that Penn hoped to establish grew to a larger than expected trading post. As Philadelphia expanded so too did its reputation as a city of liberty

and innovation. The eventual home of Benjamin Franklin, Philadelphia boasts many “firsts” including the Franklin stove, glass harmonium, and bifocals, the first public library, a fire insurance company, and the first post office.

Philadelphia is now ranked the fifth largest city by population in the country, but was once the nation’s largest. The city also holds the distinction of being North America’s first “planned city” laid out in a grid pattern with wide streets and five public squares. In addition, Philadelphia served a decade as the temporary capital of the United States before Washington, DC, assumed that position in 1800.

Local Sites

In Philly there is something for everyone – whether a history buff, a nature enthusiast, or an avid shopper. Independence National Historical Park, located less than two miles from the hotel, provides a national shrine for history buffs. Home to Independence Hall, visitors can explore the birthplace of the Declaration of Independence and the US Constitution. And of course the Liberty Bell is a must-see. This international symbol of freedom is a 12-foot in circumference bell with a 44-pound clapper. Among the numerous other historical events, Philadelphia was also an important stop on the Underground Railroad, the location where Betsy Ross sewed the first US flag in 1777, and home to the building site of first computer, ENIAC, which was created at the University of Pennsylvania in 1946.

Aside from history, Independence National Historical Park also offers a place to relax, take in nature, and enjoy the scenery. On a pleasant day, people can be seen reading in the gardens, strolling along the paths, or enjoying lunch from the various street vendors. Located a few blocks north, 7.5-acre Franklin Square, originally named North East Publick Square, is one of five original squares laid out by Penn in his original plan of the city in 1682. The Square was renamed in honor of Benjamin Franklin in 1825 and

made into a public park in 1837. It is believed to contain the oldest surviving fountain from Penn's five squares. The other four squares are known as Rittenhouse, Washington, Logan, and Center Square, where City Hall is now located.

For those wishing to stay closer to the hotel, the Franklin Institute, one of the first hands-on science museums in the US, and the Philadelphia Museum of Art, are within walking distance.

Philadelphia also offers a mix of urban shopping districts and some of the nation's largest retail centers. Featuring national and local retailers alongside trend-setting boutiques in Rittenhouse Row, Philly provides an expansive list of shops in and around the city. As an added bonus, clothing and shoe purchases are tax-free in Pennsylvania.

Optional Tour

Attendees of the Annual Meeting will have the opportunity to take in the sites of Philly during the optional tour, History and Architecture of Philadelphia, which will be held on Monday, May 21, from 1:30 - 5:15 PM for \$49 per person. Advanced registration is required. Attendees will partake in a brief motor coach tour of Society Hill and the surrounding historic area where the guide will provide commentary on Georgian, Federal, and Greek Revival architecture. The tour will take attendees past the

Pennsylvania Academy of the Fine Arts, Logan Circle, the new site for Barnes Foundation, and the Rodin Museum, which will offer a quick view of the Burghers of Calais and The Thinker.

In addition to these sites, participants will take a walking tour of City Hall where they will have the opportunity to see the Mayor's Reception Hall and Council Chambers as well as hear about the architecture and many sculptures located outside the building.

During the tour, attendees will also visit the world's first true "penitentiary," Eastern State Penitentiary, designed in 1829 to inspire true regret in the hearts of convicts. Once the most famous and expensive prison in the world, Eastern State held many of America's most notorious criminals including bank robber Willie Sutton and Al Capone.

Getting Around

Located eight miles from the Philadelphia International Airport, the Sheraton Philadelphia Downtown Hotel is set in the heart of Center City Philadelphia. Individuals arriving from the airport may take the Lady Liberty Airport Shuttle for a cost of \$10 per person one way. Tickets can be purchased via phone at 215/724-8888 or at the airport ground transportation counter located in the baggage claim area. More information is

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Photo courtesy of Paul Benchengo and the Philadelphia Convention & Visitors Bureau.

Known as the birthplace of the Declaration of Independence and the United States Constitution, Independence Hall is just one of the many Philadelphia landmarks that have influenced American history.

Philly Links

Independence National Historical Park
www.nps.gov/inde/index.htm

Independence Visitor Center
www.independencevisitorcenter.com

Franklin Institute
www.fi.edu

Franklin Square
www.visitphilly.com/museums-attractions/philadelphia/franklin-square

Philadelphia Museum of Art
www.philamuseum.org

Philadelphia Shopping
www.visitphilly.com/shopping

Rittenhouse Row
www.rittenhouserow.org

Book Your Room for Philadelphia! Special Room Rates Available Now for the 108th Annual Meeting

NABP has secured a special room rate for attendees of the 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. Attendees who reserve their room no later than **Wednesday, April 25, 2012**, will receive accommodations at the special rate of \$159 single/double occupancy plus 15.2% state and local tax. Rooms may be reserved online by visiting www.nabp.net

and clicking on the link for the hotel special group rate page, or attendees may make their reservations by calling 1-800/325-3535, and mentioning that they will be attending the NABP 108th Annual Meeting. Please be sure to use the 800 number when making room reservations by phone. The special room rate cannot be obtained by calling the hotel via their direct phone number.

Transportation

For airfare and car rental rates, attendees may contact the official NABP travel agency, Options Travel, at 1-800/544-8785. When calling Options Travel, mention the NABP meeting code number, NABP108. Please note, the last event of the 108th Annual Meeting is the Annual Awards Dinner, which takes place from 7 - 11 PM on Tuesday, May 22. Please

make your travel arrangements accordingly.

Online Meeting Registration Coming Soon

Registration for the Annual Meeting will be available in February 2012. More information will be provided in future issues of the *NABP Newsletters* as well as on the NABP Web site at www.nabp.net/meetings. 

Annual Meeting Travel Grant Program Undergoes Change; Board Member, Administrative Officer, or Voting Delegate Eligible

NABP will once again offer active member state boards of pharmacy travel grant opportunities to attend the 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. New this year, the travel grant is no longer restricted to the board's voting delegate. Now, 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 the past, only the voting delegate of each board was qualified to apply.

One individual per active member board of pharmacy is eligible to receive the grant. Though the individual applying for the travel grant need not be the voting delegate, his or her board of pharmacy must have

a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

The Association established the grant to assist boards in sending voting delegates to the Annual Meeting so they may participate in important business including discussing and voting upon resolutions and amendments to the NABP Constitution and Bylaws, electing NABP Executive Committee members and officers, and attending educational sessions regarding current issues facing pharmacy regulators.

The NABP Annual Meeting Travel Grant program lessens the costs for qualified individuals by providing funds for travel expenses, including airfare, hotel rooms, meals, taxis, parking, and tips. Eligible individuals

can receive up to \$1,500 in grant monies to attend the NABP 108th 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 Sarah Fowle, 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. Last year, NABP provided 41 state boards of pharmacy with grants to attend the NABP 107th Annual Meeting.

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

Proposed Resolutions to be Distributed in March 2012

Proposed resolutions received at NABP Headquarters by Friday, March 16, 2012, will be distributed to state boards of pharmacy on the following **Thursday, March 22, 2012**, for review prior to the 108th Annual Meeting, where the resolutions will be presented and voted upon. This mailing will constitute the only preconference distribution of proposed resolutions. All resolutions – those distributed for early review as well as those received after March 16 – will be presented to the voting delegates during the Annual Meeting on Monday, May 21,

2012, by the chair of the Committee on Resolutions.

To be considered during the Annual Meeting, resolutions must adhere to the requirements of Article IV, Section 6, Part (d) of the NABP Constitution and Bylaws, which states the following:

(d) Any active member board, District, or committee of the Association may submit resolutions to the Association. Except as otherwise provided in subparagraph (c) of this section, all resolutions submitted in writing to the Association at least twenty (20) days prior to the

date of the Annual Meeting shall be presented at the Annual Meeting for consideration. Resolutions not presented within such time limitations may be presented during the Annual Meeting and will be considered for adoption by the Association upon the affirmative vote of three-fourths (3/4) of those active member boards presented and constituting a quorum.

Questions regarding resolution procedures should be directed to the NABP Executive Office via e-mail at exec-office@nabp.net. ☎

Sponsorship and Educational Grant Opportunities for NABP 108th Annual Meeting Now Available

Organizations have an opportunity to gain exposure through numerous sponsorship and educational grant opportunities available at the NABP 108th Annual Meeting to be held May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA. Contributing organizations

help NABP provide quality programs designed to assist board of pharmacy members, executive officers, and compliance staff to meet their responsibilities for safeguarding the public health while creating visibility for the sponsoring organization.

Contributing organizations will be recognized by

session or event, and will also be identified in meeting program materials, the *NABP Newsletter*, on meeting signage, and on the NABP Web site at www.nabp.net. In addition, sponsoring organizations contributing \$5,000 or more to the meeting are entitled to two complimentary meeting registrations valued

at \$575 each. Contributions of \$1,000 to \$4,999 entitle the donors to one complimentary meeting registration.

For more details on sponsorship and grant opportunities, organizations may contact NABP via e-mail at custserv@nabp.net or via phone at 847/391-4406. ☎

Philadelphia

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available at www.ladylibertyshuttle.com. There is a \$28.50 flat rate to take a taxi from the airport to the hotel. Several rental car agencies are also available. More information on these can be found at www.phl.org/rental_cars.html. For guests choosing to rent a vehicle, the hotel has self and valet parking facilities that range from \$38-\$44 per day.

Once in Center City, the best ways to get around are by foot,

taxi, or public transportation. Rated one of the best walking cities in the country, downtown Philadelphia spans just 25 blocks between the Schuylkill and Delaware rivers and is laid out in an easy-to-follow grid street design. The north/south streets are numbered and the east/west streets have tree names. In addition, Philadelphia offers the Philly Phlash, a purple touring-bus-turned-trolley. Phlash whisks visitors through a 20-stop Center City loop around major attractions and runs daily from 10 AM to 6 PM. The cost is \$2 each time you board. Public transportation is also

available. Visitors can purchase an \$11 One-Day Independence Pass that allows them to travel on any and all Southeastern Pennsylvania Transportation Authority (SEPTA) buses, trolleys, subways, and trains as well as on the Philly Plash. More details and other transportation options are available at www.visit-philly.com/getting-around.

Additional information about the 108th Annual Meeting will be available on the NABP Web site at www.nabp.net/meetings. Online registration for the Annual Meeting will be available in February 2012. ☎

Meeting Program

May 19-22, 2012

Sheraton Philadelphia Downtown Hotel

Philadelphia, PA

Saturday, May 19, 2012

9 AM - 7 PM

Registration/Information Desk Open

2 - 4 PM

Pre-Meeting Special Program

5 - 6 PM

Annual Meeting Orientation

7 - 10 PM

President's Welcome Reception

Honoring NABP President

Malcolm J. Broussard, RPh

Dinner will be served

Dress: business casual

Sunday, May 20, 2012

6:30 AM - 5:15 PM

Registration/Information Desk Open

7:30 - 8:30 AM

NABP/AWAR_XE Fun Run and Walk

8 - 11:30 AM

Hospitality Brunch and Educational
Table Top Displays

8 - 11:30 AM

Joint CPE

Educational Poster Session –
Embracing Knowledge for Public
Protection

NOON - 4 PM

First Business Session

12:30 - 1:30 PM

Keynote Address

Chief Richard Picciotto, FDNY

4 - 5 PM

Joint CPE

Monday, May 21, 2012

7 AM - 2 PM

Registration/Information Desk Open

7 - 8:15 AM

NABP/USP Breakfast

Sponsored by United States

Pharmacoepial Convention

8:15 - 10:15 AM

Joint CPE

10:30 AM - noon

Second Business Session

Noon - 12:30 PM

Informal Member/Candidate
Discussion

1:30 - 5:15 PM

Optional Tour

History and Architecture of
Philadelphia

Reservation Required

Tuesday, May 22, 2012

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

8:45 - 10:15 AM

Compliance Officer CPE

10:30 AM - noon

Joint CPE

Noon - 1:30 PM

Lunch Break

(On your own)

1:30 - 4 PM

Final Business Session

5:45 - 6:45 PM

Awards Dinner Reception

7 - 11 PM

Annual Awards Dinner

Dress: semiformal

Note: The 108th 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 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.

Share Your Knowledge and Network: NABP Seeking Poster Session Participants for the 108th Annual Meeting

NABP is currently seeking Poster Session participants for its Annual Educational Poster Session. This year the Poster Session will focus on “Embracing Knowledge for Public Protection,” and will be held during the NABP 108th Annual Meeting, May 19-22, 2012, at the Sheraton Philadelphia Downtown Hotel in Philadelphia, PA.

The Poster Session will be held Sunday, May 20, from 8 - 11:30 AM, and will offer those displaying posters the opportunity to share information about their organization’s latest legislative issues, technology, policy development, and/or disciplinary cases as they relate to embracing knowledge for public protection, with other pharmacy professionals.

State board of pharmacy members and staff, as well as schools and colleges of pharmacy, are invited to participate.

Participants may earn one contact hour (0.1 CEU)

of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit for their attendance and participation. Presenters are not automatically qualified for CPE. To earn CPE, both presenters and participants must spend at least one hour interacting with other Poster Session presenters and complete a post-session test.

Posters must coincide with the Poster Session theme, “Embracing Knowledge for Public Protection.” Participating boards and schools and colleges of pharmacy will be provided with one four-foot by six-foot bulletin board, which should be manned by a qualified representative, such as a registered pharmacist, during display times. Assembly time will be available on Sunday, May 20, from 6:30 - 7:45 AM. Student presenters are welcome and must be accompanied by a licensed pharmacist. Phar-

macy school students will receive a free voucher valued at \$50 to take the Pre-NAPLEX®, a practice examination for students preparing for the North American Pharmacist Licensure Examination®.

Those interested in participating should contact NABP Professional Affairs Manager Eileen Lewalski via e-mail at elewalski@nabp.net by **Friday, March 9, 2012.** ☺

Guidelines for Submitting a Poster

For those interested in participating, the following is a list of suggestions on preparing a poster:

- Poster topics must adhere to the theme “Embracing Knowledge for Public Protection.”
- Keep the poster title short, highlighting the topic.
- Make the font size at least 14 point and double space paragraph lines to ensure readability from a distance of two to four feet.
- Enlist the help of students and/or interns on rotation in your office to prepare the poster.
- Prepare handouts to provide an overview of the poster and/or additional information including contact names, should attendees have questions.
- The display should be manned by a qualified representative, such as a registered pharmacist, throughout the duration of the session. Student presenters must be accompanied by a licensed pharmacist.

NABP Seeks Members for 2012-2013 Committees and Task Forces

NABP is seeking volunteers from its active member boards of pharmacy to serve on the 2012-2013 committees and task forces. Executive officers and board members interested in serving on a committee or task force are encouraged to submit a letter of interest and a current resume or curriculum vitae. In addition, NABP encourages

interested board staff to volunteer for NABP task forces.

All submissions must be sent to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters or executive@nabp.net by **Friday, June 8, 2012.** Letters should outline the volunteer’s applicable experiences and accomplishments, along

with the reasons he or she wishes to be considered for appointment to a committee or task force. All materials will be forwarded to NABP President-elect Michael A. Burluson, RPh, who will make the appointments when he becomes NABP president following the Association’s 108th Annual Meeting in Philadelphia, PA. ☺



AWAR_xE Across America: PSAs Take the Spotlight in Times Square, at NASCAR Texas 500, and Beyond

AWAR_xE Across America efforts have expanded with public service announcements (PSAs) taking the spotlight in Times Square and at the NASCAR Texas 500 (see back cover for details). AWAR_xE™ PSAs were displayed on digital billboards in both venues, bringing important messages about protecting family and friends from prescription drug misuse and abuse, and from dangerous counterfeit drugs.

The CBS Neutron Company billboard in Times Square began rotating four AWAR_xE PSAs on November 1, 2011, with display continuing through December and the New Year's Eve celebration, until 1 AM on January 1, 2012. The Times Square AWAR_xE PSAs have already reached thousands of viewers as they gathered to see the 85th Macy's Thanksgiving Day Parade on November 24, 2011. The PSAs continue to raise awareness as thousands of consumers make their way to Manhattan shops, Broadway plays, and on their daily commute.

The AWAR_xE PSAs also continue to be promoted to television broadcast companies in 16 geographical market areas, includ-

ing Arizona, Connecticut, Florida, Illinois, Kentucky, Louisiana, Massachusetts, Minnesota, Nevada, New York, North Dakota, Ohio, Oklahoma, Oregon, Texas, and Washington, DC.

A special event in Florida brought the AWAR_xE messages to college students and new board initiatives are reaching consumers in two states. Student group, The Rx Factor, highlighted AWAR_xE messages for students at the Energii Wellness Symposium and Expo, University of Tampa, November 4, 2011. The group encouraged students to use prescription medications safely, and to avoid sharing medications with friends, a dangerous trend affecting college students. The Rx Factor passed out AWAR_xE materials that directed students to www.AWARERX.ORG for more information.

The Oregon State Board of Pharmacy is encouraging pharmacists to alert their patients to AWARERX.ORG resources by passing out AWAR_xE bookmarks that highlight the dangerous trend of prescription drug misuse and encourage patients to turn to the pharmacist with medication questions. The Board will ask their inspectors to

deliver complimentary bookmarks to pharmacists at pharmacy visits. The District of Columbia Board of Pharmacy is also increasing AWAR_xE outreach by distributing bookmarks in Board mailings.

Boards of pharmacy can become involved in the AWAR_xE Across America effort by sharing resources in the following ways:

- Distribute AWAR_xE bookmarks at public board meetings or through board mailings.
- Post the AWAR_xE logo linked to www.AWARERX.ORG on the board's Web site, in addition to posting the NABP logo and link.
- Share relevant news with AWAR_xE, on drug disposal programs and other



Four AWAR_xE PSAs can be seen on display in Times Square through New Year's Day.

board programs aimed to fight prescription drug abuse.

To order bookmarks at no charge to the board, or to obtain the AWAR_xE logo for a Web site, send an e-mail to AWARERX@NABP.NET.



Student group The Rx Factor passed out AWAR_xE bookmarks, flyers, and hats to students attending the Energii Wellness Symposium and Expo, University of Tampa, November 4, 2011.

LA Board Invests in Future PMP Software Enhancements

The Louisiana Board of Pharmacy's prescription monitoring program (PMP) finished the fiscal year with some excess revenues, and the Board authorized the investment of those funds in software enhancements for the program. One of the upgrades will be to the telecommunication standard for data coming from pharmacies. Currently, the program only accepts data in the older ASAP-1995 standard. The Board intends to upgrade its capability to accept data in the newer ASAP-2007 standard. The Board notes that one of the primary advantages of that newer standard is the ability to make error corrections on single transactions instead of requiring re-transmission of entire batches. Another upgrade will prepare the program for the interstate sharing of PMP data. By the end of 2012, the Board anticipates providing data from multiple states in response to a single query.

MN Board Adopts Rules for Pharmacy Technicians

The Minnesota Board of Pharmacy adopted many significant rule changes concerning pharmacy technicians that address their registration, training and educational requirements, and the duties that they may perform.

Language has been added that clarifies that an "individual may not, under any circumstances," perform tasks

as a pharmacy technician prior to being registered as a pharmacy technician. The Board notes that this requirement has always been in place since the Board first started registering technicians. However, after years of issuing warnings to pharmacies for allowing individuals to work as pharmacy technicians without being registered, the Board has recently started initiating disciplinary proceedings against pharmacies with unregistered technicians.

Effective January 1, 2012, the minimum age for registration as a pharmacy technician will increase from 16 to 18. In addition, effective January 1, 2013, the Board will not issue an initial pharmacy technician registration to any individual who has not either graduated from high school or received a general educational development (GED) certificate.

Effective January 1, 2013, the Board will not renew the registration of a pharmacy technician who was initially registered after January 1, 2012, 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.

In addition, a pharmacy technician's registration renewal for calendar year 2014 will not be issued unless the technician has completed 20 hours of approved continuing pharmacy technician education during the two-year period between August 1, 2011 and July 31, 2013. The Board also adopted a change that clarifies that pharmacy technicians may not take new

prescription orders off of an answering machine or other interactive voice response system.

A more detailed review of the rule changes is available on the Board's Web site at www.pharmacy.state.mn.us/rulemake2010.htm.

MN Board Updates Rules Concerning Partitions in Counseling Areas

The Minnesota Board of Pharmacy has modified rules concerning patient counseling areas to include recommendations concerning the dimensions and characteristics of partitioned counseling areas. If a pharmacy uses partitions to create a consultation area in which the patient will typically remain standing, the partitions must be sound-dulling and at least seven feet high and 24 inches deep. A patient must be able to enter the partitioned area so that the partitions are on each side of the patient.

The Board notes that it may approve consultation areas without partitions if the consultation area will provide a reasonable assurance of privacy. Pharmacists must have access to patient profiles in order to comply with counseling requirements. All new and remodeled pharmacies must meet the new standards. A pharmacy licensed before January 1, 2011, must meet the new standards within two years of that date unless the pharmacy has an existing counseling area that has been deemed by the Board to provide a reasonable assurance of privacy.

More information about the rule change is available on the Minnesota Board of Pharmacy Web site at www.pharmacy.state.mn.us/rulemake2010.htm.

NC Requires Patient ID to Dispense CS II and Some CS III Drugs

The North Carolina General Assembly passed new legislation, S474 (Session Law 2011-349), that requires pharmacists to obtain a valid identification prior to dispensing any Schedule II controlled substance or certain Schedule III controlled substances, effective March 1, 2012. Valid identification may include a driver's license, a special Department of Transportation-issued identification card, military identification card, or passport. The Schedule III controlled substances that require identification are the combination products identified in North Carolina code, NCGS §90-91(d)(1) – (8) (eg, Vicodin® and its equivalents).

Pharmacists are required to "retain this identifying information on the premises or at a central location apart from the premises as part of its business records for a period of three years." Pharmacists are also required to make identifying information available to those persons legally authorized to access the North Carolina Controlled Substance Reporting System (CSRS) within 72 hours of a request. The statute specifies that this availability requirement may be satisfied by submitting identifying information

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nabp newsletter

State Board News

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to the CSRS electronically. However, officials at the Drug Control Unit of the North Carolina Department of Health and Human Services (which administers the CSRS) report that the system is not configured to receive such information and offers no timeline as to if or when such capability will exist.

In addition, the statute specifies that the person seeking dispensing of a covered controlled substance does not have to be the same person to whom the prescription was issued. However, whoever seeks to obtain the prescription must present one of the authorized forms of identification.

More information is included in the October 2011 *North Carolina Board of Pharmacy Newsletter*, available at www.nabp.net/publications/assets/NC102011.pdf.

VA Amends Proof of Identity Requirements

The 2011 Virginia General Assembly has amended the Drug Control Act regarding proof of identity when filling prescriptions. The bill amends the statute to allow an agent of the pharmacist to perform certain acts, describe information to be collected by the pharmacist or his agent, and reduce the documentation retention period from one year to one month.

In addition, the bill is written that a pharmacist, or his agent, shall require proof of identity at the time of delivery

from any person seeking to take delivery of any drug listed in Schedule II pursuant to a valid prescription unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed in Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. If the person seeking to take delivery of the Schedule II drug is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID, but no documentation is required. This amendment took effect July 1, 2011.

More information regarding Virginia's proof of identity requirement is available in the subsequently amended Guidance Document 110-11, available on the Board of Pharmacy's Web site at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

NV Board Reminders Regarding Safe Injection Practices

Effective October 1, 2011, Nevada Senate Bill 419 requires pharmacists and

intern pharmacists to practice in compliance with the Centers for Disease Control and Prevention guidelines concerning safe and appropriate injection practices. The Nevada State Board of Pharmacy notes that because many pharmacists are now giving immunizations, the new law is appropriate. To comply with the new law, the Board encouraged pharmacists to visit www.OneandOnlyCampaign.org to access and watch the 13-minute video called "One Needle, One Syringe, Only One Time."

In addition, Nevada pharmacists will also need to provide a "self-certification" to attest they have complied with the law by checking a box and signing their biennial renewal application. The Board notes that a study just completed on the influence of pharmacists in the dissemination of H1N1 influenza vaccine in Palm Beach, FL, concluded that pharmacists can be an integral part of the nation's "first line resource" for health and wellness and can extend the reach for public health initiatives.

SD Board May Require Technician Education and Certification

During the September 16, 2011 South Dakota State Board of Pharmacy meeting, Board staff presented changes and additions to rules pertaining to registered pharmacy technicians that would require mandatory education and certification for pharmacy technicians. Points for discussion included dates for adoption; defining technician-in-training and

responsibilities; and potential grandfather clauses for technicians with tenure. Updates on the Board's decision will be available on the South Dakota State Board of Pharmacy Web site at <http://doh.sd.gov/boards/pharmacy>.

SD Board Mandates Weekly PMP Reporting

The South Dakota State Board of Pharmacy began mandatory weekly reporting for its prescription drug monitoring program (PDMP) on December 12, 2011. Retroactive reporting from July 1, 2011, must be submitted by February 15, 2012. The Board staff will be able to generate patient profiles by the end of January. The Board anticipates that online access for data query by pharmacists and prescribers will be available by the end of February.

The Board of Pharmacy has selected Health Information Designs (HID) as the vendor for data collection, data storage, and data reporting for the PDMP. HID provides this service to 13 other states including North Dakota and Minnesota. HID provided all South Dakota pharmacies with instructions to access the Dispenser's Implementation Guide for the PDMP. The guide serves as a step-by-step implementation and training guide to prepare pharmacies for mandatory data submission to the program. Additional information about the South Dakota PDMP is available on the Board's Web site at <http://doh.sd.gov/boards/pharmacy>.[©]

FDA Recommends Sterile Needle and Syringe for Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that “inactivated influenza vaccines that are approved by the FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration.” Further, FDA clarifies its October 21, 2011 communication “to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector.” FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.

- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by the FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.

DEA Clarifies Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address “processing integrity” as set forth in the regulations.

Further, DEA recommends that where questions or gaps may arise in reviewing a particular application, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800–53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA’s Web site at www.deadiversion.usdoj.gov/ecommm/e_rx/thirdparty.htm#approved. Detailed background information is provided in the *Federal Register* notice, available for download at www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf.

Regulatory Authority Over Compounding Pharmacies Resides with Boards of Pharmacy, Federal Judge Holds

In the case of *United States v Franck’s Lab, Inc*, US District Court for the Middle District of Florida ruled that FDA does not have jurisdictional authority over the compounding of medications by a licensed pharmacy as long as the pharmacy’s activities are not manufacturing. Judge Timothy Corrigan held that regulatory authority over compounding pharmacies rests with individual state boards of pharmacy. The case was

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Around the Association Executive Officer Changes

William Rubenstein, JD, is serving as the Connecticut commissioner of consumer protection. Prior to his current position, Rubenstein was a partner in the law firm of Axinn, Vetrog & Harkrider, LLP, where he served as the firm’s managing partner and ethics officer. He also served on legal teams representing Connecticut in the Antitrust and Consumer Protection units of the Office of the Attorney General. Rubenstein is immediate past chair of the Antitrust Section of the Connecticut Bar Association, a Life Fellow of the James W. Cooper Fellows of the Connecticut Bar Foundation, and has taught several law-related courses.

Eric Lacefield, MBA, is serving as the executive director of the Georgia State Board of Pharmacy. Prior to joining the Board, Lacefield was a director in the Clayton County Government. He was also the deputy city manager for the city of Villa Rica, GA, and has experience working in the private sector in engineering and project management. Lacefield earned his bachelor of science degree in civil engineering from Iowa State University and a master’s degree in business administration from Clark Atlanta University.

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Professional Affairs Update

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brought against pharmacist Paul Franck by FDA, with the argument that the use of active pharmaceutical ingredients in compounding veterinary drugs for non-food-producing animals was illegal. Judge Corrigan ruled, however, that the Federal Food, Drug, and Cosmetic Act of 1938 did not grant FDA authority over compounding pharmacies. Specifically, Corrigan held that FDA lacks the authority “to enjoin the long-standing, widespread, state-regulated practice of pharmacists filling a veterinarian’s prescription for a non-food producing animal by compounding from bulk

substances.” Additional details are available in an International Academy of Compounding Pharmacists press release available for download at www.iacprx.org/site/DocServer/U.S._District_Court_Rules_Favorably_for_Pharmacy_Compoun.pdf.

Report Explores Drug Shortage Causes, Impact, and Proposed Solutions

A report on the growing shortage of life-saving cancer drugs presents some possible reasons for shortages, the impact of the problem, and solutions being explored, and stresses that regulators and lawmakers have not identified the cause of the shortage. According to the report from Reuters, many

patients must use drugs other than the one recommended for their diagnosis and some must delay treatment. Peter Lurie, a senior adviser in the FDA Office of the Commissioner, told Reuters that “There appear to be multiple factors that are playing in it and it’s very difficult to identify which one is most important.” Sandra Kweder, deputy director of the FDA’s Office of New Drugs, indicates that over half of immediate shortages in 2010 were due to product quality and “significant” manufacturing problems such as metal shavings found in vials or fungal contamination.

Another possible reason for shortages is lack of incentive for manufacturers to produce generic drugs, Reuters reports. In

addition to the impact on patient treatment, “gray market” distributors exploit shortages, selling drugs to hospitals at increased prices. Proposed solutions include:

- creating a national stockpile for emergency injectables
- offering tax incentives for manufacturers of low-cost but life-saving products
- introducing a bill that would require manufacturers to inform FDA of anticipated shortages

A Government Accountability Office report on the topic was released in November 2011. The Reuters article can be accessed at www.reuters.com/article/2011/10/14/us-drugs-shortages-idUSTRE79D4GI20111014. ©



NEWLY ACCREDITED DMEPOS FACILITIES

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

Allstar Pharmacy Inc
Flushing, NY

eRxCity Corp
New York, NY

Jolly’s Pharmacy
Renton, WA

K&K Pharmacy
Liberty, NY

Medicap Pharmacy
Memphis, TN

Old Main Pharmacy
Pembroke, NC

Orchard Diabetic Services
North Canton, OH

Ppc-RX
Counce, TN

The Medicine Shoppe Pharmacy
Concord, NC

Tucker Drugs
Hoboken, NJ

A full listing of the nearly 1,000 accredited DMEPOS companies representing more than 29,000 facilities is available on the NABP Web site at www.nabp.net. ©

Around the Association

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Board Member Appointments

- **John Cotter, RPh,** has been appointed a member of the Alaska Board of Pharmacy. Cotter's appointment will expire on March 1, 2013.
- **Stephanie O'Neal, PD,** has been appointed a member of the Arkansas State Board of Pharmacy. O'Neal's appointment will expire on June 30, 2017.
- **Joyce Palla** has been appointed a public member of the Arkansas State Board of Pharmacy. Palla's appointment will expire on June 30, 2017.
- **James Cangelosi, RPh,** has been appointed a member of the Connecticut Commission of Pharmacy. Cangelosi's appointment will expire on April 15, 2016.
- **Ronald Sherman** has been appointed a public member of the Delaware State Board of Pharmacy. Sherman's appointment will expire on December 31, 2012.
- **Jay Galloway, MS,** has been appointed a public member of the Delaware State Board of Pharmacy. Galloway's

appointment will expire on February 1, 2014.

- **Matthew Maher** has been appointed a public member of the Delaware State Board of Pharmacy. Maher's appointment will expire on March 21, 2014.
- **Chad Ullom, RPh,** has been appointed a member of the Kansas State Board of Pharmacy. Ullom's appointment will expire on April 30, 2015.
- **Joseph Bruno, RPh,** has been appointed a member of the Maine Board of Pharmacy. Bruno's term will expire on March 4, 2014.
- **Paul Chace, RPh,** has been appointed a member of the Maine Board of Pharmacy. Chace's appointment will expire on March 3, 2014.
- **Courtney Oland, RPh,** has been appointed a member of the Maine Board of Pharmacy. Oland's appointment will expire on August 11, 2013.
- **Donald Watson, RPh,** has been appointed a member of the Maine Board of Pharmacy. Watson's appointment will expire on July 20, 2014.
- **Shane Savage, RPh,** has been appointed a member of the Maine Board of Pharmacy. Savage's appointment will expire on March 23, 2014.

- **Patricia Harney** has been appointed a public member of the Michigan Board of Pharmacy. Harney's appointment will expire on June 30, 2015.
- **Nichole Penny, RPh,** has been appointed a member of the Michigan Board of Pharmacy. Penny's appointment will expire on June 30, 2015.
- **Suit Hing Moy-Sandusky, RPh,** has been appointed a member of the Michigan Board of Pharmacy. Moy-Sandusky's appointment will expire on June 30, 2015.
- **Patricia Smeelink, RPh,** has been appointed a member of the Michigan Board of Pharmacy. Smeelink's appointment will expire on June 30, 2015.
- **Phyllis Stine, BS,** has been appointed a member of the Texas State Board of Pharmacy. Stine's appointment will expire on August 31, 2017.

Board Member Reappointments

- **LuGina Mendez-Harper, RPh,** has been reappointed a member of the New Mexico Board of Pharmacy. Mendez-Harper's reappointment will expire on July 1, 2016.
- **Hao Tran, RPh,** has been reappointed an extended member of the

New York State Board of Pharmacy. Tran's reappointment will expire on September 30, 2016.

- **Richard Zeitoun, RPh,** has been reappointed an extended member of the New York State Board of Pharmacy. Zeitoun's reappointment will expire on September 30, 2016.

Board Officer Changes

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

- **Jeannine Dickerhofe, RPh,** President
- **Mary Arceneaux, RPh,** Vice President

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

- **Geoffrey Christ, RPh, Esq,** President
- **Joli Martini, PharmD,** Vice President

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

- **Richard de Blaquiére, PharmD,** Chairperson
- **Berk Fraser, RPh,** Vice Chairperson

The New Mexico Board of Pharmacy has elected the following officer to the Board:

- **LuGina Mendez-Harper, RPh,** Secretary 



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