newsletter

National Association of Boards of Pharmacy®

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the profession
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1904 to 2015

Upcoming Events

October 6-7, 2015
Tri-Regulator Symposium
Arlington, VA

October 13-14, 2015
NABP Interactive Executive Officer Forum
Northbrook, IL

November 2-13, 2015
PARE Administration

November 4-6, 2015
NABP/AACP District 4 Meeting
Milwaukee, WI

November 17-18, 2015
Task Force on the Implementation of VPP
NABP Headquarters

December 1-2, 2015
NABP Interactive Compliance Officer and Legal Counsel Forum
Northbrook, IL

States Continue to Modify Compounding Laws and Regulations to Implement DQSA Provisions

As Food and Drug Administration (FDA) has continued implementing Title I of the 2013 Drug Quality and Security Act (DQSA), states have been modifying their laws and regulations addressing drug compounding to accommodate the changes in federal law. A number of states took action on this front in 2014 and the activity has continued into 2015.

Outsourcing Facilities

The DQSA largely leaves the states in charge of regulating compounding that occurs as a result of a prescription order of a licensed medical practitioner for an identified individual patient. Prescriptions for interstate distribution that exceed certain caps may be subject to FDA regulations, the specifics of which are still being finalized.

The DQSA also impacts regulation of those facilities that engage in "office use" compounding, in which compounded, non-patient-specific medications are provided to a health care facility or practitioner's office, and which over the years developed into a large-scale, interstate business under unclear regulatory jurisdiction. Office use compounding was previously permitted in some states, though now this generally runs afoul of the new federal law. In essence, the DQSA and the amendments made to the Federal Food, Drug, and Cosmetic (FD&C) Act establish that pharmacies or other facilities that engage in "office use" compounding may do so legally only if they register with FDA as an outsourcing facility.

Because outsourcing facilities form a new regulatory category, they are not addressed in state laws or regulations that predate the DQSA; one of the purposes

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of the legislation being passed in several states is to add the category.

In North Dakota, for example, Senate Bill (SB) 2086, signed into law in April 2015, establishes the new category of "outsourcing facility," and specifies the circumstances under which a facility is permitted to provide a compounded human-use drug preparation without a patient-specific prescription. Non-patient-specific drug compounding is allowable only if the compounding entity is registered with FDA as an outsourcing

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In This Issue . . .

The *NABP Newsletter* (ISSN 8756-4483) is published 10 times a year by the National Association of Boards of Pharmacy® (NABP®) to educate, to inform, and to communicate the objectives and programs of the Association and its 66 member boards of pharmacy to the profession and the public.

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Compounding

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facility pursuant to section 503(b) of the FD&C Act, and if the entity is licensed as an outsourcing facility in North Dakota and has designated a licensed pharmacist in the state of residence as the responsible person on the license. Compounding facilities must, moreover, provide inspection reports, any FDA reports of objectionable conditions, and product distribution lists within 48 hours of a request from the North Dakota State Board of Pharmacy; the facility must also comply with those labeling and record-keeping requirements contained in section 503(b) of the FD&C Act.

In New Hampshire, SB 202-FN, signed into law in June 2015, likewise establishes outsourcing facilities, as defined in the FD&C Act section 503(b), as a licensing category and requires them to obtain a license from the New Hampshire Board of Pharmacy. The law also establishes interim requirements for outsourcing facilities, including compliance with FDA and Drug Enforcement Administration (DEA) regulations and guidelines, mandated testing of finished drug products compounded from bulk ingredients, and test-validated proof of sterility for sterile compounding. The law also directs the New Hampshire Board to adopt rules addressing such areas as application procedures, licensure standards, fees, inspections, dispensing, and record keeping. The state legislature notes that its intent is to make additional changes as necessary in the future to bring state regulations in line with as-yet-to-be-finalized federal guidelines.

Virginia's House Bill 1737, approved by Governor Terry McAuliffe in March 2015, also adds a formal definition of outsourcing facilities to the state code, establishes a regulatory framework to issue permits to those facilities located within the state, and creates an exemption to existing rules regarding confidentiality in order to allow information sharing with federal authorities in certain circumstances. It also contains provisions to register nonresident outsourcing facilities that do business in Virginia. The law adds language allowing some non-patient-specific compounding for some medical practitioners "if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations," and allows office use compounding for provision to veterinarians.

Oklahoma lawmakers added outsourcing facilities to their state laws as well. Oklahoma SB 787, approved by Governor Mary Fallin in May 2015, amends various portions of the Oklahoma Pharmacy Act, including the Oklahoma State Board of Pharmacy's power to issue licenses to outsourcing facilities, and to issue sterile compounding and drug supplier permits to pharmacies. The law refers to outsourcing facilities in its definition of "drug outlet," and defines the facilities in accordance with the FD&C Act. Resident and nonresident outsourcing facilities must be licensed as such by the Oklahoma Board, and outsourcing facilities that dispense prescriptions must be also licensed as a pharmacy. All facilities must undergo an inspection prior to licensure. While the fee is capped for in-state applicants, out-of-state applicants are required to reimburse the Board for "actual expenses incurred" for inspections.

Compounding for Office Use

State actions dealing with compounding and bringing state policies into harmony with federal laws do not stop with inclusion of outsourcing facilities in state statutes. In Oklahoma, for example, in mid-2015 the Board of Pharmacy sent out notice to all pharmacies with parenteral permits compounding sterile drugs informing them that the state rule allowing the compounding of non-patient-specific sterile drugs for sale to physician offices or hospitals had been revoked, effective August 2015, and that to continue in such activities would require licensure as an outsourcing facility by FDA and, after November 2015, by the Oklahoma Board as well.

The Louisiana Board of Pharmacy adopted an emergency rule, effective

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Compliance Officers, Legal Counsel, and Surveyors to Gather for NABP Interactive Forum in December

Provides Opportunity to Reconnect, Recharge, and Revitalize Partnerships

As part of the fall 2015 NABP Interactive Forum series, themed "Reconnect, Recharge, Revitalize – Strengthening Board of Pharmacy Collaboration," NABP will be hosting a forum on December 1-2, 2015, tailored specifically to board of pharmacy compliance officers and legal counsel. In addition, the annual NABP surveyor workshop will be held at the same time and surveyors will be participating in some of the forum sessions.

The NABP Interactive Compliance Officer and Legal Counsel Forum will provide an opportunity for attendees to meet with their peers and discuss regulatory trends and challenges faced by their boards. Programming will also include breakout sessions specific to each of the three groups – legal counsel, compliance officers, and surveyors. By combining the surveyor workshop with the forum, NABP surveyors will have the chance to learn directly from board of pharmacy compliance officers, inspectors, and investigators what some of their typical duties and challenges entail.

Invitations to attend the NABP Interactive Compliance Officer and Legal Counsel Forum will be sent to board of pharmacy executive officers in October. Each executive officer may select one compliance officer from his or her board and one attorney who serves as the board's legal counsel to participate in the forum.

Like the October 2015 Interactive Forum that will be held for board of pharmacy executive officers, travel, hotel accommodations, and meals will be paid by NABP and there is no registration fee for the meeting.

The goal of the Interactive Forums is to facilitate interaction among boards from the across the country and provide closed sessions to discuss important and timely issues related to pharmacy regulation. With the success of past forums and the eagerness of board of pharmacy staff and members to reconvene with their peers, the series returns this year to continue a partnership to protect public health through collaboration.

The Compliance Officer and Legal Counsel Forum is held biannually, alternating with the forum geared toward board members, which will return in fall 2016.

Both forums will take place at the Hilton Chicago/Northbrook in Northbrook, IL. For more information about the forums, please contact NABP Executive Office at exec-office@nabp.net, or at 847/391-4406.

Newly Accredited Vet-VIPPS Facility

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

Rood & Riddle Veterinary Pharmacy, LLC
www.rrvp.com

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

Executive Committee

Joseph L. Adams
Chairperson
One-year term

Edward G. McGinley
President
One-year term

Hal Wand
President-elect
One-year term

Jeanne D. Waggener
Treasurer
One-year term

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

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

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

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

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

John A. Foust
Member, District 6
Serving first year of a three-year term

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

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

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

Evidence of Ebriety

By Dale J. Atkinson, JD

The issue of determining whether a licensee (or applicant) maintains the physical and mental capabilities to safely and effectively practice the profession can be a challenging undertaking by a regulatory board. Arguably, only an evaluation conducted by a professional versed in the relevant field can provide credible insight into one's physical or mental well-being. More specifically, determining whether licensees suffer from impairments related to alcohol and drug abuse is equally daunting.

Boards of pharmacy must first ascertain whether they have the statutory authority to require a licensee or applicant to undergo a physical and/or mental evaluation. Further complicating matters is the ownership of the records related to the evaluation and issues regarding privacy and confidentiality. In Iowa, the relevant administrative rules define impairment as "the inability of a pharmacy professional to practice pharmacy with . . . reasonable safety and skill as a result of alcohol or drug abuse, dependency, or addiction, or any neuropsychological or physical disorder or disability." Consider the following.

A pharmacist (Licensee) had been licensed since 2010. Based upon records obtained by the Iowa Board of Pharmacy (Board), the Licensee worked for a chain drug store and lived in a hotel within walking distance of the pharmacy. His weekly paychecks were sent to his mother who apparently managed his money and provided him with an allowance. In October 2011, the Licensee was charged with operating a vehicle while intoxicated. In January 2012, the Licensee pled guilty to the charges and was sentenced to either 48 hours in jail or completion of a treatment program for addiction. Later that month, an employment supervisor contacted the Board to inquire if the Licensee had self-reported the operating while intoxicated conviction. The Licensee had not self-reported and, when eventually questioned by the Board, stated that he thought he was not required to report until he applied for renewal of his license.

In February 2012, the Board initiated an investigation of the Licensee. The supervisor reported to investigators that the Licensee "had exhibited problems with short-term memory loss, personal hygiene, and wearing of unclean clothes to work." The supervisor also provided a written report whereby he "noticed [ketone] smell on [Licensee's] breath on many occasions, indicating heavy drinking the night before," and that there had been "second hand reports of public intoxication on [two] occasions." In June 2012, the Board issued a confidential order for evaluation and required the Licensee to schedule this examination within 10 days. The evaluation was to address the Licensee's physical and mental condition and his ability to safely practice pharmacy. Under Iowa code, licensees are under a duty to submit to a physical, mental, or clinical competency examination upon probable cause and as directed by the Board.

In July 2012, the Licensee objected to the confidential order arguing that the Board did not have probable cause to mandate the evaluation. A hearing was held in March 2013, during which the Licensee submitted an evaluation completed by an assessment counselor. The evaluation, based upon an interview with the Licensee, indicated that there

was a low probability of a substance abuse disorder. The Board issued an order in April 2013 rejecting the objections and finding that probable cause existed to require the physical and mental evaluation. It found that credible evidence related to showing up to work with signs of heavy drinking the night before, memory loss, personal hygiene, and soiled clothing at work substantiated the directive to obtain an evaluation. The Board did not accept the counselor evaluation, noting the counselor had not been approved by the Board, the Board had no prior notice of the evaluation, and such evaluation was limited in scope to substance abuse. In May 2013, the Licensee filed a petition for judicial review. After a December 2013 hearing, the District Court affirmed the Board order and rejected the objections of the Licensee. Thereafter, this appeal followed.

The Court of Appeals addressed the standard of review noting that the Licensee argued that the Board order is not supported by substantial evidence. Substantial evidence is defined by statute as:

> The quantity and quality of evidence that would be deemed sufficient by a neutral, detached, and reasonable person, to establish the fact at issue when the consequences resulting from the establishment of that fact are understood to be serious and of great importance.

As with any profession, however, the interests of the public in ensuring the competence of licensees is paramount and the board authority must be recognized.

The Licensee maintains that substantial evidence does not support the decision in large part based upon the Board rejection of the "expert evaluation." He argued that the Board relied upon hearsay or secondhand evidence continued in the reports (signs of heavy drinking, reports of public intoxication) rather than the evaluator analysis. As noted by the court, the credibility of witnesses falls within the purview of the Board. The court does not reassess the evidence or make its own determinations as to the weight given to differing evidence. Related to the counselor's report, the court noted the limited scope of the evaluation based upon the limited facts provided. The rejection of the report was not based upon the qualifications (or lack thereof) of the counselor. The Board is not required to accept expert testimony "when the factual basis for those opinions is incomplete or inaccurate."

The court noted that probable cause in an administrative proceeding is the same as that of a criminal proceeding. In short, the Board must have a "reasonable ground for belief" that the Licensee had an impairment. Based upon the record, the court could sustain the reasonableness of the determinations of the Board. Based upon the foregoing, the court affirmed the lower court and upheld the Board's determination of probable cause and order requiring the Licensee to undergo a comprehensive mental and physical evaluation.

There is a fine line between the rights of the board to enforce the state's practice act and relevant laws and the rights of licensees seeking to protect the property interest in the board-issued credential. Mental health and physical evaluations implicate significant confidentiality issues. As with any profession, however, the interests of the public in ensuring the competence of licensees is paramount and the board authority must be recognized.

Doe v. Iowa Board of Pharmacy, 2014 Iowa App. LEXIS 1145 (App. Ct. IA 2014)

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

Compounding

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June 2015, that restored the capability of pharmacists to perform office use compounding for veterinarians. Following the DQSA's successful passage in late 2013, the Board had amended its rules to disallow pharmacies from compounding non-patient-specific preparations; FDA later clarified that the DQSA applies to compounding drugs for human use.

The State of Ohio Board of Pharmacy updated its guidance on compounding in mid-2015, summarizing compounding requirements. FDA-registered outsourcing facilities doing business in Ohio must be licensed in the state, for example, and pharmacies engaged in patient-specific compounding must adhere to United States Pharmacopeia (USP) Chapters <795> and <797>. In-state pharmacies may compound drugs for direct administration by a prescriber under certain circumstances. Out-of-state compounding pharmacies must submit documentation to show compliance with Ohio regulations, as well as a recent inspection report, but are never allowed to compound drugs for direct administration by a prescriber unless the compounder is registered as an outsourcing facility.

In Nebraska, Legislative Bill 37, approved by Governor Pete Ricketts in March 2015, adds language dealing with compounding to the state's Pharmacy Practice Act, although it does not reference outsourcing facilities. Compounding provisions include the requirement to compound in compliance with the USP <795> and <797> standards. Echoing DQSA strictures affecting outsourcing facilities, the law prohibits compounding any drugs that have been identified by FDA as withdrawn or removed from the market for reasons of safety or efficacy; it also prohibits compounding a drug that is a copy of an approved drug, unless the Board of Pharmacy has declared a drug shortage, or if the patient has an allergic reaction to the approved drug. In a departure from recent legislation in other states, the Nebraska law allows compounding to occur not only on the medical order of a health care practitioner, or for purposes of research, teaching, or chemical analysis, but also "for office use only and not for resale."

Many state legislatures continue to modify their state regulations addressing compounding in order to bring them in line with federal laws. NABP will continue to provide updates on the topic.

An overview of compounding-related laws passed in 2014 is available in the article "States Pass New Legislation for Oversight of Compounding Facilities" in the September 2014 *NABP Newsletter.*

2016 PARE Administration Dates Announced; This Year's Final Testing Window to Be Held November 2-13, 2015

The 2016 testing windows for the Pharmacist Assessment for Remediation Evaluation® (PARE®) will be as follows:

- February 9-20, 2016
- June 7-18, 2016
- September 13-24, 2016
- November 29-December 10, 2016

The next available PARE testing window is scheduled during the two-week time period of November 2-13, 2015. Member boards of pharmacy are encouraged to take advantage of this web-based assessment that was created to assist the boards as part of their decision-making process when considering cases of remediation or brief departures from practice. Beginning with the November 2-13 testing window, boards of pharmacy will have the option to administer the examination remotely. NABP has contracted with a remote proctoring organization, facilitating a secure, proctored test session for the PARE. More information and detailed instructions on this new feature will be provided to the boards in late October 2015.

To pre-register an individual for any of the above-mentioned PARE testing windows, boards of pharmacy may use the NABP Clearinghouse via NABP e-Profile Connect, or they may contact the NABP Competency Assessment department via email at NABP_Comp_Assess@nabp.net.

More information about PARE may be found in the Programs section of the NABP website at *www.nabp.net.*

President McGinley Appoints Members to Serve on 2015-2016 Standing Committees and Three Single-Issue Task Forces

NABP provides guidance on current topics of interest to the state boards of pharmacy through the commissioning of single-issue task forces. When an issue arises that requires special expertise or a commitment of time and funds, a task force is appointed to address an explicit charge and to report its findings to the NABP Executive Committee. When finalized, task force reports are published on the NABP website. For 2015-2016, NABP has commissioned three single-issue task forces pertaining to the following topics:

- pharmacist prescriptive authority;
- regulation of pharmacist care services; and
- implementation of the Verified Pharmacy Program™ (VPP™).

NABP President Edward G. McGinley, MBA, RPh, has finalized his appointments for the following task forces and standing committees for this year.

2015-2016 Task Forces

The **Task Force on Pharmacist Prescriptive Authority** met on September 1-2, 2015, at NABP Headquarters. The task force was established in response to Resolution No. 111-4-15, passed at the NABP 111th Annual Meeting. The resolution states that the purpose of the task force is to explore the need for and feasibility of all states granting pharmacists limited prescriptive authority in order to meet existing and future patient health care needs.

The task force was charged with the following objectives:

1. Review existing state laws and regulations addressing pharmacists' prescriptive authority and relevant *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* language.
2. Recommend revisions, if necessary, to the *Model Act* addressing this issue.
3. Propose key messages that should be conveyed to boards of pharmacy, key stakeholders, and the public about the patient care benefits of granting pharmacists limited prescriptive authority.

Chairperson of this task force was Dennis Wiesner, RPh, member, Texas State Board of Pharmacy.

Individuals appointed to serve as members included:

- Kerstin Arnold, JD, Texas
- Thomas F.X. Bender, Jr, RPh, New Jersey
- Timothy Fensky, RPh, FACA, Massachusetts
- Cathy Hanna, PharmD, RPh, Kentucky
- Virginia Herold, MS, California
- Leo Lariviere, RPh, Rhode Island
- Cathryn J. Lew, RPh, Oregon
- Michael A. Podgurski, RPh, Pennsylvania
- Joyce Tipton, MBA, RPh, Texas
- Cynthia "Cindy" Warriner, RPh, Virginia

Kenneth Saunders, PharmD, RP, of Nebraska served as an alternate. The Executive Committee liaison was James T. DeVita, RPh.

The **Task Force on the Regulation of Pharmacist Care Services** met on September 9-10, 2015, in Rosemont, IL. The task force was established in response to Resolution No. 111-6-15, passed at the NABP 111th Annual Meeting. The goal of this task force is to assist boards of pharmacy in oversight and regulation of pharmacist care outside the traditional pharmacy setting by recommending amendments to the *Model Act*.

The task force was charged with the following objectives:

1. Review existing state laws and regulations pertaining to the provision of pharmacist care outside of the traditional pharmacy setting.
2. Review, and if necessary, recommend revisions to the *Model Act* to assist boards of pharmacy in the oversight and regulation of pharmacist care services outside of the traditional pharmacy setting.

Chairperson of this task force was Joel Thornbury, RPh, member, Kentucky Board of Pharmacy.

Individuals appointed to serve as members included:

- Allison Benz, MS, RPh, Texas
- Reginald "Reggie" Dilliard, DPh, Tennessee
- Kamlesh "Kam" Gandhi, PharmD, RPh, Arizona
- John Marraffa, Jr, RPh, New York
- Dennis K. McAllister, RPh, FASHP, Arizona
- Lenora Newsome, PD, Arkansas
- Phyllis Stine, BS, Texas
- Barbara Ellen Vick, RPh, North Carolina

The Executive Committee liaison was Hal Wand, MBA, RPh.

The **Task Force on the Implementation of VPP** is scheduled to meet on November 17-18, 2015, at NABP Headquarters. The task force was developed to discuss how best to work with the state boards of pharmacy to help implement VPP into their inspection processes.

The task force is charged with the following objectives:

1. Review the status of VPP and the crosswalk of standards and inspection forms with existing state requirements and inspection forms.
2. Recommend, if necessary, revisions to the VPP standards and policies.
3. Propose key messages and strategies for providing VPP to all states in order to achieve uniformity and consis-

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Committees, Task Forces

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tency in the critical areas identified by VPP and the states.

Chairperson of this task force is Anthony Rubinaccio, RPh, executive director, New Jersey State Board of Pharmacy.

As of press time, individuals appointed to serve as members include:

- Kelly Barnes, JD, RPh, Massachusetts
- Gay Dodson, RPh, Texas
- Caroline D. Juran, RPh, Virginia
- Daniel Kelber, JD, Illinois
- Edward Maier, RPh, Iowa
- Tamara McCants, PharmD, RPh, District of Columbia
- Brenda McCrady, PD, Arkansas
- Nichole Penny, RPh, Michigan
- Mark St Cyr, DPh, Oklahoma
- Matthew R. Wetzel, New Jersey

Katie Busroe, RPh, of Kentucky, and George Lovecchio of Louisiana will serve as alternates. The Executive Committee liaison is John A. Foust, PharmD, DPh.

2015-2016 Standing Committees

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

The **Committee on Law Enforcement/Legislation** will meet on January 20-21, 2016, near NABP Headquarters. The committee is charged with the following tasks:

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

David W. Dryden, JD, RPh, executive director, Delaware State Board of Pharmacy, will serve as the committee chairperson. As of press time, committee members include:

- Buford Abeldt, Sr, RPh, Texas
- Jim Bracewell, BBA, Georgia
- Amy Buesing, RPh, New Mexico
- Diane Halvorson, RPhTech, CPhT, North Dakota
- Mark Hardy, PharmD, RPh, North Dakota
- LuGina Mendez-Harper, PharmD, RPh, New Mexico
- Pam Reed, RPh, Louisiana
- Steven W. Schierholt, Esq., Ohio
- Theresa Talbott, RPh, Pennsylvania

Michael Lonergan, RPh, of Kansas will serve as an alternate. The Executive Committee liaison is Jack W. "Jay" Campbell IV, JD, RPh.

The **Committee on Constitution and Bylaws** will meet by teleconference in April 2016. The charge of this committee, as defined by the NABP Constitution and Bylaws, is to review proposed amendments to the Constitution and Bylaws, suggest changes where appropriate, and issue a recommendation for each proposed amendment.

Patricia Smeelink, RPh, member, Michigan Board of Pharmacy will be the committee chairperson. As of press time, committee members also include:

- Lee Ann Bundrick, RPh, South Carolina
- Robert Carpenter, RPh, Vermont
- Tejal Patel, PharmD, RPh, Delaware
- Jim Spoon, DPh, Oklahoma

Christopher Dembny, RPh, and L. Suzan Kedron, JD, both of Texas, and Kilee Yarosh, RPh, of Ohio will serve as alternates. The Executive Committee liaison is Richard B. Mazzoni, RPh.

Newly Accredited DMEPOS Facility

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

Places for People Pharmacy
St Louis, MO

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

NABP Now Accepting Nominations for 2016 Awards to Be Presented at the 112th Annual Meeting in San Diego

NABP is currently accepting nominations for individuals or boards of pharmacy who represent the Association's mission to protect the public health. The awards will be presented at the NABP 112th Annual Meeting, to be held May 14-17, 2016, in San Diego, CA.

Nominations are currently being accepted for the following awards: 2016 Lester E. Hosto Distinguished Service Award (DSA), 2016 NABP Honorary President, 2016 Fred T. Mahaffey Award, and 2016 John F. Atkinson Service Award.

Lester E. Hosto DSA

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

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

Honorary President

To be considered for the position of honorary president, nominees must meet the following criteria:

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

Individuals submitting nominations for the honorary president must be from an active or associate member board.

Fred T. Mahaffey Award

This award is named after the late NABP Executive Director Emeritus Fred T. Mahaffey, who held the executive director position from 1962 to 1987. His leadership and contributions to NABP, state boards of pharmacy, and the protection of the public health were significant, and established NABP as one of the leading pharmacy organizations. The award recognizes boards of pharmacy that have made substantial contributions to the regulation of the practice of pharmacy over the past year.

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

John F. Atkinson Service Award

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

How to Submit Nominations

Individuals interested in submitting nominations are asked to fill out and complete a nomination form, which may be accessed by visiting the Meetings section of the NABP website, *www.nabp.net*. Directions for electronic and hard copy submission of the fillable PDF are provided on the online form.

Nominations for these awards must be received no later than December 31, 2015. The NABP Executive Committee will review the nominations and select the honorary president and award recipients.

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

Henry Cade Memorial Award

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

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

NABP Seeks Individuals to Serve on Advisory Committee on Examinations

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

ACE typically convenes three to four times per year to oversee the development and administration of all NABP examination and certification programs. In addition, ACE considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

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

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

Open positions on ACE are determined by the current composition of the committee and in accordance with NABP policy. Each ACE appointment is for a three-year term beginning June 1, 2016.

Interested individuals are asked to submit a written statement of interest and a current résumé or curriculum vitae to NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Drive, Mount Prospect, IL 60056 or execoffice@nabp.net no later than December 31, 2015.

Please contact the NABP Competency Assessment department at NABP_Comp_Assess@nabp.net with any questions regarding ACE.

VPP Utilization Increases Volume of Verified Data Available to Boards

Launched to help state boards of pharmacy communicate and share critical licensure and inspection information, the Verified Pharmacy Program™ (VPP™) is now being utilized in some manner by 48 member boards. Some member boards require or recognize VPP inspections as meeting nonresident inspection requirements, and boards are also using VPP to review and share their own state inspection reports.

Developed by NABP in conjunction with the state boards of pharmacy, VPP is accessed through NABP e-Profile Connect, and on July 15, 2015, a new VPP interface was launched making it easier to navigate and providing access to additional data. The system also allows the boards the capability to upload and view their own state inspection reports. Additionally, when requested, NABP has been able to provide training services to some boards through use of the VPP inspection form.

As an extension of NABP's existing pharmacist licensure transfer system, VPP is meant to serve as an enhancement to existing licensure processes by facilitating data sharing capabilities among the states. With the increased utilization by the boards of pharmacy, NABP anticipates an increase in the volume of inspection reports included in NABP e-Profile Connect. Further, VPP inspection services are being utilized by third parties, such as United Compounding Management (UCM). Third parties recognize the standardization and uniformity that boards of pharmacy and NABP are building through VPP, and UCM requires a VPP inspection as part of its accreditation process for compounding pharmacies. When such third parties utilize VPP inspections, member boards benefit from the increased volume of information available in VPP.

At press time, at least 324 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies. Of the 324 VPP facilities:

- 137 pharmacies engage in nonsterile compounding;
- 41 pharmacies engage in sterile compounding;
- 103 pharmacies engage in both sterile and nonsterile compounding;
- 40 pharmacies are general retail or mail-order pharmacies;
- 2 pharmacies are nuclear pharmacies; and
- 1 pharmacy is an outsourcing facility.

For more information about VPP, contact the NABP Accreditation department at vpp@nabp.net or visit the Programs section of the NABP website at *www.nabp.net.*

Task Force Convened to Examine Regulation of Pharmacist Care Outside the Licensed Pharmacy, Review *Model Act*

The state boards of pharmacy license pharmacies as part of their mission to regulate the practice of pharmacy and thereby protect the public health – but what happens when pharmaceutical care happens outside the pharmacy? In recent years, changes in technology and in the health care landscape have allowed the provision of pharmaceutical care to move increasingly outside the walls of the traditional (and regulated) pharmacy. The Task Force on the Regulation of Pharmacist Care Services, established pursuant to Resolution 111-6-15 passed at the NABP 111th Annual Meeting, examined this issue when it convened on September 9-10, 2015.

In recent years, one major area of change involves larger pharmacies becoming increasingly centralized with numerous tasks segmented, including drug utilization review (DUR), order entry, and final safety checks, which can take place at locations quite remote from the location where a medication is actually dispensed.

But beyond technology-enabled changes in dispensing models, the practice of pharmacy has been going through other changes. The health care field has seen an increased focus on pharmacist provision of medication therapy management (MTM) in its myriad forms, and the inclusion of pharmacists in integrated health care teams, with their attendant benefits. Pharmacists have been offering an expanding number of pharmaceutical care services that go far beyond dispensing and its related components.

Most of the non-dispensing services are not new, but for a variety of reasons they are moving into the mainstream in a way not previously seen. Those activities grouped under MTM, as well as pharmacist involvement as part of a health care team, have both repeatedly been shown to lead to better patient outcomes and decreased overall health care costs. MTM services include immunizations, medication therapy reviews, diabetes (and other disease state) management, pharmacotherapy consults, anticoagulation monitoring, health and wellness programs, and a host of other services. Not coincidentally, pharmacists are more often being looked to as an important element in the struggle to make quality health care available in medically underserved areas or populations, all the more so because of current and projected critical shortages in primary care practitioners. NABP member boards, mindful of these benefits, passed Resolution 111-5-15, "Providing Education About the Role of the Pharmacist and Pharmacist Care Services" at the 111th Annual Meeting, which instructs the Association to help educate the public and other health care professionals about these valuable pharmaceutical care services.

Many pharmacist advocates feel that this growth in pharmaceutical care services, noticeable though it is, is being held back by pharmacists' difficulty in being reimbursed for those activities by third-party payers. Several pharmacy-related industry and professional associations are pushing federal legislators to formally recognize pharmacists as health care providers under Medicare Part B, as a current bill in Congress, House of Representatives 592, proposes to do. (NABP does not hold an official position on the reimbursement issue.) Federal recognition of pharmacists as health care providers, should it occur, would likely further speed the expansion of pharmaceutical care services like MTM. Advocates pushing such change in status feel that it would not only allow for expansion in many underserved areas, but would encourage many third-party payers to cover pharmaceutical care services, with associated increase in the rate of growth.

As reflected in the proposal and passage of Resolution 111-5-15, these pharmaceutical care developments may be positive, but they also raise challenges from a regulatory perspective. Like centralized DUR or final checks, pharmaceutical care services may take place in locations other than a licensed pharmacy, including such settings as a hospital, a physician's office, a community health center, or even a pharmacist's or patient's home. As the American Pharmacists Association notes on their MTM Central web page, "Pharmacists provide medication therapy management services in all care settings in which patients take medications."

In short, a state's existing pharmacy laws and regulations may not precisely fit the evolving pharmaceutical care landscape. Currently, the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* contains only limited language that specifically addresses "provision of pharmacist care outside of a licensed pharmacy," and largely relates to record-keeping requirements. In order to provide more guidance to states that may need to adjust their laws or regulations, the Task Force on the Regulation of Pharmacist Care Services recommended amendments to the *Model Act*, which will be reviewed by the Committee on Law Enforcement/Legislation and ultimately the NABP Executive Committee.

For details about the task force's charge and makeup, see "President McGinley Appoints Members to Serve on 2015-2016 Standing Committees and Three Single-Issue Task Forces" on page 187.

PMP InterConnect Steering Committee Meeting Held; Nearly 70% of State PMPs Attend, Discuss Governance and Policy Direction

With nearly 70% of all state prescription monitoring programs (PMPs) in attendance, the NABP PMP InterConnect® Steering Committee convened on July 15-16, 2015, in Northbrook, IL, to provide governance and policy direction as it relates to the implementation of the program. During the meeting, discussions were led on how best to strengthen the network and facilitate data sharing, improve data reliability, integrate PMP data into the health care workflow, and address policy matters. In addition, with approximately one-third of the group being new to the Steering Committee meeting, including newly participating state PMPs and state PMPs not currently connected to the program, a brief overview of the PMP InterConnect program was provided.

PMP InterConnect Version Upgrades

Appriss, Inc, NABP's technology provider for PMP InterConnect, continues to work closely with the Association and participating state PMPs with upgrading the current software version utilized by all PMP InterConnect participants – application programming interface (API) Version 4. During the July meeting, Appriss provided a reminder overview of the API Version 4 feature enhancements that were requested by state participants to meet user needs. Such upgrades include new role-based permissions for requesting patient data and new response codes that give PMP users more specific details about the status of their PMP request.

Currently, all but one of the participating PMPs utilize API Version 3. The majority of states will be transitioning into Version 4 by November 2015. Also during the July meeting, the Steering Committee discussed features they would like to see with API Version 5. Of note, the Steering Committee expressed interest in proceeding to modify the PMP InterConnect home page in order to provide additional information to the public. Other desired features include access to dashboard statistics, charts, and analytics within the console and email notifications that alert users when a PMP is not available to PMP InterConnect.

Enhancing Interoperability

In addition to providing software updates that will help streamline and enhance prescription drug data sharing, the Steering Committee was presented with an overview on PMP Gateway, the service that facilitates integration of interstate PMP data into the health care workflow of third-party entities, including electronic health records and pharmacy management systems. Such workflow integrations make it easier for providers to access interstate PMP data and potentially increase the rate of use of the data.

Additional Agenda Topics

Also during the July meeting, the Steering Committee briefly discussed its plans to continue working with the Bureau of Justice Assistance (BJA) to comply with the Prescription Monitoring Information Exchange (PMIX) architecture to facilitate interstate data sharing. It was explained that NABP has been continuing to work with BJA to allow for modifications to the architecture to include PMP InterConnect. Compliance with the PMIX architecture will give additional PMPs the option to utilize PMP InterConnect as their preferred data sharing solution.

In addition, the Steering Committee discussed the types of barriers that prevent some states from sharing PMP data with other states that are connected to PMP InterConnect, new PMP research projects, and new state legislation that may provide additional PMP InterConnect growth and opportunities.

Committee Overview

Composed of representatives of PMPs that have agreed to participate in the PMP InterConnect program, the Steering Committee serves as the governing body of the program. The committee is tasked with discussing and making recommendations to the operation of the program, including dispute resolution procedures, entry and exit requirements for participation, data security, recommendations for best practices for state PMPs to facilitate interstate sharing, and other policy matters. The committee meets at least once per calendar year, in person or by teleconference.

Currently, there are 31 members on the committee, which consists of representatives from those states that have signed a memorandum of understanding (MOU) with NABP. Additional members will join as they execute an MOU with NABP. Four states/jurisdictions have MOUs under review.

The Steering Committee is expected to meet by teleconference later this year. The next in-person Steering Committee meeting is scheduled for July 20-21, 2016.

More information about PMP InterConnect, including the most up-to-date information on state participation, is available in the Programs section of the NABP website at *www.nabp.net.*

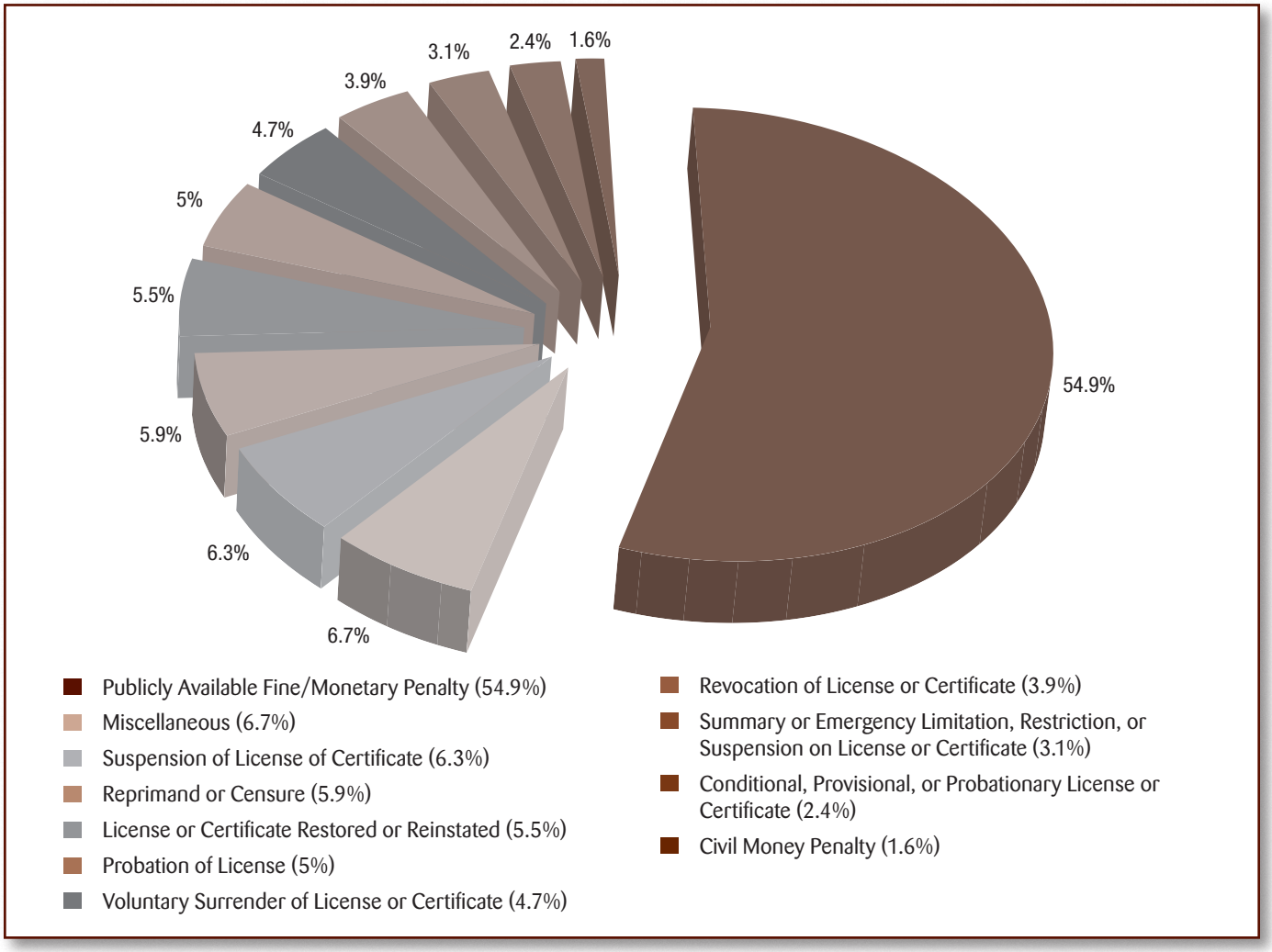
Boards of Pharmacy Report 1,914 Disciplinary Actions to the NABP Clearinghouse During Second Quarter 2015

During the second quarter of 2015, the state boards of pharmacy reported a total of 1,914 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacy technicians, pharmacy interns, pharmacies, wholesalers and manufacturers, and other licensees. Of the 1,914 actions:

- 835 actions (43.6%) were taken on pharmacies;
- 723 actions (37.8%) were taken on pharmacists;
- 255 actions (13.3%) were taken on pharmacy technicians;
- 38 actions (1.9%) were taken on other licensees;
- 28 actions (1.5%) were taken on wholesalers and manufacturers;
- 17 actions (0.9%) were taken on pharmacy interns;
- 17 actions (0.9%) were taken on mail-order pharmacies; and
- 1 action (0.1%) was taken on a controlled substance licensee.

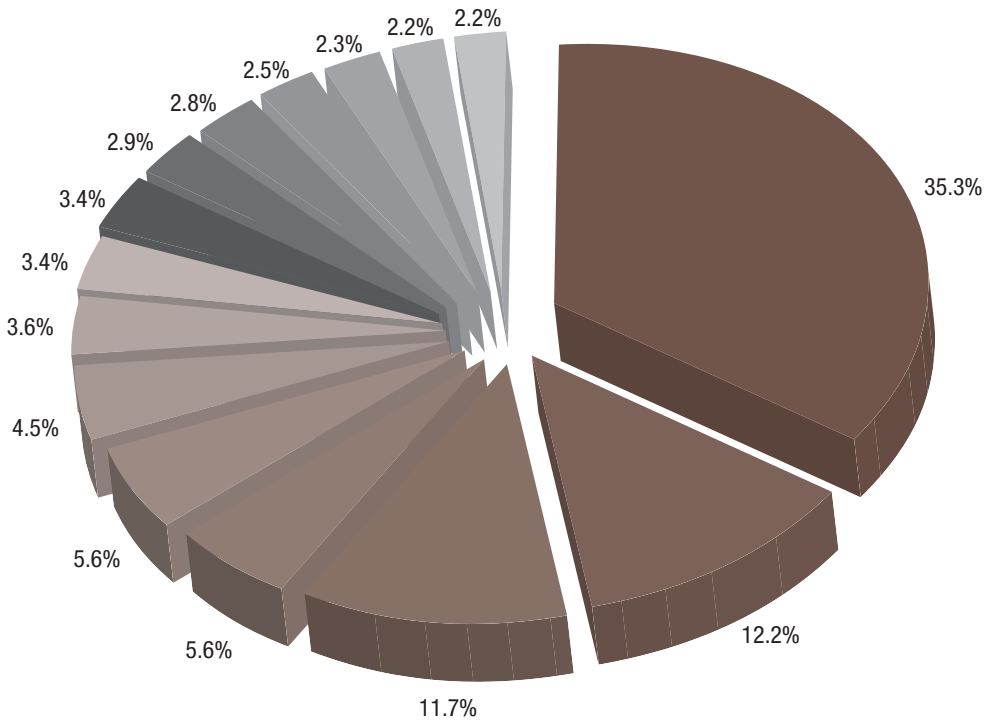
For a full breakdown of the actions taken and the bases for actions taken during second quarter 2015, see Figure A and Figure B. Additional information about the NABP Clearinghouse is available under Member Services in the Programs section of the NABP website at *www.nabp.net.*

Figure A: Disciplinary Actions Reported During Second Quarter 2015



*The miscellaneous category includes; denial of initial license or certificate; denial of license renewal; directed in-service training; directed plan of correction; extension of previous licensure action; limitation or restriction on license; interim action – agreement to refrain from practice during investigation; modification of previous licensure action; on-site monitoring; other licensure action – not classified; and voluntary limitation or restriction on license.

Figure B: Bases for Disciplinary Actions Reported During Second Quarter 2015



*The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; disruptive conduct; diverted conviction; drug screening violation; failure to comply with patient consultation requirements; failure to cooperate with board investigation; failure to disclose; failure to maintain equipment/missing or inadequate equipment; failure to maintain supplies/missing or inadequate supplies; failure to meet the initial requirements of a license; financial insolvency; immediate threat to health or safety; improper or abusive billing practices; improper or inadequate supervision or delegation; inadequate or improper infection control practices; inadequate security for controlled substances; inappropriate refusal to treat; incompetence; lack of appropriately qualified professionals; misappropriation of patient property or other property; misbranding drug labels/lack of required labeling on drugs; misleading, false or deceptive advertising or marketing; negligence; nolo contendere plea; operating beyond scope of license; other licensure action – not classified; other unprofessional conduct; practicing beyond the scope of practice; sexual misconduct; unable to practice safely; unable to practice safely by reason of physical illness or impairment; unable to practice safely due to psychological impairment or mental disorder; and violation of or failure to comply with licensing board order.

.Pharmacy TLD Initiative to Expand Focus on Public Outreach in US and Abroad

Now that the .pharmacy Top-Level Domain (TLD) is operational, NABP has turned its focus to outreach among consumers, stakeholders, and regulators both in and outside the United States.

In its April 30, 2015 meeting report, approved by the NABP Executive Committee in August, the .Pharmacy Supporter Advisory Committee emphasizes the importance of raising awareness about the .pharmacy TLD. This recommendation was made in the context of an overview of NABP's consumer outreach efforts and successes to date, which have included television, radio, and online transmission of public service announcements in the US, as well as internationally distributed consumer news releases.

Until the start of General Availability, the final launch phase, on June 3, 2015, NABP has focused its attention on operationalizing the .Pharmacy TLD Program. In the current phase, NABP is increasing its communications with its advisory committees and its outreach to consumers and to international regulators.

The advisory committee encourages NABP to reach out to additional boards of pharmacy in the US and schools and colleges of pharmacy in Canada to encourage them to register and use .pharmacy domain names. Currently, 33 .pharmacy domain names have been registered to NABP's member and associate member boards of pharmacy. Several additional boards have expressed interest in registering a .pharmacy domain name but either have not yet formally requested a name or have not yet registered their approved domain name. NABP continues to reach out to the remaining boards of pharmacy to encourage and assist them in registering .pharmacy domain names, as well.

The advisory committee suggested that NABP also reach out to schools and colleges of pharmacy. Currently, 138 schools of pharmacy are affiliated with International Pharmaceutical Federation (FIP), and a few national or regional federations of schools of pharmacy are members of FIP. It was suggested that NABP draft a brief document explaining the value, process to apply, and cost, as well as inclusion and exclusion criteria for a school of pharmacy applying for a .pharmacy domain name. FIP has offered to distribute this information through channels including the schools of pharmacy affiliated with FIP.

The advisory committee encourages NABP to explore questions of strategy relating to the integration of .pharmacy at the national level in various countries, in the context of existing laws and regulations in those countries. This recommendation was made in the context of an overview of NABP's current and potential international partnerships. For instance, representatives of NABP, the Alliance for Safe Online Pharmacies, and the European Alliance for Access to Safe Medicine recently met with regulators and stakeholders in the European Union (EU). Much attention is being given to the EU's implementation of the "Common Logo," an image that must be posted on all websites selling medicine online in EU member states to show that they are appropriately licensed to operate there. The advisory committee members advised NABP to continue exploring opportunities to dovetail the .pharmacy initiative with requirements for the common logo in EU member states.

Advisory committee members with international ties said they would work to help other regulators understand the process of implementing .pharmacy and suggested giving presentations about .pharmacy at upcoming international conferences, holding out implementation of .pharmacy in the US as a model for how the program works.

Advisory committee members observed that feedback received about .pharmacy in other countries has been primarily positive, although questions remain about how it would function in the various countries. For instance, a common question has focused on how .pharmacy will be adaptable to each country without imposing US standards, or, how those countries could introduce .pharmacy in a way that will be acceptable to the regulators there.

Additionally, the advisory committee recommended that NABP explore opportunities to optimize search engine results for .pharmacy domain names. Committee members noted that high search engine rankings would be a strong way to start to bring Internet users searching for pharmacy-related key words to a safe place. NABP recognizes the value in search engine optimization for .pharmacy domain name registrants and for consumers alike, and will explore these tactics further in the near future.

On the recommendation of the .Pharmacy Executive Board and the approval of the NABP Executive Committee, the .Pharmacy Supporter Advisory Committee has divided into two separate committees, one composed of regulators, the other composed of registrants and supporters. The advisory committees convened again in late August to push ahead with public outreach efforts following the successful program launch.

More information about the .pharmacy initiative, including a list of approved entities with registered .pharmacy domain names, is available at *www.safe.pharmacy.*

AWAR$_X$E Resources Available to Help Educate Attendees at Community Events

Did you know that resources are available to help educate your patients and community about the dangers of prescription drug abuse and misuse? The AWAR$_X$E® Prescription Drug Safety Program has flyers and posters on a variety of topics available to download and print online at *www.AWARERX.ORG*, as well as PowerPoint presentations with presenter notes available via email request (AWARERX@NABP.NET). Topics include medication safety, proper drug disposal, prescription drug misuse and abuse dangers, and the safe online acquisition of medication.

If you have taken the AWAR$_X$E pharmacist's pledge to fight against prescription drug abuse (found on the Pharmacists page on AWAR$_X$E's website), then you know that AWAR$_X$E provides 10 ways to implement the pledge. One way is to host an educational event in your community.

Success Story

Vanessa LeSure-Walker, RPh, is a pharmacist who has hosted events in her community with help from the AWAR$_X$E program's flyers.

LeSure-Walker started hosting educational events at the end of last year and AWAR$_X$E flyers have been an integral part of her presentations and resource tables. Given her 17 years as a pharmacist, LeSure-Walker was familiar with NABP, so she decided to reach out to AWAR$_X$E to see if the program could assist in providing professional materials for her presentations. LeSure-Walker felt that if she was going to start holding presentations to educate her community about safe medication use, she needed the help of an organization or program "whose credibility [she] could borrow from to help get the word out." AWAR$_X$E was the perfect solution.

The presentations have been held in the New York City area and attracted groups of many sizes, from 10 to 100 people. Locations have included churches, nonprofit organizations, and community centers. LeSure-Walker has noticed that event attendees are "both excited and curious" to learn about medication safety and all that pharmacists provide beyond simply handing a patient medication. Presentations give pharmacists a chance to highlight their skills, while helping to prevent the misuse and abuse of prescription drugs. LeSure-Walker noted that "being able to use the flyers helps to break the ice, because you have something that people not only need but want."

Getting Started

How did LeSure-Walker start the process of holding presentations? Her advice: "Determine your target audience. You may relate to a particular group; identify who they are and where they are, then start reaching out to them." It could be as easy as reaching out to the local volleyball team that you play with or your book club members. Host an event at your pharmacy for your patients. Do you live in a condo building? Contact building management to see if you can hold a presentation for your neighbors. Get creative!

Start small until you become comfortable with hosting presentations. If you are nervous about speaking in front of groups, you could partner with a colleague to hold an event. Set up a table for questions and provide the flyers as a resource, or use AWAR$_X$E's PowerPoint presentations for a more formal event. The accompanying talking points will give you the details on the slide content and help answer questions that you may be asked.

AWAR$_X$E is here to help, so take advantage of the materials that are just a click away. To learn more, visit the Resources section of *www.AWARERX.ORG*.

Pharmacist Distributes AWAR$_X$E Flyers to Share Prescription Drug Safety Information

The AWAR$_X$E® Prescription Drug Safety Program offers many resources to help individuals and groups educate their communities about prescription drug misuse and abuse, proper drug disposal, purchasing medications safely online, and other prescription drug safety topics. Pictured left, Vanessa LeSure-Walker, RPh, utilizes AWAR$_X$E flyers available at *AWARERX.ORG* during an educational event to help further spread her message.

Around the Association

Executive Officer Changes

- **Shauna White, PharmD, RPh**, is serving as the inspector/interim executive director of the District of Columbia Board of Pharmacy, replacing Patricia D'Antonio, MS, MBA, RPh, CGP.

Board Member Appointments

- **Julia Wheatley** has been appointed a public member of the Delaware State Board of Pharmacy. Wheatley's appointment will expire January 1, 2018.
- **Richard Mazzotti, RPh**, has been appointed a member of the Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy. Mazzotti's appointment will expire April 1, 2019.
- **Kristal Williams, PharmD, RPh**, has been appointed a member of the Indiana Board of Pharmacy. Williams' appointment will expire March 31, 2019.
- **John Wilson, JD**, has been appointed a public member of the Indiana Board of Pharmacy. Wilson's appointment will expire March 31, 2019.
- **Philippe Bouvier, RPh**, has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Bouvier's appointment will expire May 31, 2020.
- **Andrew Stein, PharmD, RPh**, has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Stein's appointment will expire May 31, 2020.
- **Cynthia Boston, BHS, RPhT**, has been appointed a member of the Michigan Board of Pharmacy. Boston's appointment will expire June 30, 2018.
- **David Hills** has been appointed a public member of the Michigan Board of Pharmacy. Hills' appointment will expire June 30, 2019.
- **Kurt Henn, PharmD, RPh**, has been appointed a member of the Minnesota Board of Pharmacy. Henn's appointment will expire January 7, 2019.
- **Clayton Farmer, RPh**, has been appointed a member of the Mississippi Board of Pharmacy. Farmer's appointment will expire June 30, 2020.
- **Christian Tadrus, PharmD, RPh**, has been appointed a member of the Missouri Board of Pharmacy. Tadrus's appointment will expire June 10, 2020.
- **Michael Bertagnolli, RPh**, has been appointed a member of the Montana Board of Pharmacy. Bertagnolli's appointment will expire July 1, 2020.
- **Mona Chitre, PharmD, RPh**, has been appointed a member of the New York State Board of Pharmacy. Chitre's appointment will expire April 30, 2020.
- **Renee Hofman, MS, RPh**, has been appointed a member of the New York State Board of Pharmacy. Hofman's appointment will expire April 15, 2020.
- **L. Stan Haywood, RPh**, has been appointed a member of the North Carolina Board of Pharmacy. Haywood's appointment will expire April 30, 2020.
- **Eric Strauss, PharmD, RPh**, has been appointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Strauss's appointment will expire June 30, 2020.
- **Cheryl Adams, PharmD, RPh**, has been appointed a member of the Washington State Pharmacy Quality Assurance Commission. Adams' appointment will expire January 19, 2016.
- **Olgy Diaz** has been appointed a public member of the Washington State Pharmacy Quality Assurance Commission. Diaz's appointment will expire January 19, 2017.
- **Judy Guenther** has been appointed a public member of the Washington State Pharmacy Quality Assurance Commission. Guenther's appointment will expire January 19, 2019.
- **Arundhati Sambataro, MPP**, has been appointed a public member of the Washington State Pharmacy Quality Assurance Commission. Sambataro's appointment will expire January 19, 2018.

Board Member Reappointments

- **Nichole Penny, RPh**, has been reappointed a member of the Michigan Board of Pharmacy. Penny's appointment will expire June 30, 2019.
- **Patricia Smeelink, RPh**, has been reappointed a member of the Michigan Board of Pharmacy. Smeelink's appointment will expire June 30, 2019.
- **Stuart Williams** has been reappointed a public member of the Minnesota Board of Pharmacy. Williams' appointment will expire January 7, 2019.
- **Patricia Gollner, PharmD, RPh**, has been reappointed a member of the Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit. Gollner's appointment will expire November 30, 2019.
- **Penny Reher, RPh**, has been reappointed a member of the Oregon State Board of Pharmacy. Reher's appointment will expire June 30, 2019.

Washington State Passes Overdose Drug, Medication Synchronization Laws

The following legislation addressing opioid overdose medications and medication synchronization passed into law during the 2015 Washington State Legislative Session.

ESHB 1671 – Opioid Overdose Medications went into effect July 24, 2015, and is intended to increase access to opioid overdose medications. Health care providers may administer, prescribe, and dispense, directly or by collaborative drug therapy agreement or standing order, opioid overdose medications to people at risk of experiencing a drug overdose. They may also prescribe or dispense to first responders, family members, or anyone in a position to assist a person at risk. The practitioner must inform the recipient of the opioid overdose prescription that soon after administration, the person at risk must be transported to a hospital or the recipient must call 911 for assistance. The law requires pharmacists who dispense naloxone pursuant to a prescription or protocol order for opioid overdose prevention to provide written instruction on the proper response to an opioid overdose at the time the prescription is dispensed.

ESSB 5441 – Patient Medication Coordination went into effect July 24, 2015, and requires health benefit plans that provide prescription coverage to implement a medication synchronization policy for the dispensing of prescription drugs for the 2016 plan year.

New Jersey Launches PMP Mobile App, Issues Reminder on New Prescription Blank Security Features

The New Jersey Prescription Monitoring Program (PMP) recently completed the development of a new mobile application (app) for Apple devices. The app is located at *https://appsto.re/us/oUv23.i* and is free of charge to New Jersey PMP-authorized users. An Android Mobile version of the app became available this past summer. A Windows Mobile version will soon be available. The app will allow authorized users to receive push notifications about suspicious activity, pharmacy practice updates, or other important notifications.

New Jersey PMP staff has also become aware of an increase in counterfeit prescription blanks in the central New Jersey area. The Board reminds pharmacists that the new prescription blanks implemented in 2014 contain features that are designed to allow for easier identification of counterfeit prescriptions.

Pharmacists who believe a prescription may be counterfeit should verify the prescription with the prescriber; attempt to verify that the phone number is correct, as counterfeit prescriptions may contain altered phone numbers; and if a prescription is determined to be counterfeit, pharmacists should contact their local police department as well as follow-up with the New Jersey PMP. More details are available in the July 2015 *New Jersey State Board of Pharmacy Newsletter.*

Louisiana Adopts Compounding Rule for Office Use by Veterinarians

Following the passage of the federal Drug Quality and Security Act of 2013, the Louisiana Board of Pharmacy revised its compounding rules to conform to the new federal law provisions relative to compounding. Within that rule change, effective January 2015, the authority for pharmacies to compound medications for office use for practitioners was removed from the Board's rules. The Board responded to concerns from the veterinarian community regarding compounding authority with a proposed change in its compounding rules to allow pharmacies to compound medications for office use for veterinarians, and further, to establish a limitation on the amount of such products the pharmacy may distribute: 5% of the total number of dosage units distributed and/or dispensed by the pharmacy as calculated on a monthly basis. With respect to nonresident pharmacies, the 5% calculation applies only to the pharmacy's operations directed to Louisiana. Given that some of the compounded medications required by veterinarians are used in emergency conditions, the Board authorized the adoption of the emergency rule, effective June 1, 2015, while the formal rulemaking process is completed.

Minnesota Implements Immunization Legislation

Effective July 1, 2015, pharmacists are allowed to administer "influenza vaccines to all eligible individuals six years of age and older and all other vaccines to patients 13 years of age and older." The new statutory language requires pharmacists to report the administration of all vaccine doses to the Minnesota Immunization Information Connection (MIIC). Reporting separately to the patient's primary physician is not required. In addition, pharmacists are required to utilize MIIC to "assess the immunization status of individuals prior to the administration of vaccines, except when administering influenza vaccines to individuals age nine and older."

The Minnesota Board of Pharmacy will exercise enforcement discretion and not require pharmacies and pharmacists to immediately begin following the new provisions related to MIIC on July 1, 2015. The Board urges all pharmacies to begin complying with the legislation as soon as possible, following the expectations outlined in the July 2015 *Minnesota Board of Pharmacy Newsletter.*

Acino Products in New Jersey Ordered to Stop Selling Unapproved Products

Under the direction of Food and Drug Administration (FDA), a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in their possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm*.

Baxter International, Inc, Recalls Two Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, Lot Numbers P319921 and P327635, which were distributed to United States customers between October 7, 2014, and July 14, 2015. Baxter is allowing the product to be returned to the company for credit, and customers are advised to contact the company using information provided in an FDA press release available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm*.

Consumers should contact their physician or health care provider if they have experienced any problems that may be related to using these drug products. Health professionals are advised to report adverse events through FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/Safety/MedWatch/default.htm*.

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm*.

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain nonsteroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Reading Medicine Labels Helps Reduce Acetaminophen Overdoses

With half of all acetaminophen overdoses being unintentional, the Acetaminophen Awareness Coalition reminds pharmacists and other health care providers to encourage patients to properly read medicine labels. The coalition's Know Your Dose campaign reminds patients to:

- Read and follow the label
- Check whether a medicine contains acetaminophen
- Take only one medicine at a time that contains acetaminophen
- Talk to their health care providers for questions about dosing

The coalition provides information cards, flyers, and other educational materials to assist health care providers in educating their patients about using medicine labels to find vital acetaminophen safety information. More information and resources are available at *www.knowyourdose.org.*

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