newsletter

National Association of Boards of Pharmacy®

AWARE GET INFORMED. PRESCRIPTION DRUG SAFETY®

September 2013 / Volume 42 Number 8

aid to government
the profession
the public
1904 to 2013

Upcoming Events

September 8-11, 2013
NABP/AACP Districts 6, 7, & 8 Meeting
Boulder, CO

September 16-27, 2013
PARE Administration

September 24-25, 2013
Interactive Executive Officer Forum
Northbrook, IL

September 30, 2013
FPGEE Administration

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

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

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

.PHARMACY Program Moves Closer to Launch

In an important step toward greater online safety for pharmacy consumers, NABP's application to own and operate the .PHARMACY domain suffix passed the Internet Corporation for Assigned Names and Numbers (ICANN) initial approval process in May 2013. With this large hurdle cleared, NABP is laying the groundwork to operationalize the .PHARMACY program while awaiting completion of the final stages in ICANN's evaluation process. Through the work of a .PHARMACY gTLD Advisory Committee that includes international partners, policies and procedures are being finalized, technical processes are under development, and public awareness efforts are in planning. Meanwhile, final steps in the ICANN process consist of executing a registry agreement between NABP and ICANN, and conducting pre-delegation testing to ensure that NABP and its technical partners are able to operate the .PHARMACY domain in a stable and secure manner. NABP aims to establish .PHARMACY as a secure, trustworthy domain, giving consumers worldwide a way to know that the medications they buy online from .PHARMACY sites are authentic and safe.

NABP, with the support of an international coalition of stakeholders, in 2012 submitted an application for the .PHARMACY generic Top-Level Domain, or gTLD. (A gTLD refers to an Internet address's suffix, with best-known examples including .com, .org, .gov, and .edu.) Once approved as the gTLD's registry operator, NABP will ensure all Web site operators that use the .PHARMACY designation are appropriately licensed and legitimate in

©iStockphoto.com/snapphoto

the locations in which they do business, and that they operate in compliance with international as well as country-specific pharmacy standards. NABP intends for the .PHARMACY gTLD to be available for purchase by the pharmacy community – not only pharmacies, but also pharmacy benefit management companies; schools and colleges of pharmacy and continuing professional education providers; wholesale drug distributors; pharmaceuti-

(continued on page 162)

In This Issue. . .

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

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

Carmen A. Catizone
Executive Director/ Secretary

Deborah Zak
Communications Manager

.PHARMACY Update

(continued from page 161)

cal manufacturers; durable medical equipment providers; prescription drug-related patient advocacy groups; prescription drug information sites; and many other pharmacy-related entities. (For more details on gTLDs and NABP's initial application, see "NABP Submits Application to Create and Operate Safeguarded .Pharmacy Domain," in the May 2012 *NABP Newsletter*, available at *www.nabp.net/publications/nabp-newsletters*.)

Setting Up Shop

After a lengthy revision process, ICANN released its new template registry agreement on July 3, 2013, which it needed to finalize prior to initiating contract negotiations with NABP or other new gTLD applicants. In addition to completing the ICANN approval process, before launching the .PHARMACY gTLD, NABP must complete operational preparations for the program.

Early in 2013, NABP convened a .PHARMACY gTLD Advisory Committee meeting to make recommendations regarding a system of governance for the program, core standards that will be required of all .PHARMACY domain registrants, and such issues as defining the domain name registration criteria, authorized usage policy, and compliance/take-down strategy for the domain. The committee also made recommendations regarding public awareness efforts. The advisory committee is made up of international and national institutions and organizations that have supported the .PHARMACY application and other industry experts, including pharmacy regulatory authorities, industry leaders, patient advocacy groups, enforcement authorities, Internet technology experts, and others.

NABP introduced a draft governance document to the advisory committee during the meeting, and the committee continued to share thoughts on the document and other policy matters via an online discussion group. NABP incorporated the group's comments and

(continued on page 166)

NABP Issues Report Emphasizing Deceptive Practices of Illegal Online Drug Sellers Used to Lure Consumers

In the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2013*, NABP emphasized the deceptive practices that illegal online drug sellers use to make consumers believe they are legitimate, safe, and trustworthy. Some examples include sites falsely claiming to be VIPPS® (Verified Internet Pharmacy Practice Sites℠) accredited; sites selling counterfeit versions of brand-name drugs; and sites claiming to be Canadian that dispense prescription drugs without any prescription and sell counterfeit versions of brand-name drugs.

As detailed in the July 2013 report, NABP has reviewed more than 10,500 Web sites and the vast majority of sites (97%) operate out of compliance with pharmacy laws and practice standards established in the United States, and many other developed countries, to protect patient health and are listed as Not Recommended on NABP's consumer protection Web site at *www.AWARERX.ORG*. Of the 10,081 Internet drug outlets currently listed as Not Recommended:

- 4,935 offer foreign or non-Food and Drug Administration-approved drugs
- 8,961 do not require a valid prescription
- 2,372 have a physical address located outside of the US
- 1,181 dispense controlled substances

When purchasing medications online, consumers are encouraged to look for the VIPPS Seal, or check NABP's Recommended Internet pharmacies on the AWAR$_X$E® Web site.

The full report with detailed findings on the characteristics of rogue Web sites, is available in the Get Informed section of the AWAR$_X$E Web site at *www.AWARERX.ORG/get-informed/safe-acquisition/not-recommended-sites*.

Interactive Forums Return: Executive Officers to Unite in September; Compliance Officers and Legal Counsel to Gather in December

This fall, the NABP Interactive Forums return and focus on the theme, "Creating New Tools to Maintain and Enhance Board Authority."

Set to take place September 24-25, 2013, the NABP Interactive Executive Officer Forum will provide board of pharmacy executive officers the opportunity to network with their peers while discussing challenges faced by their boards on a daily basis. The forum will take place over two days and programming will focus on state and federal regulatory updates related to compounding, state compounding inspection updates, an update on the .PHARMACY generic Top-Level Domain, NABP PMP InterConnect®, Verified Pharmacy Program™, and accreditation, as well as panel discussions on reciprocity, practitioner dispensing, and the NABP support services available to boards of pharmacy. In addition, the New Executive Officers Orientation Program will take place the morning of September 24.

In August, NABP invited each board of pharmacy executive officer to attend the Executive Officer Forum at no charge. As with previous forums, travel, hotel accommodations, and meals will be paid by NABP. In addition, there is no registration fee for the meeting.

Following the Executive Officer Forum, on December 3-4, 2013, NABP will hold another forum tailored specifically to compliance officers and legal counsel. Invitations for the NABP Compliance Officer and Legal Counsel Forum will be sent to board of pharmacy executive officers in September. Additionally, NABP plans to hold a forum for board of pharmacy members in fall 2014.

The goal of the Interactive Forums is to facilitate interaction among boards from across the country and provide closed sessions to discuss important and timely issues related to pharmacy regulation.

Committee Members Dedicate Time and Expertise to Review Items for the NAPLEX

North American Pharmacist Licensure Examination® (NAPLEX®) Review Committee members met at NABP Headquarters to examine test questions best suitable to assess the knowledge, judgment, and skills expected for entry-level pharmacists. Pictured above from left to right: William Kehoe, Jr, MA, PharmD, FCCP, BCPS, University of the Pacific, and David W. Newton, PhD, Shenandoah University. Pictured below from left to right: John L. Szarek, PhD, The Commonwealth Medical College and Darla Gallo, RPh, pharmacist, Philadelphia, PA.

Executive Committee

Michael A. Burleson
Chairperson
One-year term

Karen M. Ryle
President
One-year term

Joseph L. Adams
President-elect
One-year term

Edward G. McGinley
Treasurer
One-year term

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

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

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

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

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

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

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

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

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

Policy + Rule = Rulicy

By Dale J. Atkinson, JD

Based upon technological advancements and an increasingly mobile society, professionals are seeking licensure in multiple jurisdictions. Recognition of a state-based licensure system with its genesis in the United States Constitution makes the notion of a uniform licensure system across state lines seem unattainable or at least unlikely in the near future. Of course, NABP was originally created in 1904 with an eye toward mobility of practitioners and a licensure transfer system.

With multiple licenses comes the age-old question of reciprocal discipline. That is, the authority of State B to sanction the same individual based upon an administrative disciplinary action taken by State A. The initial inquiry is whether the State B practice act provides as a basis for the disciplinary action in another state, such as State A. Thereafter, State B must determine what sanction can be imposed, assuming the authority does exist. If the grounds for discipline in the statute provide for the authority of State B to discipline a licensee based upon the final adverse action of State A, State B does not need to "re-prosecute" the licensee. Instead, State B may introduce the final adverse action (order) into the record and proceed directly to the sanction phase of the administrative proceedings. Certain procedural nuances may have to be undertaken, but board counsel can provide guidance in this regard.

Finally, the extent of the sanction(s) must be determined. If grounds exist for the imposition of disciplinary action in State B based upon adverse action taken in State A, the sanction(s) entered may be referred to as reciprocal discipline. In some cases, the board in State B may be tempted to administer *identical* reciprocal discipline. Or, alternatively, the board in State B may feel inclined to *always* impose identical reciprocal discipline. Consider the following.

A pharmacist (Licensee) received her license from the Texas State Board of Pharmacy (Board) in 1987. In 1992, she received her North Carolina license through reciprocity where she practiced pharmacy. In 2007 and a few weeks after her marriage, her husband died in a car accident. Near the one-year anniversary of his death, the Licensee became so intoxicated that she had to be hospitalized for alcohol poisoning. On the advice of a colleague, the Licensee self-referred to the North Carolina Pharmacist Recovery Network (NCPRN). In January 2009, the Licensee voluntarily entered into a monitoring contract with the NCPRN.

The Licensee failed to comply with the terms of her monitoring contract and eventually came under the scrutiny of the North Carolina Board of Pharmacy. In 2010, the North Carolina Board suspended her North Carolina license finding that she "indulged in the use of drugs to an extent that renders [her] unfit to practice pharmacy" and "developed a physical or mental disability that rendered her unfit to practice pharmacy with reasonable skill, competence and safety to the public." The North Carolina order required that only the NCPRN may monitor her recovery and must advocate on her behalf to qualify for licensure reinstatement.

The Licensee returned to Texas to live with her father as she lacked the means to support herself in North Carolina, had lost her home to foreclosure, and had no family or support system in North Carolina. Based upon the active suspension in North Carolina, the Texas Board instituted disciplinary proceedings against the Licensee. The Board filed an administrative motion for summary disposition arguing that the Texas statute allows for discipline based upon

the North Carolina action; that the violations in North Carolina were, as a matter of law, substantially equivalent to conduct described under Texas law; and that the appropriate sanction was a suspension period in Texas to run concurrently with the North Carolina suspension.

The administrative law judge, after an evidentiary hearing, recommended a five-year probated suspension. The administrative law judge further held that the Licensee was "not seeking to evade compliance with the reinstatement provisions of the North Carolina order, but only to avoid the considerable financial hurdles she would face to achieve that compliance." The Texas Board adopted all of the administrative law judge findings without modification. However, "in keeping with the Board's previously articulated policy that a pharmacist with an active suspension in another state cannot practice pharmacy in Texas," the Board rejected the administrative law judge recommended sanction and instead suspended her license until such time as the North Carolina license was reinstated. The Texas Board also required the Licensee to simultaneously be monitored by the Texas Pharmacist Recovery Network even though the NCPRN and Texas Pharmacist Recovery Network both require physical presence at meetings and screenings.

The Licensee filed for judicial review in the Texas trial court. The trial court found that an enforced suspension of the license was arbitrary and capricious. The trial court also found that the Board used an unwritten reciprocal sanctions policy that, in reality, was an improper *ad hoc* rule enforced without following the relevant rulemaking procedures of the Administrative Procedures Act (APA). The trial court reversed the indefinite suspension and remanded the matter to the Board to determine an appropriate sanction consistent with the court order.

The Texas Board appealed the matter to the appellate court, arguing that the sanction order was not arbitrary because the Board has the exclusive authority to impose penalties and the sanction was within such authority. Further, the Texas Board order was consistent with the statutory provisions that automatically deny licensure to new applicants who are subject to an active suspension in another state, as well as consistent with Board policy, practice, and precedent of imposing reciprocal sanctions on Texas licensees disciplined in other states.

The appellate court reviewed the authority of the Texas Board to discipline pharmacists for acts that violate the Texas laws or based upon discipline in another state if such acts are substantially equivalent to Texas violations. The court also recognized the variety of sanction options available to the Board including revocation, suspension, probated action, and licensure restrictions. The court next identified the fact that the Board "formally promulgated rules setting forth guidelines to be considered in assessing sanctions for violations of the [practice act]." The guidelines are intended to protect the public, deter future violation, and promote consistent sanctions for similar violations.

While the court noted that the Texas Board had the authority to discipline the Licensee, the issue to be determined on appeal was whether the imposition of a concurrent suspension with the North Carolina suspension resulted from the improper application of a rule, as defined in the APA. As cited by the court, a rule not promulgated under mandatory APA procedures is invalid. Thus, the court directed its attention to the "non-binding policy, practice, or precedent of imposing reciprocal sanctions on Texas licensees who have been disciplined by licensing authorities of other states . . . "

Among other contentions, the Texas Board argued that the policy was not a rule. The Licensee argued that the policy falls squarely within the APA definition of a rule. The court noted that to constitute a rule, "an agency statement interpreting law must bind the agency or otherwise represent its authoritative position in matters that impact personal rights." According to the court, the Texas disciplinary order, coupled with the

(continued on page 166)

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

.PHARMACY Update

(continued from page 162)

recommendations into the draft governance document, and the Association's Executive Committee reviewed and approved the document in mid-2013. The advisory committee will hold a follow-up meeting via teleconference later in 2013. Meanwhile, NABP is in the process of finalizing baseline standards that each .PHARMACY registrant will have to meet and is working closely with entities such as the International Pharmaceutical Federation in establishing *ad hoc* national standard-setting committees that will help to define supplementary specifications appropriate to particular geographic areas.

Further, NABP is working to finalize relationships with partners to assist in such areas as the initial screening of applicants, the domain name registration process, and the provision of a Web-based Who-Is service (a public record of all registrants in the gTLD). NABP will also call upon its partners to assist in public outreach and patient education.

Getting the Word Out

NABP is also laying the groundwork for the public outreach needed to raise awareness of the .PHARMACY gTLD and build trust among consumers. Among other efforts, the Association will leverage its AWAR$_X$E® Consumer Protection Program, in particular the program's Web site, *www.AWARERX.ORG*, to launch an awareness campaign. Other stakeholders are encouraged to also use their platforms to spread the word about the .PHARMACY designation and what it means.

Along with details such as the eligibility standards and other information about the registry, NABP plans to develop a "hub" Web site that will provide specifications for the use of the .PHARMACY gTLD, as well as general information for consumers on the program; the risks of purchasing medications online; and the reasons for the .PHARMACY gTLD program. Registrant-specific information will also be provided to enable consumers to learn more about the entities that are approved as .PHARMACY sites.

NABP's application for the .PHARMACY gTLD is unusual in that it does not seek to benefit a commercial interest as do most of the hundreds of new gTLD applicants; instead, it seeks to protect the public health on a global scale. The Internet has internationalized the accessibility of prescription-drug-related goods and services, making regulation increasingly difficult and public health risks increasingly high. NABP has therefore broadened its scope, and with the .PHARMACY gTLD has made a large foray into partnerships on an international level in order to protect the global public health. Entities that establish Web sites with a .PHARMACY domain address will not only buy a Web site name, they will be buying a form of validation that demonstrates to potential customers their legitimacy. Consumers will receive the assurance that these entities meet all applicable regulatory standards, including standards related to pharmacy licensure, drug authenticity, patient care, and valid prescription requirements.

NABP will provide updates as the .PHARMACY gTLD program progresses toward its anticipated launch.

Legal Briefs

(continued from page 165)

evidence developed in the administrative hearing, "leave little doubt that the Board's reciprocal-sanctions policy is a statement implementing, interpreting, or prescribing the agency's policy that affects private rights, has implications beyond the parties to the underlying proceeding, and is, therefore, a rule within the meaning of the APA."

Citing evidence established in the hearings, the court noted that the Texas Board's reciprocal sanctions apply not just to the Licensee at issue, but to all pharmacists licensed in more than one state. In essence, the Board is duty-bound to impose reciprocal discipline without regard to other factors. Further, the court noted the Texas imposed sanction of concurrent compliance with both the Texas and North Carolina PRN conditions, a requirement not reasonably possible, as evidence of the rigidity of the policy in spite of any mitigating circumstances. Finally, the court noted the adoption by the Texas Board of the administrative law judge finding that the Licensee was not seeking to evade compliance of the North Carolina order as further evidence of an application of a rule, not subject to flexibility.

The court distinguished cases cited by the Board and held that "the Board's informally announced reciprocal-sanctions policy constitutes an agency 'rule' as that term is defined in the APA." Accordingly, the appellate court affirmed the lower court and upheld the reversal of the Board sanctions imposed on the Licensee. The matter has been remanded to the Board to determine the appropriate sanctions pursuant to the judicial opinion.

This case presents many interesting issues for NABP member boards to consider when fashioning sanctions against licensees. Of further interest is the issue of reciprocal discipline and the authority of a board of pharmacy to premise reinstatement of a license on the reinstatement of licensure in another state. Of course, this case also focused on distinguishing a policy from a rule and the consequences of applying a policy with little or no flexibility. Regardless, enforcement of concurrent discipline may be the next legal challenge.

Texas State Board of Pharmacy v. Witcher, 2013 Tex. App. LEXIS 5482 (App. Ct. TX 2013)

Association Supports Member Boards With Development of Electronic Resource for Verifying Pharmacy Licensure

State Compounding Pharmacy Inspection Programs Continue

NABP member boards continue efforts to ensure the safety of compounded drug products, including a new initiative undertaken by the Association.

At the request of member state boards of pharmacy, NABP has begun developing an electronic resource to facilitate the sharing of pharmacy licensure and related information among the states. The Verified Pharmacy Program™ (VPP™), scheduled to launch by the end of 2013, will store licensee data and inspection report components in a uniform format. Data will be available to boards of pharmacy with the aim of supporting licensing decisions, of particular interest when boards are considering applications for nonresident licensure. In addition to developing VPP, NABP continues to conduct pharmacy inspections, including surveys of compounding pharmacies, on behalf of the Iowa Board of Pharmacy and in partnership with state agencies in New Jersey.

Verified Pharmacy Program

Relevant data on licensed pharmacies will be stored in VPP in the form of a pharmacy e-Profile. Pharmacy e-Profiles will allow NABP to collect and verify the following information for reporting to the boards of pharmacy:

- Pharmacy licenses (resident and nonresident).
- Pharmacist-in-charge (PIC) licenses (resident and nonresident).
- Disciplinary information.

The pharmacy e-Profile will also indicate whether a qualified inspection has been performed by the resident state or a designated agent.

Information in the pharmacy e-Profiles will be accessible to boards through the Board e-Profile Connect interface. The information will also be proactively reported to boards.

In requesting that the Association initiate the development of VPP, member boards noted that the system would be particularly beneficial when considering applications for licensure from nonresident pharmacies. Under the current system, boards may be asked to make licensing decisions about nonresident pharmacies with incomplete or outdated information. Challenges creating this situation include differing laws and regulations, as well as differing levels of resources from board to board. For example, some boards may not have the fiscal or human resources to conduct the same frequency and type of pharmacy inspections as others with more robust budgets.

To help address the differences in regulatory structure and operations among the boards, VPP will facilitate the sharing of licensure information about pharmacies across the country. Several existing NABP programs and services are the foundation for the development of VPP, including the Electronic Licensure Transfer Program® (e-LTP®); NABP Clearinghouse, which includes disciplinary information; accreditation programs; and inspection services.

In fact, VPP is a natural extension of e-LTP, on which the Association was founded. In developing VPP, the Association is building on the success of e-LTP to create a means for boards to share information pertinent to the licensure of pharmacies. Pharmacy e-Profiles will allow boards to verify that a qualified inspection of the facility has been conducted and its licensure status in other states. A future planned capability is for the pharmacy e-Profiles to be interconnected with e-Profiles for pharmacists and pharmacy technicians. This capability would assist boards in tracking PICs to ensure they meet state requirements, including verifying licensure and reviewing disciplinary information of both resident and nonresident PICs.

The primary impetus for the VPP was the linking of the November 2012 multistate fungal meningitis outbreak to contaminated injectable drugs compounded by the New England Compounding Center (NECC), a tragedy that brought to the forefront the need for boards to be able to verify inspection and other data when licensing nonresident pharmacies. More information about VPP and an application will be available on the NABP Web site by the end of September 2013. In addition to initiating the development of VPP following the NECC compounding tragedy, some member state boards of pharmacy requested NABP's assistance in conducting compounding pharmacy inspections.

Iowa Inspection Program

NABP began conducting pharmacy inspections on behalf of the Iowa Board of Pharmacy in December 2012. As of press time, NABP surveyors have conducted inspections of 384 nonresident pharmacies dispensing drugs to patients in Iowa. Inspections are ongoing across the nation and as such are not consigned to any one state. Aggregate data reports with relevant survey findings are submitted directly to the Iowa Board. Trends from

(continued on page 168)

Pharmacy Inspection Update

(continued from page 167)

the reports were shared by Lloyd K. Jessen, JD, RPh, executive director/drug control program administrator, Iowa Board of Pharmacy, during a continuing pharmacy education session at the NABP 109th Annual Meeting, May 18-21, 2013. (See the 2013 Special Issue of the *NABP Newsletter* for details.) Additional observations from Iowa inspections include the following:

- Compounded products being shipped to states where the pharmacy did not hold a pharmacy license.
- Products being shipped "for office use" to entities that did not hold a pharmacy license in that state.
- Sterile products being improperly labeled.
- Facilities with improperly labeled or expired compounded drugs that were "returned to stock."
- A facility where a cleanroom was identified as ISO Class 7 certified, though it failed to meet the criteria for that designation.
- Air changes per hour did not meet the standards at some facilities and were significantly below the average observed at other pharmacies.

(Cover articles in the May 2013 *NABP Newsletter* and the June-July 2013 *NABP Newsletter* provide additional background and updates on the Iowa compounding inspection program.)

New Jersey Inspections

The state of New Jersey has also requested the assistance of NABP to conduct inspections of New Jersey pharmacies engaged in the practice of compounding. NABP surveyors are assisting the New Jersey Division of Consumer Affairs (Division) with planned inspections, under a contract with the Division and the state's Attorney General Jeffrey S. Chiesa. NABP surveyors began inspections in mid-July 2013. Updates on the program will be provided in future *Newsletters*.

Future Actions

Through the leadership and guidance of its member boards, NABP will continue efforts aimed toward ensuring the safety of compounded medications. At the NABP 109th Annual Meeting in May 2013, members adopted three resolutions pertaining to compounding. Resolution 109-1-13 in particular calls on the Association to encourage boards of pharmacy to reference sterile compounding quality standards, including but not limited to those contained in United States Pharmacopeia Chapter <797>, as the standard for sterile compounding in their state. Further, in accordance with the resolution, NABP will also encourage boards to conduct qualified surveys of pharmacies. NABP will also review its *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* and determine if it is necessary to make amendments addressing the appropriate regulation and inspection of pharmacies engaged in sterile compounding.

The Association will continue to provide updates on actions taken to support member boards in their efforts to strengthen regulation of compounding in order to prevent another incident such as the meningitis outbreak linked to NECC products.

NABP PMP InterConnect Steering Committee Convenes

The NABP PMP InterConnect Steering Committee met at NABP Headquarters August 1-2, 2013, to discuss current operational items, policy considerations, and significant projects. Topics featured during the meeting included an update on Prescription Monitoring Information Exchange architecture, current integration projects, NAR$_x$CHECK®, and an update on the new prescription monitoring program software.

NABP *Model Act* Amended to Address Shared Service Concept, Medication Reuse Programs, and Internet Pharmacy Safety

NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* in its effort to assist the state boards of pharmacy as they work to protect the public health. Changes made to the *Model Act* were incorporated as a result of the Executive Committee-approved recommendations of the Task Force on Pharmacy Practice Technology Systems, the Task Force on Internet Pharmacy Practice, the Task Force on Drug Return and Reuse Programs, and the 2012-2013 Committee on Law Enforcement/Legislation.

As suggested by the Task Force on Pharmacy Practice Technology Systems, the *Model Act* was revised to replace technology-specific language such as "central fill" and "remote dispensing" with shared services conceptual language. These *Model Act* revisions also address accountability in regard to the practice of multi-jurisdictional shared services and revised language notes that the responsibility shall be placed on the pharmacist-in-charge to possess licenses in those states in which services are being performed. A comment was also added to clarify that the licensing of the pharmacist-in-charge should be required until such time when provisions for a multistate licensure system are in place.

Additionally, the *Model Act* was revised based on suggestions from the Task Force on Internet Pharmacy Practice to further enhance public protection against rogue Internet drug outlets. The Committee on Law Enforcement/Legislation approved the task force's suggestions to strengthen penalties for unlicensed practice and prohibit licensees from affiliating with Web sites that may deceive or defraud patients and that violate state or federal pharmacy practice laws and regulations. In addition, amendments were made to clearly define the definition of "practice of pharmacy" so that Web sites accepting and processing prescriptions must obtain a pharmacy license from the states in which they are dispensing drugs to patients. Language was also added stating that if a pharmacy is conducting business over the Internet then they shall be accredited by a program approved by the board.

The Committee on Law Enforcement/Legislation also approved the recommendations of the Task Force on Drug Return and Reuse Programs to revise the *Model Act* to reflect the revised language in the *National Association of Boards of Pharmacy Position Statement on the Return and Reuse of Prescription Medications*. The *Model Act* now includes specific language to address the return and reuse of medications in both community and repository settings to provide guidance to states that have already implemented or will implement legislatively mandated return and reuse repository programs.

Additional revisions to the *Model Act* address appropriate regulation for prescriber dispensing or prescriber drug outlets. The revised language indicates that a licensed practitioner authorized to dispense medication should meet the same standards, record-keeping requirements, counseling, and other requirements applicable to pharmacists.

Lastly, the *Model Act* was amended to clarify language pertaining to telemedicine practices. The updated *Model Act* now provides additional guidance on telemedicine practices, including a clarification that only non-controlled substance legend drugs can be prescribed without a face-to-face physical examination to comply with the federal regulations pursuant to the Ryan Haight Online Pharmacy Consumer Protection Act.

The updated *Model Act* will soon be available for free download in the Publications section of the NABP Web site at *www.nabp.net/publications/model-act.*

District of Columbia Board Wins *Survey of Pharmacy Law* Luncheon Drawing

NABP would like to congratulate the District of Columbia Board of Pharmacy for winning the 2014 *Survey of Pharmacy Law* Luncheon Drawing. The Board was awarded $175 toward a Board member and staff luncheon for returning updates to the *Survey* by the July 22 deadline. These important updates are requested annually by NABP to all the boards of pharmacy for inclusion into each updated *Survey's* issue. NABP would like to thank all boards for their participation, which makes the publication a valuable resource for many.

Revised and published each December, the *Survey of Pharmacy Law* serves as a convenient reference source for individuals seeking an overview of laws and regulations that govern pharmacy practice in 53 jurisdictions. For more information about the *Survey,* visit *www.nabp.net/publications.*

Biosimilars Update: States Develop Legislation In Anticipation of Product Approvals

Following the passage of the Hatch-Waxman Act in 1984, which allowed an abbreviated approval process for follow-on chemical-based medications, generic drugs rapidly entered the marketplace. In sharp contrast, three years after the Biologics Price Competition and Innovation (BPCI) Act of 2009 (enacted in 2010) created an abbreviated pathway for the approval of follow-on biologic drugs, or biosimilars, no such drugs have entered the United States market as the US Food and Drug Administration (FDA) has yet to receive an application seeking biosimilar licensure approval. However, progress, though slow, has occurred.

In the last two years, FDA released four draft guidance documents and has received meeting requests regarding the development of 12 different potential biosimilar products. On the state level, activity on the topic has increased noticeably, as individual states have begun to prepare for the entry of biosimilars into the marketplace by considering legislation governing how and under what circumstances pharmacists may substitute a biosimilar for its reference product.

There are several complex challenges in creating an approval pathway, as discussed in the article, "Paving Approval Pathway for Biosimilars Presents Unique Challenges for FDA," published in the April 2011 *NABP Newsletter*. FDA has noted that "The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured." Unlike small-molecule drugs made through chemical synthesis, biologics are often produced inside living systems such as microorganisms or plant or animal cells, and may be sensitive to small changes in manufacturing conditions or processes that can affect the way the drug functions in a patient's body. Indeed, because follow-on biologics may only be highly similar to the reference product rather than a copy, and because laboratory testing methods may be inadequate to prove similarity to the reference product, they are called "biosimilars," rather than generics.

As part of FDA's efforts to develop the abbreviated approval pathway as mandated by the BPCI Act, the agency released three draft guidance documents in early 2012: *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product,* and *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009.* In April 2013, FDA issued a fourth draft guidance document, *Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.* Overall, the draft guidance indicates that FDA plans to use a risk-based, totality-of-the-evidence approach in evaluating the data submitted in support of a biosimilar's application, and advises that sponsors use a "stepwise" approach when developing evidence to demonstrate biosimilarity.

This approach, FDA noted, would allow the sponsor at each step to "evaluate the extent to which there is residual uncertainty about the biosimilarity of the proposed product and identify next steps to try to address that uncertainty." The formal meetings discussed in the fourth draft guidance document would allow FDA to provide feedback and help resolve issues through the process. Applicants may need to conduct animal studies to demonstrate biosimilarity, and additional clinical studies may be required to demonstrate safety and effectiveness. Ultimately, according to FDA, a biological product may be deemed "biosimilar" to a reference product "if data show that the product is highly similar to the reference product nothwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product."

Challenging though it might be for a biologic product to obtain status as a biosimilar, it would have to meet a higher standard to be deemed "interchangeable." Interchangeable products may be substituted for the reference product without intervention by the prescriber. To be considered interchangeable, a biosimilar would "be expected to produce the same clinical result as the reference product in any given patient," stated FDA. "In addition, for a biological product that is administered more than once to an individual . . . the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch." In fact, follow-on products may not be able to achieve interchangeability status in the near future. While possible in theory, "[a]t this time, it would be difficult as a scientific matter for a prospective biosimilar applicant to establish interchangeability . . . given the statutory standard for interchangeability and the sequential nature of that assessment," noted FDA.

State Lawmakers Prepare for Biosimilars' Arrival

Despite the lack of biosimilar approvals, activity anticipating the future dispensing of the drugs has picked up noticeably in the last year on the state front. In expectation of eventual approved biosimilar products, lawmakers in at least 19 states had considered or were considering biosimilar-related legislation in the first half of 2013 alone. These bills generally sought to allow the substitution of a biosimilar in place of its prescribed reference product, and to define the circumstances under which such a substitution could take place. Many states considered more closely regulating the substitution of biosimilars than that of most small-molecule drugs, including adding such requirements as prescriber notification, patient consent, and maintaining records for a period of years after the biosimilar is dispensed.

As lawmakers deliberated over such matters, various groups, such as current manufacturers of biologic products and would-be producers of biosimilars, as well as a number of other stakeholders have presented varied perspectives for consideration. Entities such as individual biotechnology companies, the Biotechnology Industry Organization (BIO), the Alliance for Safe Biologic Medicines (which also includes patient advocacy groups among its members), and physician organizations have lobbied state lawmakers to include particular measures in biosimilars legislation. Emphasizing the complex nature of biologics and the need for safeguards to protect the patient, BIO has publicized its five principles on biologic substitution: the

(continued on page 172)

Biosimilars Update

(continued from page 171)

importance of only substituting biologic products that FDA has deemed interchangeable, the need for the prescribing practitioner to be able to prevent substitution, the notification of the prescribing practitioner, the notification (and possibly consent) of the patient, and the need for the prescriber and pharmacist to each keep records of the substitution.

Other stakeholders recommend fewer restrictions on biosimilar substitution, and include such entities as the Generic Pharmaceutical Association, manufacturers of generics and biosimilars, insurers and pharmacy benefit managers, and pharmacist organizations. In general, these groups convey that the stringent standards biosimilars must meet for FDA to deem them interchangeable provides sufficient patient protection, and that other measures may create barriers to biosimilars.

In March, Virginia became the first state to pass a law regarding the substitution of FDA-designated interchangeable biosimilars. In many respects, pharmacists must follow the same rules as for small-molecule drugs, including informing the patient and recording the drug's manufacturer and product or brand name on the prescription label and dispensing record and noting that it is a substitute; for both types of medication, the prescriber may prevent substitution by writing "brand medically necessary" on the prescription. However, when substituting a biosimilar, pharmacists must notify

In March, Virginia became the first state to pass a law regarding the substitution of FDA-designated interchangeable biosimilars.

the prescriber within five business days, and must provide the patient with retail cost information for the biosimilar and the prescribed product. The prescriber notification and price notification provisions expire on July 1, 2015.

Following on Virginia's heels, North Dakota's and Utah's governors quickly became the second and third to sign biosimilars substitution legislation into law. North Dakota's provisions are similar to Virginia's, though prescriber notification must happen within 24 hours and both prescriber and pharmacist must retain a record of the interchangeable biosimilar substitution for at least five years; there is no sunset provision. In addition, the state board of pharmacy must maintain on its Web site a list or link to a list of FDA-approved interchangeable biosimilars. Utah's new law includes similar provisions, though it requires prescriber notification within three days of dispensing the biosimilar and the notification provision expires May 15, 2015. In a departure from the new Virginia or North Dakota laws, Utah's law requires the pharmacist or pharmacy intern to counsel the patient on the use and expected response to the biological product, whether a substitute or not. The Utah law also requires out-of-state mail service pharmacies to adhere to the provisions.

In June, Oregon's governor also signed into law a bill allowing substitution of interchangeable biosimilars, again with similar provisions: The prescriber may designate that substitution is prohibited, the pharmacist must notify the patient of a substitution prior to dispensing and the prescriber within three business days, and the pharmacist must retain a record of the substitution for three years. Like Virginia and Utah, the notification provision has an expiration date – in Oregon's case the date is January 2016.

Florida also passed a law permitting substitution of interchangeable biosimilars in 2013, although without a provision requiring prescriber notification. The pharmacist does have to notify the person presenting the prescription, and retain a written record for at least two years. In addition, the state board of pharmacy must maintain on its Web site a current list of FDA-designated interchangeable biosimilars.

At press time, states with pending legislation regarding biosimilars included California, Massachusetts, and Pennsylvania. The Massachusetts bill would require interchangeability and allow the prescriber to instruct the pharmacist not to substitute a biosimilar, but specifically states, "No additional restrictions, limitations or requirements shall be imposed related to biological product substitution unless such restrictions, limitations or requirements also apply in the case of all other drug product substitution." Each of the other bills would mandate prescriber notification.

A number of state legislatures considered but did not pass bills regulating the substitution of biosimilars in 2013. These included Arizona, Arkansas, Colorado, Illinois, Indiana, Maryland, Mississippi, Nevada, Texas, and Washington – although future legislative sessions could see a renewal of bills in these states.

The complexities surrounding biosimilars would seem to indicate that FDA actions will continue to occur relatively gradually – but activity on the state level may well continue apace, and will directly affect the boards of pharmacy. NABP will continue to provide updates on the topic.

Board of Pharmacy Staff Attend Annual Program Review and Training to Network and Learn of NABP Programs and Services

To further familiarize themselves with NABP programs and services, board of pharmacy staff, both new employees and those seeking a refresher course, attended the NABP Annual Program Review and Training Session on July 23-24, 2013, at NABP Headquarters.

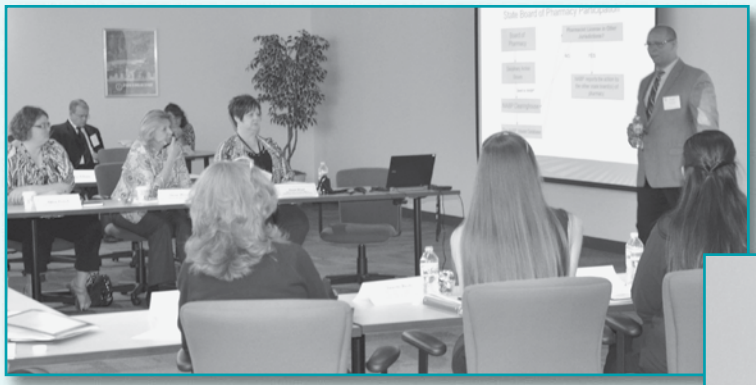
Seventeen participants representing 14 state boards of pharmacy attended this two-day interactive session that provided board staff with information about NABP's examinations, licensure transfer, accreditation programs, and more. In addition, this informational session provided board staff with a unique opportunity to network with other board of pharmacy staff.

The event began with a group dinner on July 23, which provided board staff the opportunity to network with one another and NABP representatives.

On July 24, board staff convened for breakfast, a brief facility tour, welcome, organization overview, and then began the educational portion of the meeting. The educational portion provided attendees with an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (e-LTP®), license verification, and NABP Clearinghouse/Healthcare Integrity and Protection Data Bank reporting
- Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification Program
- Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) and Pre-FPGEE®
- North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), and Pre-NAPLEX®
- Pharmacist Assessment for Remediation Evaluation℠ (PARE℠) and Pharmacy Curriculum Outcomes Assessment® (PCOA®)
- Board e-Profile Connect
- Communications Department
- AWAR$_X$E® Consumer Protection Program
- Internet Drug Outlet Identification program and .PHARMACY generic Top-Level Domain
- Verified Internet Pharmacy Practice Sites℠ (VIPPS®), Vet-VIPPS®, Verified-Accredited Wholesale Distributors® (VAWD®), durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation programs, NABP e-Advertiser Approval℠ Program, and Field Services
- Professional Affairs Department
- NABP PMP InterConnect®
- NAR$_X$CHECK®
- Government Affairs Department
- CPE Monitor®

For more information about future training sessions or to obtain training materials provided at the session, please contact NABP at custserv@nabp.net.



NABP Staff Presentations

(Left) On Wednesday, July 24, 2013, attendees of the Program Review and Training received valuable information about the Association's programs and services from NABP staff. Pictured left: Neal Watson, licensure programs manager, shares information about the Electronic Licensure Transfer Program® with board of pharmacy staff.

Networking Opportunities

(Right) The Program Review and Training offered attendees the unique opportunity to network with other board of pharmacy staff about important issues related to their fields. Pictured right: Susan McCoy, compliance agent, Mississippi Board of Pharmacy (left) and Cynthia Reich, MBA, PharmD, inspector, South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy (right).

AWARXE Medication Safety Messages Greet Nearly 750,000 Race Fans

Program Promotes Next Drug Take-Back Day

Impressed by AWARXE®'s impactful public service announcements (PSAs), car racing event promoters requested to present the videos to more race fans at the Brickyard 400. Fans attending the race that took place July 26-28, 2013, at the Indianapolis Motor Speedway were greeted at the gates by four rotating AWARXE PSAs. The messages were displayed on the jumbotrons over 380 times during the event, presenting nearly 750,000 attendees the opportunity to view the videos. Each PSA alerted viewers to a medication safety fact, helping to raise consumer awareness of prescription drug abuse trends and counterfeit drug dangers.

Along with these efforts, AWARXE will use its existing outreach vehicles to alert consumers to the next Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day, October 26, 2013, as a means for helping to prevent drug abuse in their communities. DEA will once again coordinate with state and local law enforcement and community organizations to provide thousands of collection sites across the country for consumers to safely dispose of unused, unneeded prescription drugs. DEA collected 2.8 million pounds of unused drugs from the last six take-back events combined. Through the AWARXE biweekly e-newsletter, the AWARXE Web site, and the AWARXE Facebook page, the program will alert consumers to this seventh opportunity to dispose of unneeded medications, including controlled substances.

In addition, AWARXE continues educational presentations on a local level, providing prescription drug abuse prevention information, as well as Internet drug safety information. NABP staff will deliver an AWARXE presentation at the Gail Borden Public Library in Elgin, IL. The presentation will be open to the public, and the library's educational offerings attract many seniors, a key audience for the AWARXE message.

AWARXE also shares Internet drug safety information through its Web site by posting the NABP Not Recommended list of rogue Internet drug sites and the Recommended list of Internet pharmacies that are VIPPS® (Verified Internet Pharmacy Practice Sites℠) accredited. The latest Internet Drug Outlet Identification program progress reports are also posted on the site, giving details on the characteristics of sites classified as Not Recommended.

AWARXE will continue to educate on these topics and will be expanding its messaging to raise public awareness about the new .PHARMACY generic Top-Level Domain (see cover story for more information).

AWARXE Reaches Out to Race Fans at the Brickyard 400

NASCAR fans attending the Brickyard 400 during the July 26-28, 2013 weekend, encountered AWARXE® public service announcements (PSAs) displayed on the jumbotron at the front entrance of the Indianapolis Motor Speedway. The AWARXE PSAs, shown on the practice day and during the three-day event, displayed over 380 times to over 750,000 race fans.

NAPLEX and MPJE Fee Adjustments to Take Effect January 1, 2014

To ensure continued protection of the integrity and security of its examinations, NABP will be adjusting the fees of the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®).

Beginning January 1, 2014, the fees will be adjusted as follows:

- NAPLEX fee will increase from $485 to $505
- MPJE fee will increase from $200 to $210

The NAPLEX and MPJE fees were last adjusted in May 2010. The newly implemented fee adjustments were approved by the NABP Executive Committee during its February 2013 meeting.

For more information or questions on these fee adjustments, contact the NABP Competency Assessment Department at 847/391-4406, or NABP_Comp_Assess@nabp.net.

MPJE Review Committee Members Convene to Review Test Questions

Members of the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee gathered at NABP Headquarters to review and examine test questions. Pictured from left to right are Randy Jones, RPh, South Dakota State Board of Pharmacy; Vickie Seeger, RPh, Midlothian, VA; Grace Cheung, RPh, Kenmore, WA; and Vance Alexander, JD, RPh, Alabama State Board of Pharmacy.

Registration Opens Soon for the January 13 to February 7 PCOA!

The deadline for schools and colleges of pharmacy to register their students for the first 2014 Pharmacy Curriculum Outcomes Assessment® (PCOA®) testing window is October 15, 2013.

The testing window runs from January 13 to February 7, and schools and colleges that would like to participate are encouraged to contact Gene Johannes, PCOA operations manager, at 847/391-4429 or via e-mail at gjohannes@nabp.net.

Appropriate for administration to students in all professional years, the PCOA is an excellent resource for pharmacy educators as they review pharmacy curricula, design courses, and assess student performance.

More information, including registration materials and future PCOA testing windows for 2014, is available on the NABP Web site at *www.nabp.net/programs/assessment/pcoa*.

Kansas Board Expedites CS Reporting With LACIE

The Kansas State Board of Pharmacy entered into an agreement with the Lewis and Clark Information Exchange (LACIE) to provide approved providers access into the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) reporting system. LACIE will act strictly as a conduit to help expedite information that resides in the K-TRACS system to approved providers.

LACIE provides pharmacists with medical information from a variety of providers that they may not normally have easy access to, such as current medications, immunizations, allergies, medical/discharge history, problem lists, lab results, and clinic visits. LACIE plans to work directly with the Board to ensure the information that is provided through its exchange provides optimum value to participating pharmacists as well as meeting the minimum data sharing requirement as defined by the Health Insurance Portability and Accountability Act.

LACIE, through its partnership with Cerner, has actively been sharing data between discrepant organizations for more than three years. LACIE covers the whole state of Kansas as well as parts of Missouri.

For more information on LACIE, visit its Web site, *www.lacie-hie.com*.

North Dakota Revises Scheduling of Cannabinoids, Bath Salts, and Tramadol

The North Dakota House and Senate passed North Dakota House Bill 1070, which includes revisions to Schedule I through V controlled substances (CS) based on federal Drug Enforcement Administration scheduling changes. The bill included scheduling of multiple spiced cannabinoids and substances marked as bath salts as Schedule I CS.

In addition, tramadol and tramadol-containing products are now listed as Schedule IV substances. An initial inventory should have been taken after the date of scheduling, and the handling of prescriptions for tramadol-containing products should conform to the requirements set forward in state law. The North Dakota State Board of Pharmacy notes that state law does allow electronic prescribing of CS outside of the stricter federal standards. Since tramadol, at this time, is only a state CS, the electronic prescribing of prescriptions for tramadol is not subject to federal regulations.

Wyoming Revises Immunization Age Requirement

During the Wyoming Legislative Session, House Bill 0094 was introduced and passed, which now allows pharmacists to prescribe and administer immunizations to healthy individuals age seven and older rather than the current age of 19 and older. Parental consent shall be required as will recording the vaccine in the registry operated by the Wyoming Department of Health (Wyoming Immunization Registry). The Wyoming State Board of Pharmacy and the Wyoming Board of Medicine have met to discuss rules including which vaccines will be specified and the requirements for a "private space" where immunizations may be administered by a pharmacist or intern. Pharmacists will need to obtain proof of education regarding immunizations in the pediatric population.

However, the bill does have a provision that states it is not a requirement for a pharmacist to administer immunizations to individuals who are less than 13 years of age. In addition, the provision states that no employer shall discriminate against a pharmacist on the basis that the pharmacist determines not to administer immunizations to individuals who are less than 13 years of age.

Indiana Pharmacists Able to Provide More Immunizations

Indiana House Bill 1464 was passed, which authorizes Indiana pharmacists to administer additional immunizations under a protocol approved by a physician. Under the new law, Indiana pharmacists may now administer immunizations for pneumonia, tetanus, diphtheria, acellular pertussis (Tdap), human papillomavirus (HPV) infection, and meningitis. Previously, Indiana pharmacists were authorized to administer the influenza and herpes zoster (shingles) vaccines under a physician protocol. The new law also authorizes pharmacist interns or pharmacy students to administer immunizations under supervision. The *Indianapolis Business Journal* notes that the law is intended to make vaccinations more accessible for Indiana residents. House Bill 1464 became effective July 1, 2013. To view the bill in its entirety visit *www.in.gov/apps/lsa/session/billwatch/billinfo?year=2013&session=1&request=getBill&doctype=HB&docno=1464*. More information on this new law may also be found on the Indiana Pharmacists Alliance Web site at *https://netforum.avectra.com/eWeb/DynamicPage.aspx?Site=INPHARM&WebCode=ArticleDetail&faq_key=a393333a-6084-4d58-96fd-f4c68efa76ed*, and in an article from the *Indianapolis Business Journal* at *www.ibj.com/new-law-lets-pharmacists-provide-pneumonia-hpv-vaccines/PARAMS/article/41902*.

Kentucky Bill Adds Provisions for Naloxone Administration

During the 2013 Kentucky Legislative Session, HB 366 was passed, which adds several provisions pertaining to the administration of the drug naloxone. The new bill now

(continued on page 178)

Americans Rated Poor in Medication Adherence Survey

A new patient survey commissioned by the National Community Pharmacists Association (NCPA) indicates that many Americans are not adhering to prescribed medication regimens. The survey asked 1,020 adults about specific non-adherent behaviors, graded the responses, and determined that participants with chronic medical conditions averaged a C+ in medication adherence. One in seven respondents with chronic conditions received an F. Behaviors tracked included whether patients failed to fill prescriptions, whether they took a lower dose than prescribed, and whether they stopped a prescription early. The survey also revealed that the biggest predictor of medication adherence was patients' personal connection (or lack thereof) with a pharmacist or pharmacy staff. NABP highlighted the role of pharmacist communication in increasing medication adherence in a May 2010 *NABP Newsletter* article, "Pharmacist Communication Shown to Increase Medication Adherence and Reduce Errors." More information from the patient survey may also be found in an NCPA news release at *www.ncpanet.org/index.php/news-releases/1702-new-report-card-on-medication-use-gives-americans-a-c.*

Enteric Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

Advance Pharmaceutical Inc, initiated a voluntary recall from Rugby Laboratories of Lot 13A026 (expiration date: January 2015) due to a complaint that a bottle labeled as enteric coated aspirin tablets, 81 mg, actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code number 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, by following the directions on the label, can lead to danger of an acetaminophen overdose and severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall may also be found on the FDA Web site at *www.fda.gov/Safety/Recalls/ucm357909.htm?source=govdelivery.*

ISMP Launches Safety Alert Newsletter Tailored for LTCFs

The Institute for Safe Medication Practices (ISMP) has launched a new *Medication Safety Alert!* publication – *Long-Term Care Advise-ERR* – as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With ISMP *Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP National Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at *www.ismp.org/Newsletters/longtermcare.*

Survey Results Show Pharmacists Likely to Recommend Safe, Effective OTC Products

According to a recent survey by Nielsen and IMS, 98% of pharmacists recommend or have no reservations recommending OTC products to treat ailments such as coughs, headaches, migraines, and allergies. The survey, developed to better understand what drives consumer and health care provider trust in OTC products, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. Over 60% of pharmacists surveyed recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

Results from the survey are presented in the Consumer Healthcare Products Association's (CHPA) report, *Understanding Trust*

(continued on page 178)

State Board News

(continued from page 176)

allows a licensed health care provider who, acting in good faith, directly or by standing order, prescribes or dispenses the drug naloxone to a patient who, in the judgment of the health care provider, is capable of administering the drug for an emergency opioid overdose, shall not, as a result of his or her acts or omissions, be subject to disciplinary or other adverse action under KRS Chapter 311, 311A, 314, or 315 or any other professional licensing statute. In addition, the new bill states that a prescription for naloxone may include authorization for administration of the drug to the person for whom it is prescribed by a third party if the prescribing instructions indicate the need for the third party upon administering the drug to immediately notify a local public safety officer of the situation necessitating the administration. A person acting in good faith who administers naloxone as the third party under this section shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct of the person administering the drug.

Professional Affairs Update

(continued from page 177)

in OTC Medicines: Consumers and Healthcare Provider Perspectives. CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

More information on these findings are available in the CHPA report at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

Newly Accredited DMEPOS Facilities

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

Denver Health Montbello Family Health Center Pharmacy
Denver, CO

Manhattan Chinatown Pharmacy, Inc
New York, NY

Medicap Pharmacy
Sikeston, MO

Peninsula Pharmacy
Marquette, MI

Vital Rx, LLC
Chicago, IL

Z-Stop Drugs
Bronx, NY

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

Newly Approved e-Advertisers

The following entities were accredited through the NABP e-Advertiser Approval℠ Program:

Dramatic Weight Loss
www.dramaticweightloss.com

Express Scripts Holding Company dba Express Scripts
www.express-scriptspharmacy.com

Fagen Pharmacy
www.shopfagen.com

Halozyme, Inc
www.hylenex.com

Pharmaca Integrative Pharmacy
www.pharmaca.com

Publix Super Markets, Inc
www.publix.com

ShopKo Stores Operating Co, LLC
www.shopko.com
www.shopko-pharmacy.com

West-Val Pharmacy
www.westvalpharmacy.com

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

Around the Association

Board Member Appointments

- **Kristina Jonas, PharmD,** has been appointed a member of the Idaho State Board of Pharmacy. Jonas's appointment will expire June 30, 2016.
- **Patrick Gannon, MS, FABC, RPh,** has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Gannon's appointment will expire November 30, 2017.
- **Jane Franke, RN, MHA,** has been appointed a public member of the Massachusetts Board of Registration in Pharmacy. Franke's appointment will expire December 1, 2017.
- **Edmund Taglieri, MSM, NHA, RPh,** has been appointed a member of the Massachusetts Board of Registration in Pharmacy. Taglieri's appointment will expire December 1, 2017.
- **Justin Wilson, PharmD,** has been appointed a member of the Oklahoma State Board of Pharmacy. Wilson's appointment will expire June 30, 2018.

Board Member Reappointments

- **Buffie Saavedra** has been reappointed a public member of the New Mexico Board of Pharmacy. Saavedra's appointment will expire June 30, 2016.
- **Patricia Donato, RPh,** has been reappointed a member of the New York State Board of Pharmacy. Donato's appointment will expire September 30, 2017.
- **David Flashover, RPh,** has been reappointed a member of the New York State Board of Pharmacy. Flashover's appointment will expire September 30, 2017.
- **Gary Dewhirst, RPh,** has been reappointed a member of the North Dakota State Board of Pharmacy. Dewhirst's appointment will expire May 8, 2018.

Board Officer Changes

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

- **Thomas Van Hassel, RPh,** President
- **James Foy, MBA, PharmD,** Vice President

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

- **Edward Maier, RPh,** Chairperson
- **James Miller, RPh,** Vice Chairperson

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

- **James T. DeVita, RPh,** President
- **Anita Young, EdD, RPh,** Secretary

The Nebraska Department of Health and Human Services, Division of Public Health, Licensure Unit has elected the following officers to the Board:

- **Michael Losee, MA,** Vice Chairperson
- **Robert Marshall, RP, PharmD,** Secretary
- **Kenneth Saunders, PharmD, TTS, RP,** Chairperson

Errata

Please note the following corrections to the Ohio State Board of Pharmacy officers: Kevin Mitchell, RPh, is president, and Michael Moné, JD, RPh, is vice president. On page 141 of the June-July 2013 *NABP Newsletter's* Around the Association, Brian Joyce, RPh, and Kevin Mitchell were incorrectly identified as president and vice president of the Ohio State Board of Pharmacy, respectively. NABP regrets the error.

Newly Accredited Vet-VIPPS Facilities

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

Butler Animal Health Supply, dba Butler Schein Animal Health Supply
www.myvetdirect.com

California Pet Pharmacy
www.californiapetpharmacy.com

PetMart Pharmacy, dba Lehman's PetMart Pharmacy
www.petmartpharmacy.com

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

nabp newsletter

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

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

Newly Accredited VIPPS Facilities

The following Internet pharmacies were accredited through the NABP Verified Internet Pharmacy Practice Sites℠ (VIPPS®) program:

Allcare Specialty Pharmacy
www.allcarepharmacy.com

CoramRx
www.coramrx.com

Giannotto's Specialty Pharmacy, dba Meera, Inc
www.giopharm.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies are available on the NABP Web site at *www.nabp.net.*

Newly Accredited VAWD Facilities

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

Anda Pharmaceuticals, Inc
Olive Branch, MS

Atlantic Biologicals Corp, dba Atlantic Biologicals
Miami, FL

J.T. Posey Company
Arcadia, CA

Medline Industries, Inc
Canton, OH
Mansfield, MA

Tri-anim Health Services, Inc
Cudahy, WI

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