Task Force Recommends Changes to Model Act to Clarify Definition of Medication Synchronization

Recognizing that medication synchronization programs are a useful method of improving medication adherence and patient outcomes, the Task Force on Medication Synchronization made several recommendations to aid board of pharmacy efforts to implement regulations to support these programs. The Task Force on Medication Synchronization met on October 8-9, 2014, at NABP Headquarters, where they also discussed ways to improve awareness and acceptance of medication synchronization programs by national pharmacy professional organizations and other health care stakeholders. In its recommendations, the task force encouraged the state boards of pharmacy to adopt new language in the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act), to facilitate acceptance and incorporation of medication synchronization into pharmacy practice, and to collaborate with state and national health care organizations to improve understanding of medication synchronization programs.

The task force reviewed the current Model Act definition of medication synchronization and amended it to recognize the existing authority of pharmacists to provide better patient-centered care through the implementation of medication synchronization programs. Members also revised the Model Act definition to emphasize the value of enhanced communication between patients and pharmacists to maximize drug therapy adherence and outcomes. The revised definition is as follows:

"Medication Synchronization" refers to a component of Medication Therapy Management that recognizes the authority of the pharmacist, at the patient’s direction, to proactively adjust the medication quantity or refill schedule and to manage a patient’s maintenance medications by coordinating the refill schedules to improve patient outcomes.

The task force members also determined that the definition of medication synchronization should allow pharmacists to adjust...
Medication Synchronization Task Force
(continued from page 117)

refill schedules without having to seek approval from the prescriber for each scheduling adjustment.

Further, the definition was broadened to allow a pharmacist to adjust a refill schedule, rather than only a single refill, since ongoing changes may be necessary when chronic drug therapy regimens are altered by addition or discontinuation of prescribed drugs. Members stressed that medication synchronization must be clarified to prevent confusion related to emergency fills, automatic refills, or adding refills beyond what the prescriber has authorized.

In addition, the task force agreed that the Model Act language should explicitly state that medication synchronization programs are tailored for maintenance medications, but do not apply to controlled substances or prescriptions that are taken on an as-needed basis.

In addition to the Model Act revisions, the task force recommended that NABP encourage the state boards of pharmacy to adopt the NABP medication synchronization Model Act language. The task force determined that state boards of pharmacy should review their practice acts and regulations to determine if medication synchronization authority presently implicitly or explicitly exists. When reviews highlight a need for regulatory language regarding medication synchronization, the task force recommends adopting the Model Act language. Further, such boards are encouraged to consider any additional language that will help facilitate the incorporation of medication synchronization into standard pharmacy practice.

The task force identified a lack of uniformity among state pharmacy acts and state boards of pharmacy regulations for providing explicit authority for pharmacists to adjust a patient’s chronic medication quantity as a barrier to initiating medication synchronization. Whereas implicit authorization may exist in many states, the task force suggested that NABP communicate the importance of adopting medication synchronization regulatory language with the boards in order to develop uniform acceptance across the country.

To facilitate the acceptance and incorporation of medication synchronization into pharmacy practice, the task force also recommended that NABP increase efforts to collaborate with state and national pharmacy groups. The task force members supported NABP collaborating with other professional pharmacy associations to educate pharmacists and their employers about the benefit of medication synchronization for patients. The task force also suggested that NABP work with the American Association of Colleges of Pharmacy to support the introduction of medication synchronization to future pharmacists.

To encourage understanding and interprofessional collaboration, the task force further recommended that NABP collaborate with state and national health care stakeholders to provide education regarding the positive

Task Force Charges

The Task Force on Medication Synchronization met at NABP Headquarters and accepted the following charges:

1. Review existing state laws and regulations pertaining to the provision of medication synchronization services within the legal scope of pharmacy practice.
2. Identify circumstances where medication synchronization services should be offered and/or provided.
3. Identify factors that may impact access to medication synchronization services.
4. Review and, if necessary, recommend amending the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy language addressing medication synchronization.
April 2015 FPGECE Scores Available at NABP.net; Fall Administration Approaching

Score reports from the April 20, 2015 Foreign Pharmacy Graduate Equivalency Examination® (FPGECE®) administration are now available via the NABP website. Candidates who sat for the April 20 administration may now enter their equivalency examination number and date of birth to access their score report through the NABP secure network login page. The login page may be accessed through the Programs section of the NABP website at www.nabp.net/programs/examination/fpgee.

A total of 778 candidates sat for the April 20, administration. The next FPGECE is scheduled for September 28, 2015. More information about the FPGECE is available in the Programs section of the NABP website at www.nabp.net.

Medication Synchronization Task Force

(continued from page 118)

impact of medication synchronization on patient outcomes.

The task force members agreed that NABP should promote medication synchronization as a patient care service that improves adherence and outcomes while reducing health care costs.

Members stressed that since the medication synchronization model integrates comprehensive medication therapy maintenance reviews into the dispensing process, the resulting patient benefits from increased pharmacist attention must not be undervalued.

The task force did identify third-party payer reluctance as a barrier to implementing medication synchronization programs.

The members unanimously agreed that reimbursement and/or coverage policies should support and not impede patient participation in medication synchronization programs. Therefore, task force members encouraged NABP to collaborate with the Pharmaceutical Care Management Association, corporate employers, and other stakeholders to inform them about the health benefits and decreased health care costs resulting from medication synchronization programs that have already been recognized by Centers for Medicare and Medicaid Services.

The Task Force on Medication Synchronization was established in response to the NABP Executive Committee’s recommendation to explore this concept. Task force members included Rich Palombo, RPh, chair; Todd Barrett, RPh; Gayle A. Cotchen, MBA, PharmD, RPh; Don Johnson, RPh; Michael Lonergan, RPh; Suzanne Neuber, RPh; Tejal Patel, PharmD, RPh; and Joyce Tipton, MBA, RPh, FASHP. The Executive Committee liaison was Gary Dewhirst, RPh.

The task force’s recommended revisions to the Model Act were reviewed and amended by the Committee on Law Enforcement/Legislation in January 2015, and were reviewed and amended by the Executive Committee during its May 2015 meeting. The task force report was approved by the Executive Committee during its December 2014 meeting and is available in the Members section of 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.
On February 25, 2015, the United States Supreme Court ruled on an important case relevant to the regulatory community and the antitrust protections afforded to state regulatory boards. In *North Carolina State Board of Dental Examiners v. Federal Trade Commission*, 574 U.S. (2015), the Supreme Court addressed the issue of whether a state agency, in this case the North Carolina State Board of Dental Examiners (Board), is immune from the application of the antitrust laws. The court held it was not immune.

“The Court holds today that a state board on which a controlling number of decision makers are active market participants in the occupation the board regulates must satisfy [the] active supervision requirement in order to invoke state-action antitrust immunity.”

The basis for the litigation was the administrative complaint filed by the Federal Trade Commission (FTC) alleging the actions of the Board were anti-competitive and violated the antitrust laws set forth under federal law. The Board, a statutorily created and empowered state regulatory agency, interpreted the scope of practice contained in the North Carolina Dental Practice Act (practice act) to include teeth whitening activities, admonishing such participants that they were engaging in the unlicensed practice of dentistry. In addition, cease and desist letters were sent to landlords and suppliers of products warning them about the perils of facilitating the unlicensed practice of dentistry and referencing the potential criminal liability to such activities.

Citing the actions of the Board, the FTC initiated an administrative action alleging violations of federal antitrust laws. In defense of its actions, the Board argued that it was immune from antitrust liability under a “state action” doctrine that provides state actors with a defense to such allegations. This state action doctrine is a defense established through previous judicial decisions dating back to a Supreme Court opinion from 1943. In short, state actors are immune from antitrust scrutiny so long as they are acting under a clearly articulated state policy to displace competition. Indeed, a licensure process whereby some applicants are granted approval to practice and some are not, in and of itself, is anti-competitive and displaces competition in the marketplace. Further, some “private actors” are also immune from antitrust scrutiny if they are acting not only under a clearly articulated state policy, but are also acting under active state supervision. The crux of this case involved the question of whether the Board must meet the second prong (active state supervision) of the legal analysis.

The Supreme Court agreed with the lower court’s decision and the FTC’s administrative ruling that the Board was a nonsovereign (private) entity required to meet both prongs of the test: first, a clearly articulated and affirmatively expressed state policy to displace competition, and second, active supervision by the state. All parties and the court agreed that the Board was operating under a clearly articulated state policy. However, the court ruled that the Board was not being actively supervised by the state and, thus, was not immune from the application of the antitrust laws.
laws. Consequently, the court affirmed the Fourth Circuit Court of Appeals and FTC rulings that the Board violated the antitrust laws.

The purpose of the NABP 2015 Report of Counsel is not to provide a detailed analysis of the facts of administrative and judicial opinions, as such will be available through countless sources. The purpose of this 2015 Report of Counsel is to use this case and selected passages therefrom to explore the philosophical approaches to regulation and the potential consequences of this significant opinion. Excerpts from the Supreme Court opinion will be strategically placed to enhance the points being made in each section below.

Why Is There Regulation of the Professions?

“The Board’s chief operations officer remarked that the Board was ‘going forth to do battle’ with nondentists.”

The philosophical question of why there is regulation of the professions is sometimes lost in the regulatory structure as licensees compose the majority of seats on the regulatory boards. While state board members can recite the public protection mantra when describing the purpose of regulation and the mission of the board, masked professional promotion can surface. It is this professional promotion attitude that creates the perception, whether justified or not, that the professionals are protecting their turf.

Boards are encouraged to understand the purpose of a regulatory scheme and recite its mission statement into the record at the commencement of every board meeting. Introductory statements by the board chair identifying board members and staff in attendance, and their titles, as well as citation to the practice act and open meetings laws, how the board meeting was noticed to the public, a review of the agenda, and relevant operational procedures are essential to not only create a consistent record of this valuable information, but also to inform the public and remind board members of this unique regulatory perspective.

The very nature of regulation encompasses displacement of competition in that eligibility criteria are set forth in statute and some applicants may not meet such prerequisites to licensure. In addition, boards enforce the legislative scheme through removal of licensure under circumstances justified by the law. The key is to enforce the regulatory statutes in a manner that eliminates the professional promotion aspects of the legal structure. Professional trade associations exist to promote the profession and address issues related to the economic and financial aspects of the profession. Professional promotion must be left up to the professional trade association and removed from consideration in state regulatory board operations.

Delegation: What Do Boards Do?

“Limits on state-action immunity are most essential when the State seeks to delegate its regulatory power to active market participants, for established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern.” (emphasis added)

Regulatory boards enforce the practice acts and other relevant statutes and rules/regulations to carry out the mission intended by the legislative framework. State governmental boards are created and empowered by statutes and must operate within the parameters of the legislative authority. The legislature “delegates” this enforcement authority to the governmental board. Based upon an obvious need for expertise, the boards are composed of “licensees;” i.e., those working within the field that bring an element of specified knowledge to the governmental body. Board members are predominantly appointed by the governors and serve as volunteers. (However, it must be noted that the members of the North Carolina State Board of Dental Examiners are elected to serve by their colleague licensees.) To elim-
In the opinion, the court determined that active state supervision is more similar to private trade associations vested by States with regulatory authority than to the agencies [case name omitted] considered.

By active market participants, the court is referring to licensees regulating other licensees within the same profession. The court compared regulatory boards to “trade associations,” a designation that is not justified, unless the board members are treating regulation like professional promotion. This confusion of roles between the trade association and the regulatory board and its board members adds to the blurring of legal and practical lines and threatens the root of regulation of a profession.

Who Sits on Boards?

“The Act provides that six of the Board’s eight members must be licensed dentists engaged in the active practice of dentistry, §90–22. They are elected by other licensed dentists in North Carolina, who cast their ballots in elections conducted by the Board. The seventh member must be a licensed and practicing dental hygienist, and he or she is elected by other licensed hygienists. The final member is referred to by the Act as a ‘consumer’ and is appointed by the Governor. Limits on state-action immunity are most essential when the State seeks to delegate its regulatory power to active market participants, for established ethical standards may blend with private anticompetitive motives in a way difficult even for market participants to discern. Dual allegiances are not always apparent to an actor.”

In many professions, the regulatory boards are composed of licensees with additional representation of “public” members. It is readily apparent why expertise on boards is needed. However, this expertise is only beneficial if used in a public protection manner. Understanding and applying these obligations will enhance the regulatory scheme and diminish the criticism levied on state boards.

An understanding of the roles and conflict of interest principles by individual board members is, in part, a personal endeavor. Adequately trained and knowledgeable state volunteers can alleviate some of these personal and professional promotion agendas and other perspectives reserved for the trade associations. In the Supreme Court opinion, the justices emphasize the fact that “active market participants” serve on and make up a majority of the Board.

In the opinion, the court questions the presumption that board members act in a manner consistent with the public protection mandate, a presumption developed and recognized by decades of numerous judicial opinions. Perhaps the rejection of such a presumption is justified under some circumstances. At times, some state board members exhibit promotional and “turf protection” perspectives when undertaking board business. Undoubtedly, readers of this report have experienced such activities. These self-serving and professional-promoting perspectives create doubt in the regulatory system and fuel cries for change. Indeed, the court stated:

“State agencies controlled by active market participants, who possess singularly strong private interests, pose the very risk of self-dealing [the supervision requirement] was created to address. This conclusion does not question the good faith of state officers but rather is an assessment of the structural risk of market participants’ confusing their own interests with the State’s policy goals.”

It is thus incumbent on board members to understand the role of the board, the role of the board members, and the relevant laws and operational aspects of the state agency. An understanding of and adherence to these roles and responsibilities will diminish the criticisms of self-regulating and self-promotion that follow. As noted by the court, “. . . established ethical standards may blend with private anticompetitive motives in a way difficult for even market participants to discern.”

(continued on page 124)

It has been an exciting year since the 110th Annual Meeting! NABP unveiled the groundbreaking Pharmacy Top-Level Domain (TLD) Program and sold its NAR, CHECK software to a company that is better positioned to make the software widely available to assist pharmacists and prescribers in evaluating prescription monitoring program (PMP) data. The Association continues to grow current programs and board services, including the Verified Pharmacy Program™ and NABP PMP InterConnect®. Likewise, the Legal Affairs staff remains focused on enhanced internal services and board support to facilitate the Association and its members meeting their public health protection goals.

Board Support

NABP assists the boards of pharmacy in a variety of ways by providing financial, educational, and other resources to help boards meet regulatory targets. Frequently, NABP’s support affords protections against claims of unfairness or subjectivity. For example, the boards of pharmacy rely upon the North American Pharmacist Licensure Examination® (NAPLEX®) and Multistate Pharmacy Jurisprudence Examination® (MPJE®) because the exams provide fair and standardized measurement of each candidate’s knowledge and skills. Through the Accreditation Council for Pharmacy Education, uniform standards are established and accredited schools of pharmacy implement them, but some variation may still exist among the colleges of pharmacy, such as grading policies. The NAPLEX and MPJE impartially evaluate graduates so that boards can make objective licensure decisions. Moreover, the NABP Internet Drug Outlet Identification and accreditation programs help identify websites, pharmacies, and other health care-related entities that do not comply with applicable law and the Association provides this information to the boards of pharmacy. Legal Affairs collaborates with staff to help maintain consistent program processes as well as negotiate favorable contract terms with parties participating in or supporting the NABP examination and accreditation programs.

Pharmacy TLD

Launched in December 2014, the .Pharmacy TLD Program has received hundreds of requests for pharmacy domains. NABP hopes to increase the number of registered domains in the near future now that the dispensing pharmacy and general availability purchase periods have commenced in June 2015. Legal Affairs created many supporting documents in connection with the program and will continue to partner with the .pharmacy team to enhance NABP’s key global consumer health protection program.

Upcoming Forum

The Legal Affairs team looks forward to hosting board attorney colleagues who participate in the Interactive Compliance Officer and Legal Counsel Forum, scheduled for December 1-2, 2015. Educational sessions, group discussions, and more are planned; we simply ask counsel to save the dates.

The NABP-member partnership is crucial to successfully taking on challenges that impede board of pharmacy operations or the realization of consumer safety objectives. The Legal Affairs team continues to work closely with Association staff to foster and strengthen this key relationship with members.
Legal Briefs
(continued from page 122)

How Do Board Members Become Board Members?

“They are elected by other licensed dentists in North Carolina, who cast their ballots in elections conducted by the Board. The seventh member must be a licensed and practicing dental hygienist, and he or she is elected by other licensed hygienists.”

In most regulatory structures, board members are appointed by the governor. Some states require confirmation by the state senate or other congressional means. In many states, the professional trade association submits names to the appointing authority that forms the basis for board appointments. Again, this blending of roles between the trade association and the governmental appointments creates a perception of self-dealing and professional promotion. It is these perceptions that fuel the legal challenges and public opinions.

In the current case and while the court did not appear to be overly focused on the method by which board members are selected, it must be noted that North Carolina State Dental Board members are elected by licensees under a process overseen by the Board. This election by peers distinguishes the facts of this case from most other regulatory boards. Nonetheless, it is likely that the outcome of the case would not have been altered by a governor appointment process. However, a concurring judge in the lower court ruling noted that had the members been appointed by the governor, the Board would be considered a state actor subject only to the clearly articulated state policy and there would be no need to meet the active state supervision criterion.

Is Pharmacy Practice Profession Self-Regulated?

“The Board argues entities designated by the States as agencies are exempt from [the] second requirement. That premise, however, cannot be reconciled with the Court’s repeated conclusion that the need for supervision turns not on the formal designation given by States to regulators but on the risk that active market participants will pursue private interests in restraining trade.”

The question of whether the professions are self-regulated will be argued by some as having been answered in the affirmative by the Supreme Court through its determination that active market participants have the potential for private interests to infringe on public decision making. However, an argument can and must be made to reaffirm the presumption of board member objectivity established by previous case law. It is essential that board members act to regulate the profession in the interest of public protection and consistent with the stated Board mission and not in the promotion of the profession.

Pharmacy is not self-regulated; it is regulated by a combination of persons with expertise in the field as well as consumer representatives. Board members carry out the intent of the statutes and rules/regulations using expertise and experience necessary to be efficient and effective. In order to meet this philosophical conclusion, board members must actually internalize and live by this mantra. As board members stray from this approach and allow professional and/or personal promotion perspectives to infringe on public protection decisions, legal, political, public perception, and other damaging images result.

Now What?

“The Court has identified only a few constant requirements of active supervision: The supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy; and the “mere potential for state supervision is not an adequate substitute for a decision by the State.” Further, the state supervisor may not itself be an active market participant. In general, however, the adequacy of supervision otherwise will depend on all the circumstances of a case.”

Regulatory boards are encouraged to review this case and seek legal assistance and guidance as to its consequences. By no means is this judicial opinion reason to overreact and institute processes and procedures that unduly infringe on board operations and promote inefficiencies in government. Many jurisdictions already have in place mechanisms that would survive judicial scrutiny under the Supreme Court analysis. The amount of “oversight” by the state regarding board activities varies from jurisdiction to jurisdiction. Further, fundamental decisions of determining individual licensure eligibility or investigating and rendering adverse actions against those found to have violated the applicable law will not draw the scrutiny of antitrust analysis. In the North Carolina case, the court noted the fact that the Board bypassed the opportunity to seek injunctive relief through judicial proceedings as provided for in the practice act and proceeded directly to administrative cease and desist letters on a large scale.

While the first prong of the test, a clearly articulated state policy, was agreed to exist, boards are encouraged to review the practice act and determine if this policy is explicit. Every practice act should contain a statement of purpose and legislative declaration. Readers are encouraged to consult with the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy as a reference. The oversight criterion, however, is subject to significant debate and interpretation and will spawn fodder for the immediate and, likely, long-term future.

Additional considerations include changing board
Legal Briefs
(continued from page 124)

Membership to include persons not considered to be “active market participants,” a phrase not defined by the court. Also, much more drastic approaches include creating an oversight committee or person to assess and “approve” certain board decisions, creating composite boards to combine and, thus, arguably dilute market participants, departmentalize boards into a bureaucratic system, or do nothing.

Many boards are under a structure that already recognizes state oversight and the “do nothing” option may prevail. Indeed, state oversight can be arguably interpreted to include attorney general representation and legal review prior to taking significant actions, rulemaking as a means to interpret statutory language, and a close examination of the appointment process and elimination of trade association dominance.

This Supreme Court opinion is not a reason to overreact or for rash political fallout. However, the opinion is a reason to reassess the nature of regulation, rejuvenate boards and board members, scrutinize the mission of the boards, emphasize the consumer protection nature of the regulatory framework, and assure board members undergo significant training regarding the unique role of regulation.

This topic cannot be reviewed without reference to the dissenting opinion which declares that the federal antitrust laws are inapplicable to the North Carolina State Board of Dental Examiners as it is a state entity:

“Today, however, the Court takes the unprecedented step of holding that [state actor doctrine] does not apply to the North Carolina Board because the Board is not structured in a way that merits a good-government seal of approval; that is, it is made up of practicing dentists who have a financial incentive to use the licensing laws to further the financial interests of the State’s dentists. There is nothing new about the structure of the North Carolina Board. When the States first created medical and dental boards, well before the Sherman Act was enacted, they began to staff them in this way. Nor is there anything new about the suspicion that the North Carolina Board—in attempting to prevent persons other than dentists from performing teeth-whitening procedures—was serving the interests of dentists and not the public. Professional and occupational licensing requirements have often been used in such a way . . .

[T]he Sherman Act (and the Federal Trade Commission Act), do not apply to state agencies; the North Carolina Board of Dental Examiners is a state agency; and that is the end of the matter. By straying from this simple path, the Court has not only distorted; it has headed into a morass.”

Editor’s Note: Citations have been omitted in all quotations from the published opinion. The published opinion of the US Supreme Court is available online at www.supremecourt.gov/opinions/14pdf/13-534_19m2.pdf.


Newly Accredited VAWD Facilities

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

Actavis Pharma, Inc
Gurnee, IL

AMD Pennsylvania, LLC, dba American Medical Depot AMD Primary Care
Indianapolis, IN

Cardinal Health 200, LLC, dba Cardinal Health
Sao Paulo, SP, Brazil

Clint Pharmaceuticals, Inc
Old Hickory, TN

Exel, Inc
Mechanicsburg, PA (Two locations)

Flywheel Healthcare, LLC, dba Young at Heart Distribution
Indianapolis, IN

GENCO I, Inc, dba GENCO
GSK Colonial Heights
Colonial Heights, VA

GENCO I, Inc, dba GENCO
GSK Knoxville
Knoxville, TN

HyGen Pharmaceuticals, Inc
Redmond, WA

McKesson Medical-Surgical, Inc
Gahanna, OH

Medline Industries, Inc
Denver, CO

Merz North America, Inc
Sturtevant, WI

Pharmalink, Inc, dba Pharmalink
Largo, FL

Priority Air Express, LLC,
dba Priority Solutions International
Swedesboro, NJ

Proficient Rx, LP
Thousand Oaks, CA

Smiths Medical ASD, Inc
Olive Branch, MS

The Harvard Drug Group, LLC, dba Major Pharmaceuticals; Harvard Third Party Logistics
Indianapolis, IN

UPS Supply Chain Solutions
Durham, NC

A full listing of more than 540 accredited VAWD facilities is available on the NABP website at www.nabp.net.
NABP Visits European Union to Introduce .Pharmacy

Aimed at offering assistance to address the problems surrounding illegal online sales of prescription medications, NABP and other United States advocates for safe online pharmacy attended a series of meetings with members of European Union (EU) agencies, European member state representatives, and European national pharmacy regulators in March 2015. Melissa Madigan, policy and communications director, NABP and representatives of the Alliance for Safe Online Pharmacies (ASOP) and the Center for Safe Internet Pharmacies (CSIP) also offered assistance regarding the implementation of the EU Falsified Medicines Directive, and also introduced the .Pharmacy Top-Level Domain (TLD) Program.

Several of the meetings included an overview of the implementation process for an EU-wide logo to identify legal online pharmacies, referred to as the “Common Logo.” The Common Logo is an image that European consumers can look for to confirm the safety and legitimacy of an online pharmacy. EU representatives showed interest in learning more about the .Pharmacy TLD Program and how it might coincide with requirements for use of the Common Logo.

Specifically, NABP, ASOP and CSIP representatives met with:
- Representative of European Federation of Pharmaceutical Industries and Associations
- Representatives of the US Mission to the EU, US Department of Commerce
- Representative of the Luxembourg Mission to the EU
- Representatives of three separate departments of the European Commission
- Representatives of the European Association of Pharmaceutical Full-line Wholesalers

The meetings provided an important introduction of NABP programs to these groups, and may help to increase global awareness of NABP’s .Pharmacy TLD Program.

.Pharmacy Executive Board Meets at NABP Headquarters to Discuss Program’s Progress and Policies

On April 16, 2015, members of the .Pharmacy Top-Level Domain Program Executive Board met at NABP Headquarters to discuss progress of the program’s launch and to finalize the governance structure for approval by the NABP Executive Committee. Pictured from left to right: Karen M. Ryle, MS, RPh, 2014-2015 NABP chairperson; Ronald Guse, registrar, College of Pharmacists of Manitoba, representing National Association of Pharmacy Regulatory Authorities; Virginia Herold, MS, executive officer, California State Board of Pharmacy, representing the .Pharmacy Supporter Advisory Committee; Luc Besançon, MS, PharmD, International Pharmaceutical Federation; Joseph L. Adams, RPh, 2014-2015 NABP president; and Malcolm J. Broussard, RPh, executive director, Louisiana Board of Pharmacy.
NABP began accepting applications for .pharmacy domain names from all eligible pharmacy-related entities on June 3, 2015. Those eligible to apply include pharmacies, pharmacy benefit management companies, prescription drug information and pharmacy referral sites, prescription drug-related patient advocacy and consumer education sites, medical professionals’ offices, schools and colleges of pharmacy, continuing pharmacy education providers, wholesale drug distributors, pharmaceutical manufacturers, consultant pharmacists, and pharmacy associations. Organizations that are authorized to obtain their requested domain name(s) will be able to register through an approved registrar.

NABP’s member boards of pharmacy had the first opportunity to obtain a .pharmacy domain during a special registration period beginning in November 2014. Member boards were eligible to obtain a board-specific domain name at no cost and register that name for a period of five years. Boards of pharmacy that have not yet requested their .pharmacy domain name may send a request by email to custserv@safe.pharmacy. NABP will continue making the registration of these domain names available at no cost to the boards.

In mid-June 2015, NABP contacted boards who had not yet registered domains with reminder information on how to do so.

Then, in December 2014, NABP began accepting the first .pharmacy applications from trademark holders who had entered their trademarks into the Internet Corporation for Assigned Names and Numbers (ICANN) Trademark Clearinghouse (TMCH). Known as the Sunrise Registration Period, this phase was mandated by ICANN to protect intellectual property rights by allowing eligible trademark holders to apply for domain names that exactly match their trademark names in the TMCH prior to the general public.

Following the Sunrise period, NABP offered a limited registration phase to entities that are accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) or Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) programs, or approved through the NABP e-Advertiser Approval Program. To receive accreditation or approval under these programs, VIPPS, Vet-VIPPS, and NABP e-Advertiser websites have undergone a thorough review process establishing their compliance with NABP standards for legitimate online practice. As such, all previously reviewed content was prequalified and considered eligible for a .pharmacy domain name without the usual .pharmacy application and fee.

A final limited application and registration period for all dispensing pharmacies was held from April 1 through June 2, followed by the start of general availability on June 3. At press time, NABP had received a total of 441 .pharmacy domain name requests and registered 96 domains including 25 boards of pharmacy domain names.

Except for those already VIPPS-or Vet-VIPPS-accredited or NABP e-Advertiser-approved, entities seeking a .pharmacy domain name must first submit an application, supporting documentation, and an application fee to NABP. NABP will evaluate these materials to ensure compliance with program standards. As part of the application process, the content of the proposed website must be available for review by NABP either on an existing website or a staging site. NABP is establishing a network of international regulatory groups to facilitate evaluation of domain name applications from countries worldwide. Once approved, applicants may register the domain names through one of NABP’s participating registrars. Those entities that hold a .pharmacy domain must reapply and re-register annually.

More information about the .Pharmacy TLD Program is available at www.safe.pharmacy.

Eligible Entities Now Able to Apply for .Pharmacy Domain Names

- Pharmacies
- Pharmacy benefit management companies
- Prescription drug information and pharmacy referral sites
- Prescription drug-related patient advocacy and consumer education sites
- Medical professionals’ offices
- Schools and colleges of pharmacy
- Continuing pharmacy education providers
- Wholesale drug distributors
- Pharmaceutical manufacturers
- Consultant pharmacists
- Pharmacy associations
**Consensus Document Addresses ‘Red Flags’ and Challenges Related to Prescribing and Dispensing Controlled Substances**

In March 2015, NABP, along with a coalition of stakeholder organizations, released a consensus document representing the medical, pharmacist, and supply chain spectrum, highlighting the “red flag” warning signs and challenges related to prescribing and dispensing controlled substance (CS) prescriptions. As detailed in the consensus document, the goal is to provide health care practitioners with an understanding of their shared responsibility to ensure all CS are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny. Overall, challenges faced by health care practitioners in regard to prescribing and dispensing CS can be overcome through collaboration, communication, and broader efforts to prevent the diversion and misuse of CS while ensuring access to the medications for patients who need them for legitimate reasons.

The stakeholders initially met on October 2, 2013, and subsequently met numerous times over the course of 2013 and 2014 to discuss the aforementioned challenges and red flag warning signs including categorizing the signs to indicate the likelihood that diversion, misuse, or abuse are occurring. Discussions aimed to foster the understanding of health care practitioners’ roles, and the dialogue and resulting consensus document shed light on unappreciated challenges, such as the demands placed on physicians to provide direct patient care and the pharmacist’s corresponding responsibility under Drug Enforcement Administration regulations to ensure CS prescriptions are legitimate. The red flag warning signs for both physicians and pharmacists were placed into two categories – those factors more indicative of substance abuse or diversion, and other aberrant medication-related behaviors and factors potentially indicative of substance abuse or diversion.

The coalition of stakeholders that, along with NABP, supports the consensus document includes the following organizations:
- American Academy of Family Physicians
- American College of Emergency Physicians
- American Medical Association
- American Osteopathic Association
- American Pharmacists Association
- American Society of Anesthesiologists
- American Society of Health-System Pharmacists
- Cardinal Health
- CVS Health
- Express Scripts
- Healthcare Distribution Management Association
- National Association of Chain Drug Stores
- National Community Pharmacists Association
- Pharmaceutical Care Management Association
- Purdue Pharma L.P.
- Rite Aid
- Walgreens Boots Alliance

The consensus document, “Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances,” is available under Position Papers in the Members section of the NABP website, www.nabp.net.

---

**JCPP Addresses Role of Pharmacist in Preventing Misuse and Abuse**

The Joint Commission of Pharmacy Practitioners (JCPP) has released a statement acknowledging the nationwide epidemic of prescription drug abuse and misuse. The statement outlines nine principles that JCPP member organizations believe must be considered when developing policy to address this issue, including the pharmacists’ role in preventing misuse and abuse while ensuring that patients with legitimate need for prescription medications have appropriate and timely access.

The statement also identifies prescription monitoring programs (PMPs) as a useful clinical tool to identify and prevent prescription drug abuse, and reiterates JCPP’s support of pharmacist access to PMPs to provide pharmacists with the tools to make appropriate decisions regarding medication therapy.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.
During the first quarter of 2015, the state boards of pharmacy reported a total of 1,665 disciplinary actions to the NABP Clearinghouse, including actions taken against pharmacists, pharmacy interns, pharmacies, wholesalers and manufacturers, and other licensees. Of the 1,665 actions:

- 676 actions (40.6%) were taken on pharmacists;
- 491 actions (29.5%) were taken on pharmacies;
- 427 actions (25.6%) were taken on pharmacy technicians;
- 27 actions (1.6%) were taken on other licensees;
- 17 actions (1%) were taken on wholesalers and manufacturers;
- 12 actions (0.7%) were taken on pharmacy interns;
- 11 actions (0.7%) were taken on mail-order pharmacies; and
- 4 actions (0.2%) were taken on controlled substance licensees.

For a full breakdown of the actions taken and the bases for actions taken during first 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 First Quarter 2015

*The miscellaneous category includes denial of initial license or certificate; denial of license or certificate renewal; directed in-service training; directed plan of correction; extension of previous licensure action; interim action – agreement to refrain from practice during investigation; limitation or restriction on license; modification of previous licensure action; other licensure action – not classified; publicly available negative action or finding; reduction of previous licensure action; restrictions on admissions or services; and voluntary limitation or restriction on license.
Association News

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

The miscellaneous category includes breach of confidentiality; conduct evidencing ethical unfitness; conduct evidencing moral unfitness; deferred adjudication; drug screening violation; expired drugs in inventory; failure to comply with patient consultation requirements; failure to cooperate with board investigation; 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; failure to pay child support/delinquent child support; failure to take corrective action; immediate threat to health or safety; improper or inadequate supervision or delegation; inadequate or improper infection control practices; inadequate security for controlled substances; incompetence; lack of appropriately qualified professionals; misappropriation of patient property or other property; negligence; nolo contendere plea; operating beyond scope of license; other licensure action – not classified; other unprofessional conduct; practicing beyond the scope of practice; unable to practice safely; and violation of or failure to comply with licensing board order.
The new North American Pharmacist Licensure Examination® (NAPLEX®) competency statements will go into effect November 2015, along with a new passing standard. The NAPLEX standard setting committee convened during a two-day workshop held at NABP Headquarters on March 6-7, 2015. During the workshop, 20 panelists met to reassess the NAPLEX passing standard. The committee included members of the NABP Executive Committee, members of the NABP Advisory Committee on Examinations (ACE), the NAPLEX Review Committee, and 14 pharmacist practitioners recruited from respondents to the 2014 NABP Pharmacy Practice Analysis Survey. The outcome of the standard setting produces a recommendation that takes into consideration all of the expert participants’ contributions to the process.

The recommendation was reviewed by the NAPLEX Review Committee, ACE, and the NABP Executive Committee for a final determination of a passing standard. The Executive Committee approved the passing standard at its May 2015 meeting. NABP plans to implement the revision to the passing standard effective November 2015. More information about the revised competency statements is available in the January 2015 NABP Newsletter.

Standards Setting Process

Upon convening for a two-day workshop at NABP Headquarters in Mount Prospect, IL, the committee received training consisting of an overview and discussion of test development and standard setting. Written instructions, practice examples, and opportunities for discussion and questions were also part of the training process. The participants were also provided with an overview of the NAPLEX and how the examination is used by the boards of pharmacy in licensure decisions. An explanation of how the results of the study would be used to establish a cut score was included in the training.

Throughout the workshop, the committee actively participated in discussions framed by the test blueprint or competency statements, which describe the knowledge, skills and abilities of the entry-level competent pharmacist. They used that information to create a working document that outlines the qualifying attributes for entry-level pharmacist competency.

The committee then provided ratings for 200 NAPLEX items. The ratings were estimates of the percentage of borderline candidates that, in their opinion, would answer the item correctly. After the committee finished rating each item on the reference form, ratings were collected and analyzed.

The outcome of the ratings was applied to historical score data from exams administered between March 1, 2010, and December 31, 2014, to estimate impact to expected pass rates.

On the second day of the workshop, following a discussion of first ratings and outcomes, the participants were instructed to rate each item on the NAPLEX form for a second time. These second ratings were subsequently analyzed and the data was presented back to the group. Predictions of the impact to the pass rate based upon the average ratings were provided to the group. The committee engaged in further discussion to address their impressions of the outcomes prior to making its recommendation. The minimum required scaled score will remain 75.

In June 2015, NABP provided notice to the boards of pharmacy and schools and colleges of pharmacy of the revision to the passing standard. Additional information about the NAPLEX and NABP’s other examinations is available in the Programs section of the NABP website, www.nabp.net.
2015-2016 Advisory Committee on Examinations
Appointments Announced, Including Two New Members

NABP is pleased to announce that the following individuals have been appointed to serve on the 2015-2016 Advisory Committee on Examinations (ACE). This standing committee, established by NABP in 1912, was created to safeguard the integrity and validity of NABP examinations.

ACE oversees the development and administration of all of the Association’s examination and certification programs. ACE also considers policy matters, evaluates long-range planning strategies, and recommends appropriate action to the NABP Executive Committee.

ACE typically convenes three to four times per year. The committee consists of individuals who are affiliated members of NABP, including current active board of pharmacy members and administrative officers, individuals who have served within the last five years as a member or administrative officer of a board of pharmacy, and non-affiliated individuals who are practicing pharmacists or serving as pharmacy school faculty. Members serve three-year terms and ex officio members serve one-year terms.

2015-2016 ACE Members

The following members began their terms on June 1, 2015. Gary Dewhirst, RPh, is serving as the Executive Committee liaison.

- Carl W. Aron, RPh, Monroe, LA
- Kay L. Hanson, RPh, Brooklyn Park, MN
- Debra Glass, BPharm, RPh, Tallahassee, FL
- Neal F. Walker, RPh, Hibbing, MN
- Anita Young, EdD, RPh, Boston, MA
- David Chikao Young, PharmD, RPh, Salt Lake City, UT
- Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Las Vegas, NV (Ex Officio Member, one-year term)
- Holly L. Mason, PhD, West Lafayette, IN (Ex Officio Member, one-year term)
- Amy Mattila, PharmD, RPh, Washburn, WI (Ex Officio Member, one-year term)

Color denotes new members

Enhanced VPP Interface Available to the Boards in July 2015

An enhanced Verified Pharmacy Program™ (VPP™) interface with a new and improved look is now available for the state boards of pharmacy. The updated interface will provide the boards with the ability to more easily view vital information for use when making licensure and registration decisions for nonresident pharmacies. Through VPP, board of pharmacy staff will continue to receive information including licensure, inspection, and disciplinary action information.

Developed by NABP in conjunction with the state boards of pharmacy, VPP allows the boards to communicate and share critical information, in addition to providing access to verified data collected directly through the program. 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 this data sharing capability.

At press time, at least 297 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 nonresident pharmacies.

Of the 297 VPP facilities:
- 125 pharmacies engage in nonsterile compounding;
- 39 pharmacies engage in sterile compounding;
- 93 pharmacies engage in both sterile and nonsterile compounding;
- 38 pharmacies are general retail or mail-order pharmacies; and
- 2 pharmacies are nuclear pharmacies.

The Association recently updated the VPP inspection forms based on feedback from members of the January VPP Working Group and Inspection Blueprint Development Workshop meetings. In addition, NABP presented on the Multistate Pharmacy Inspection Blueprint, inspection tools, and VPP at the NABP 111th Annual Meeting in New Orleans, LA, as well as provided the member boards with additional tips for utilizing VPP.

For more information about VPP or the inspection sharing network, contact the NABP Accreditation department at VPP@nabp.net. Additional information is also available in the Programs section of the NABP website at www.nabp.net.
NABP hosted the fourth annual Pharmacy Curriculum Outcomes Assessment® (PCOA®) forum on April 23, 2015, at NABP Headquarters in Mount Prospect, IL. Each year, the PCOA forum is held to provide PCOA users, prospective users, stakeholders, and developers an opportunity to meet and share insights and experiences regarding the assessment in an educational, collaborative environment.

The 2015 forum began with an overview of the 2014–2015 administrations of the assessment, including information about the background and developmental history of the PCOA and a review of the past years’ administration results to date. Attendees also reviewed program development updates regarding the curriculum survey of the schools and colleges of pharmacy, testing windows, and a forthcoming score interpretation guide.

Following the program updates, a representative from the Accreditation Council for Pharmacy Education (ACPE) provided updated information about the Accreditation Standards and Key Elements for the Professional Program Leading to the Doctor of Pharmacy Degree (Standards 2016), which will go into effect in July 2016. ACPE’s presentation included information about how the schools and colleges of pharmacy can use the PCOA to assess the effectiveness of various curricular designs and teaching methods across programs.

The remainder of the meeting consisted of presentations of research initiatives at institutions utilizing the PCOA. Research topics included the implementation of the PCOA in doctor of pharmacy curricula at the schools, the PCOA’s role in predicting candidate success on the North American Pharmacist Licensure Examination®, and the association of curricular integration and institutional or program characteristics to performance on the PCOA.

The PCOA is an independent, objective, and external measure of student performance in United States pharmacy curricula. Since its operational launch in 2009, the assessment has been administered to more than 31,000 students from 65 different schools and colleges of pharmacy. The PCOA is the only standardized national assessment that compares school outcomes with national scores, providing a way for institutions to monitor student progress and pharmacy curricula in compliance with ACPE recommendations for assessment.

More information about the PCOA can be found in the Programs section of the NABP website at www.nabp.net. Details about the 2016 PCOA registration and administration process will be sent to the schools and colleges of pharmacy in summer 2015.

Participants Discuss Implementation of ACPE 2016 Standards and Curricular Integration at Fourth Annual PCOA Forum

On April 23, 2015, representatives from schools and colleges of pharmacy, the American Association of Colleges of Pharmacy, and the Accreditation Council for Pharmacy Education gathered at NABP Headquarters for the fourth annual Pharmacy Curriculum Outcomes Assessment® (PCOA®) forum. Pictured above: Tom Campbell, PharmD, associate dean of pharmacy practice, Lipscomb University College of Pharmacy (left), shares with attendees his experiences regarding the assessment with other representatives. (Right) Guest Speaker Justine Schuller Gortney, PharmD, RPh, BCPS, assistant professor of pharmacy practice, Wayne State University, Eugene Applebaum College of Pharmacy, shares her insight on the assessment with attendees.
AWARxE Shares Prescription Drug Safety Information Through Local Outreach Efforts

It has been a busy couple of months for the AWARxE® Prescription Drug Safety Program. The AWARxE team hosted resource tables at events throughout the Chicagoland area. In addition to prescription drug abuse, many of the events address heroin use in response to the alarming new trend for those who are addicted to prescription drugs (mainly opioids) to move on to heroin to receive a similar high at a cheaper price.

At each event, AWARxE hosts a resource table with flyers on topics such as proper medication disposal, safe online prescription shopping, and drug misuse and abuse facts. Branded bookmarks, bracelets, USB thumb drives, and sweet treats draw in event attendees while the AWARxE team speaks with guests on ways to prevent misuse and abuse of prescription medications. A sign-up sheet is provided for the AWARxE Prescription Drug Safety Newsletter so that interested parties can stay informed about the latest news related to prescription drugs for consumers.

The first resource table of the year was in February at a forum in Lake County, IL, on heroin and opioid abuse awareness. The forum was for residents and parents hoping to learn about the drug problems facing Lake County communities. Several speakers, including recovering substance abusers and the Lake County state’s attorney, made the event memorable and poignant.

Next, AWARxE staff hosted a resource table in Evergreen Park, IL, at the Serenity Family Outreach’s Health, Drug Prevention, and Education Fair held in March. AWARxE staff was able to interact with residents, students, parents, community leaders, and other advocacy organizations. The goal of the event was to increase drug abuse awareness, and to provide services and resources to those affected by the epidemic.

April was a flurry of activity, with a total of five resource tables! The HERO and Will County HELPS event focused on action strategies to combat the heroin epidemic. Featured speakers ranged from a Substance Abuse and Mental Health Services Administration representative, to Representative Sam Yingling of the Illinois Heroin Task Force.

The second half of the month took the AWARxE team to school-related events that ranged from high schools to a graduate school. Vernon Hills High School hosted Rebound: The Chris Herren Story, which was a talk by a former NBA player who fought and overcame addiction to prescription drugs and alcohol. It taught students and parents that even people in the limelight can succumb to addiction if prescription drugs are misused. The Parent Empowerment event was held for the parents of eighth grade students. The AWARxE resource table enabled parents to learn about the dangers of prescription drug abuse during a vulnerable time in a child’s life: the transition from grade school to high school.

AWARxE staff also attended the 7th Annual Alcohol and Drug Awareness Health Fair at Moraine Valley Community College. The AWARxE team had great success at this event for students studying addiction. Many students signed up for the AWARxE newsletter and stopped by to learn about ways to avoid prescription drug misuse and abuse.

Finally, AWARxE took part in University of Illinois at Chicago College of Pharmacy’s Prescription Drug Abuse in Action event that taught students in the addiction studies program about signs of prescription abuse for patients. This event was a great opportunity for AWARxE to reach out to future pharmacists.

AWARxE looks forward to continuing to provide much needed information to the public about the dangers of misusing or abusing prescription drugs.

AWARxE Hosts Resource Tables at Events Around Chicagoland in Spring 2015

In Spring 2015, the AWARxE Prescription Drug Safety Program team hosted a number of resource tables at local events throughout the Chicagoland area. Such events include the HERO and Will County HELPS forum (pictured left) that focused on action strategies to combat the heroin epidemic.
NABP Seeks Individual to Represent Association on ACPE Board

NABP is currently accepting letters of interest and curricula vitae (CVs) from individuals interested in serving a six-year term as one of the Association’s three representatives to the Board of Directors of the Accreditation Council for Pharmacy Education (ACPE).

Interested active board of pharmacy members, administrative officers, or individuals who have served within the last five years as members or administrative officers of an active board of pharmacy are encouraged to submit a current CV and a letter of interest to NABP Executive Director/Secre-
tary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056, no later than September 1, 2015. Appointees must be available to attend two to three board meetings per year, three to four school or college of pharmacy on-site visits, an ACPE annual meeting, and an orientation program to be held in January 2016. The term will officially begin on July 1, 2016.

Letters should be a short narrative, no longer than one page, highlighting relevant experiences and talents that qualify candidates for service, their views on educational and accreditation issues facing the ACPE Board of Directors, why they wish to serve, and what they would contribute as an appointee of NABP.

On June 30 of every even-numbered year, the six-year term of one NABP representative expires. A subcommittee of the NABP Executive Committee will present a recommendation for the appointee to the full Executive Committee at its December 2015 meeting for final approval.

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

NABP Report Highlights Need for Continued Consumer Outreach Efforts to Combat Rogue Online Drug Seller Activity

In April 2015, NABP issued a report that profiled the continued pervasiveness of illegal online drug seller activity and the need for increased awareness about the risks such activity poses to public health.

As detailed in the Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: April 2015, the threat posed by illegal online drug sellers underscores the necessity of ongoing consumer education efforts. Specifically, the report highlighted consumer outreach being done through the Association’s .Pharmacy Top-Level Domain (TLD) and AWARERx® Prescription Drug Safety programs. Consumer education is one of NABP’s primary goals, and in 2015, the Association is sharing patient safety information through television, radio, online advertising, and social media.

The report detailed NABP’s data collected on websites selling medicine illegally online to United States patients since 2008. In that time, NABP has reviewed nearly 11,000 Internet drug outlets, finding that 96.2% (10,544) of the sites reviewed operate out of compliance with US pharmacy laws and practice standards. Currently, approximately 88.3% of “Not Recommended” sites are selling prescription drugs without requiring a valid prescription. In addition, approximately 62% do not provide a valid address, and nearly 50% offer drugs that are either foreign, or not approved by the US Food and Drug Administration. Further, of the 10,521 Not Recommended sites, 91% can be traced to affiliate networks of rogue Internet drug outlets, and more than 12% dispense controlled substances in violation of US laws and regulations.

The frequency of such characteristics among online drug sellers poses a danger to public health, and was the impetus for NABP launching the .Pharmacy TLD Program. Only legitimate Internet pharmacies and pharmacy-related websites will qualify for .pharmacy domains, giving consumers a way to distinguish safe and legal online pharmacies and resources from rogue sites. On June 3, 2015, NABP began accepting .pharmacy domain name applications for all entities with a pharmacy or pharmacy-related website.

For the full report with detailed findings on the characteristics of rogue websites and the list of Not Recommended sites, visit www.AWARERx.org/get-informed/safe-acquisition/not-recommended-sites.

To find the safest sources for purchasing medicine online, consumers are encouraged to look for the Verified Internet Pharmacy Practice Sites® (VIPPS®) Seal on an accredited site and check NABP’s list of accredited sites on its prescription drug safety website, www.AWARERx.org. More information about the .pharmacy TLD is available on page 127 of this Newsletter and at www.safe.pharmacy, and .pharmacy sites will be listed there as approved entities register .pharmacy domain names.
Around the Association

Executive Officer Changes

- Jonathan Harris, JD, is serving as the commissioner of the Connecticut Commission of Pharmacy, replacing William Rubenstein, JD. Throughout his career, Mr Harris has been involved in a number of public service positions including serving as mayor of West Hartford, CT, a state senator from the fifth district, and a member of the West Hartford Town Council. In addition, he served as the state’s deputy treasurer and as the executive director for the Connecticut Democratic Party. Mr Harris received his bachelor of arts degree from Brandeis University and his juris doctorate degree from the New York University School of Law.

- Allison Dudley, JD, is serving as the executive director of the Florida Board of Pharmacy, replacing Patrick Kennedy, MA. Prior to this position, Ms Dudley served as the executive director of the Florida Board of Medicine. She also served as the assistant attorney general for the Florida Office of the Attorney General. Ms Dudley received her juris doctorate degree from the University of Florida.

- Terry Witkowski is serving as the acting executive director of the Iowa Board of Pharmacy, replacing Lloyd K. Jessen, JD, RPh.

- Kathie Lueke is serving as the office administrator of the Nebraska Board of Pharmacy, replacing Becky Wisell.

Board Member Appointments

- Michael Blaire, RPh, has been appointed a member of the Arizona State Board of Pharmacy. Blaire’s appointment will expire January 20, 2020.

- Kristen Snair, CPhT, has been appointed a member of the Arizona State Board of Pharmacy. Snair’s appointment will expire January 20, 2020.

- Corey Duteau, RPh, has been appointed a member of the Vermont Board of Pharmacy. Duteau’s appointment will expire December 31, 2019.

Board Member Reappointments

- Kyra Locnikar has been reappointed a public member of the Arizona State Board of Pharmacy. Locnikar’s appointment will expire January 1, 2020.

- Joseph Bruno, RPh, has been reappointed a member of the Maine Board of Pharmacy. Bruno’s appointment will expire November 30, 2017.

- Joseph Pietroski has been reappointed a public member of the Maine Board of Pharmacy. Pietroski’s appointment will expire November 30, 2017.

- Katherine Orr, PharmD, RPh, has been reappointed a member of the Rhode Island Board of Pharmacy. Orr’s appointment will expire November 21, 2017.

- Diane Dady, RPh, has been reappointed a member of the South Dakota State Board of Pharmacy. Dady’s appointment will expire October 1, 2017.

- Nancy Hecox, PharmD, RPh, BSPharm, CDP, has been reappointed a member of the Washington State Quality Assurance Commission. Hecox’s appointment will expire January 19, 2019.

- Elizabeth Jensen, PharmD, RPh, has been reappointed a member of the Washington State Quality Assurance Commission. Jensen’s appointment will expire January 19, 2019.

Newly Accredited VIPPS Facility

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

Prime Aid Pharmacy Corp
www.primeaidrx.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP website at www.nabp.net.
NABP Continues Funding to Support State Participation in PMP InterConnect; Twenty-Nine States Now Live and Sharing Data

Recognizing the importance of prescription monitoring programs (PMPs) and other state efforts to fight against prescription drug abuse and diversion, NABP approved continued funding to support participation in NABP PMP InterConnect® through June 2018 at no cost to the state PMPs.

In a June 2015 news release, NABP President Edward G. McGinley, MBA, RPh, highlighted the progress of PMP InterConnect in assisting states in their efforts to combat prescription drug abuse and diversion. He noted that while some critics suggest a national PMP is needed, the Association and its member boards continue to see the benefits of the state-based PMPs and how the success of PMP InterConnect has enhanced their effectiveness.

The news release highlighted how PMP InterConnect enhances the benefits of state PMPs by providing health care providers with access to a more complete record of a patient’s controlled substance (CS) medication history. More comprehensive data can assist health care providers in identifying patients who may be misusing controlled substances or struggling with abuse, especially those patients that cross state lines to obtain multiple CS medications.

PMP InterConnect is also unique in its ability to facilitate the integration of interstate PMP data directly into health care providers’ workflow, 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.

State Participation Update

Currently, 29 states are participating in PMP InterConnect, with Iowa being the latest state to go live in May 2015. Iowa joins PMPs in the states of Arizona, Arkansas, Colorado, Connecticut, Delaware, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Virginia, West Virginia, and Wisconsin. Several other states have signed memorandums of understanding to participate in the program. NABP anticipates that 70% of the state PMPs will be either connected to or working toward a connection in 2015. Since launching in 2011, PMP InterConnect has processed more than 14 million requests from authorized users, and PMP InterConnect is now processing an average of over 1 million requests per month for a consolidated multistate PMP report.

On July 15-16, 2015, the NABP Steering Committee met in Northbrook, IL, to discuss these updates and other information related to the administration and function of PMP InterConnect. To encourage national interoperability, additional state PMPs not currently connected to PMP InterConnect were also invited to attend. More information about this meeting will be available in future NABP communications.

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

Newly Accredited DMEPOS Facilities

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

<table>
<thead>
<tr>
<th>Facility Name</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clayworth Healthcare Pharmacy</td>
<td>Castro Valley, CA</td>
</tr>
<tr>
<td>Pawleys Island Pharmacy at Litchfield</td>
<td>Pawleys Island, SC</td>
</tr>
<tr>
<td>Robinson Drug Shop</td>
<td>Mendham, NJ</td>
</tr>
</tbody>
</table>

A full listing of over 500 accredited DMEPOS companies representing nearly 28,000 facilities is available on the NABP website at www.nabp.net.
North Carolina Issues Reminder Regarding Proper Identification of Compounding Risk Levels

Pharmacies that hold a permit from the North Carolina Board of Pharmacy and that engage in any type of compounding are required to notify the Board. Such pharmacies must report (both on an initial permit application and as part of each annual renewal): (1) whether the pharmacy compounds; (2) a good-faith estimate of the percentage of the pharmacy’s dispensing that involves compounded products; (3) whether the pharmacy engages in nonsterile compounding; (4) whether the pharmacy engages in sterile compounding; and if so, (5) what risk level of sterile compounding, as defined by United States Pharmacopeia Chapter <797>, the pharmacy performs.

Accurate reporting of this information is crucial for at least two reasons. First, failure to provide accurate information in connection with seeking or renewing a permit is grounds to revoke or void a pharmacy permit (NCGS §90-85.38). Second, the Board’s risk-based inspection intervals are driven by the scope and type of service provided at a pharmacy, particularly compounding services.

In at least one recent case, a pharmacy reported that it was only engaged in low-risk sterile compounding. An inspection showed that the pharmacy was, in fact, engaged in high-risk sterile compounding. Such misreporting is a serious issue, and will be treated as such.

In an effort to reduce any confusion concerning this reporting requirement, Board staff has developed a guidance document, which may be found at [www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf](http://www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf).

New Law in South Dakota Allows First-Responder Naloxone Administration

South Dakota’s Senate Bill 14, signed by Governor Dennis Daugaard on February 18, 2015, will allow trained first responders to administer naloxone to anyone who is experiencing symptoms of an opiate overdose. The act provides for the possession and administration of opioid antagonists by first responders, including law enforcement officers, emergency medical personnel responding to an emergency call, and firefighters, for the treatment of drug overdoses.


Washington State Pilots New Alert System to Address Prescription Fraud

To address the prescription drug overdose epidemic, the Washington State Department of Health is piloting a new alert system. This system would allow a health care provider who becomes aware of a fraudulent prescription to fill out a web-based form with specific information regarding the prescription and submit it to the Department of Health. The Department of Health would then make that information available to the pharmacies registered with the public listserv DOH-RX-FRAUD-ALERT, on the Washington State Pharmacy Quality Assurance Commission’s web page, and in the prescription monitoring system. The hope is that this tool will help prevent additional fraudulent prescriptions from being filled. The pilot started on April 15, 2015, and ends October 15, 2015.

After an eightfold increase during the previous decade, the prescription drug overdose rate in Washington State has declined by 29% between 2008 and 2013. The decline in deaths associated with prescription drug overdose seems to be leveling off – there were 381 of these deaths reported in 2013, down by seven from 2012. While the trend is encouraging, too many people are still dying due to misuse of these medications.

While working on this issue, the Commission often gets calls from health care providers who have become aware of fraudulent prescriptions through forgery or theft of prescription pads. The alert system was created to respond to this issue.

Washington State pharmacies can sign up to receive alert notices via email by providing a pharmacy site-specific email address to DOH-RX-FRAUD-ALERT at [http://listserv.wa.gov/cgi-bin/wa?A0=DOH-RX-FRAUD-ALERT](http://listserv.wa.gov/cgi-bin/wa?A0=DOH-RX-FRAUD-ALERT).

California Rule Allows Dispensing of Naloxone Without Prescription

Pharmacists in California may now provide naloxone, the medication that can help to reverse the effects of an opioid overdose, without a prescription after the California State Board of Pharmacy approved new emergency regulations. To be eligible to dispense the drug under the new regulations, pharmacists must complete one hour of continuing education on the use of the drug. When dispensing the drug, pharmacists must screen for any hypersensitivity, and must provide the recipient with training in opioid overdose prevention, recognition, response, and on the administration of naloxone. The pharmacist must also provide the recipient a naloxone fact sheet, which has been approved by the Board.

Additional information about the new regulations in California is available on the California State Board of Pharmacy website, [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).
Fayetteville, NC
Pharmacy Shuts Down, Products Recalled

The North Carolina Board of Pharmacy has shut down Prescription Center Pharmacy in Fayetteville, NC, and recalled all of its nonsterile and sterile compounded products. In a press release, the Board cited concerns that the pharmacy was unable to ensure the sterility, stability, and potency of its products. The Board has not received any complaints of injuries related to the products. The recall covers all nonsterile and sterile products compounded, repackaged, and distributed by Prescription Center Pharmacy from September 10, 2014 to March 10, 2015. The products were distributed to all 50 United States and Canada. The Board recommends that health care providers and patients stop using the products and dispose of them according to state or local government guidelines. Additionally, any adverse events should be reported through the Food and Drug Administration (FDA) MedWatch Adverse Event Reporting program or to the North Carolina Board.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommends FDA in a Safety Alert posted to the FDA website. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and died, despite veterinary care. A third cat in the second household also died after the owner had stopped using the medication. Necropsies on the three cats found evidence that was consistent with NSAID toxicity. The pet owners had applied the drug to their own necks or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, FDA notes. Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pet to the medication. Additional information is available in the FDA safety alert on the agency’s website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm.

Pharmacists Are Performing More Patient Care

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the 2014 National Pharmacist Workforce Survey. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%. Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, www.aacp.org.

New FDA Drug Info Rounds Training Video Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm442182.htm.


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

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

To subscribe, visit the News section on the NABP website at www.nabp.net/news and click the subscribe button located along the top right of the page titled “Sign Up for NABP News.”

Questions? Contact custserv@nabp.net.
Advisory Committee on Examinations Meets to Review NABP Examination and Certification Programs

In March 2015, members of the 2014-2015 Advisory Committee on Examinations (ACE) met at NABP Headquarters to review the Association’s examination and certification programs. During the meeting, member Michael Duteau, RPh, New York State Board of Pharmacy, was awarded with a certificate for his dedication and contributions as a member of ACE during his seven years of service. Front row pictured from left to right: Philip P. Burgess, MBA, DPh, RPh, NABP Executive Committee liaison; Carl W. Aron, RPh, Louisiana Board of Pharmacy; Anita Young, EdD, RPh, former member, Massachusetts Board of Registration in Pharmacy; David C. Young, PharmD, RPh, Utah Board of Pharmacy; and Amy Mattila, PharmD, RPh, former member, Wisconsin Pharmacy Examining Board (ex officio member). Back row pictured from left to right: Holly L. Mason, PhD, Purdue University College of Pharmacy (ex officio member); Neal F. Walker, RPh, Fairview Range; Kay L. Hanson, RPh, Minnesota Board of Pharmacy; Duteau; and Mark Decerbo, PharmD, RPh, BCNSP, BCPS, Roseman University of Health Sciences (ex-officio member).