NEWSLETTER OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY®

INNOVATIONS

Updates to NABP *Model Act* Address Evolving Pharmacy Practice

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INNOVATIONS
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Innovations
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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 $70 per year.

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NABP Mission Statement
NABP is the independent, international, and impartial association that assists its member boards and jurisdictions for the purpose of protecting the public health.

NABP Streamlining Online Programs, Transitioning Vet-VIPPS and e-Advertiser Approval Into .Pharmacy

In August, NABP announced its intention to begin the process of streamlining its accreditation and approval programs. This effort includes incorporating its Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) and NABP e-Advertiser Approval℠ programs into the .Pharmacy Top-Level Domain (TLD) Program.

Online commerce has changed considerably since the Vet-VIPPS and e-Advertiser programs were launched. The first pharmacy was accredited through Vet-VIPPS in April 2009, and interest in the program has been steady over the last seven years, with 25 online veterinary pharmacies currently accredited. Vet-VIPPS was designed specifically for veterinary pharmacy practice sites that dispense medications for companion animals or non-food producing animals over the internet. The e-Advertiser Approval Program was developed by NABP to identify internet advertisers that offer only limited pharmacy services or other prescription drug-related services online. The program helped internet search engines such as Google, Yahoo!, and Bing make it more difficult for rogue internet drug outlets to advertise and demonstrated the search engines' commitment to patient safety. As online safety and security challenges continue to evolve, NABP recognizes that its internet programs, including Vet-VIPPS and e-Advertiser, must likewise evolve and progress to protect public health.

NABP believes the .pharmacy verified TLD is the way to turn the tide against sophisticated criminals who can easily duplicate verification logos on authentic-looking sites to trick unsuspecting consumers into thinking they are visiting a legitimate online pharmacy. With .pharmacy, the "seal of quality" is built into the web address.

A TLD is represented in the suffix of every internet address. Familiar TLDs include unrestricted domains, such as .com or .net, which do not offer consumers the security of a safe online space like verified TLDs (eg, .pharmacy). The .pharmacy TLD is restricted to legitimate website operators throughout the world that adhere to the pharmacy laws specific to the jurisdictions in which the pharmacy is domiciled and to which it sells prescription drugs. More information about the importance of verified TLDs is provided on page 17 of this newsletter.

NABP ceased accepting new Vet-VIPPS and e-Advertiser Approval applications and renewal applications in August. Current participants were notified that they would be able to maintain their status in the programs through August 31, 2017, allowing them the opportunity to transition to the .Pharmacy TLD Program. Vet-VIPPS and e-Advertiser-approved websites are automatically approved to register .pharmacy domains. NABP is encouraging those businesses with currently accredited and approved sites to obtain a .pharmacy domain name before the aforementioned end date so that the entities can maintain ongoing NABP approval and ensure uninterrupted online program privileges.

In addition, NABP announced a price change for the .Pharmacy TLD Program. In an effort to bring costs in line with the e-Advertiser Approval Program, the .pharmacy application fee was reduced from the original price of $2,000 annually. The annual application/renewal fee is now $975 and includes website content review, licensure verification, and other standards review. The annual domain name registration fee is approximately $1,050 (prices vary by registrar). The price quoted is for a non-premium-priced name and applies to the domain name registration only.

The .Pharmacy TLD Program offers a superior means of identifying legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies. NABP has registered a .pharmacy domain name for its own website and will begin using *www.nabp.pharmacy* as its primary URL and will transition to .pharmacy email addresses in fall 2016. The Association transitioned its AWAR$_X$E® Prescription Drug Safety Program website to the .pharmacy domain as the program's primary web address in November 2015, and it also directs consumers to *safe.pharmacy* for information on buying prescription medication safely online.

Information about the program transition can be obtained by emailing info@safe.pharmacy.

Robotic Compliance

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

In addition to compliance with state practice acts and relevant standards of practice – with one's license at the risk of administrative action – pharmacists are also subject to potential civil liability under tort theories, specifically negligence. Harmed patients may seek redress under allegations of negligence and may also allege violations of the practice as a basis for substantiating wrongdoing. Pharmacists may assert that a physician's prescription accurately filled should insulate the pharmacist from liability. Consider the following.

In a civil wrongful death action, an executor of an estate alleged that the defendant, a compounding pharmacy, "negligently filled a prescription that was unreasonable on its face due to the strength of the pain medication prescribed, and that it knew or should have known that the drug was potentially fatal in the dosage prescribed . . . " The decedent, a male who suffered from chronic back pain due to an automobile accident, managed his pain by administering hydromorphone through a pain pump inserted in his spine. The decedent, an Ohio resident, was vacationing in Florida and visited a pain clinic based upon a referral from his Ohio treating physician. A physician at the Florida pain clinic wrote a prescription for hydromorphone that increased the concentration from 10 mg/mL to 30 mg/mL. The Florida physician transmitted the prescription directly to the compounding pharmacy, which compounded the medication and released it to the pain clinic. The pain clinic administered the medication through the decedent's pain pump, and the decedent died that same day.

The executor filed a lawsuit against the pain clinic, several health care providers, and the compounding pharmacy. For purposes of this article and the judicial opinion, the scope of the ruling only addresses the allegations against the compounding pharmacy, referred to as Defendant. Allegations against the other defendants remain pending, but have been stayed awaiting the outcome of the dispute with the Defendant.

The executor alleged that the Defendant was negligent in preparing and dispensing the prescription in an unreasonable dosage. She also alleged negligence per se based upon the fact that the Defendant was not registered or licensed in Florida as required by law. Based upon a motion to dismiss filed by the Defendant, the lower court dismissed with prejudice the relevant counts, finding that the executor failed to allege a cognizable duty that the Defendant owed to the decedent. The lower court also dismissed the negligence per se count related to the Defendant's lack of licensure in Florida, holding that the legislative intent of the pharmacy licensure laws did not create a private cause of action for failure to comply. The executor appealed.

The Florida Court of Appeals framed the issue as whether the lower court properly dismissed the negligence cause of action due to the absence of a cognizable duty owed from the Defendant to the decedent. In its analysis, the appellate court referenced a 1965 Florida Supreme Court case concluding that a pharmacist warrants that:

(1) He will compound the drug prescribed;

(2) He has used due and proper care in filling the prescription (failure of which

might also give rise to an action in negligence);

(3) The proper methods were used in the compounding process;

(4) The drug has not been infected with some adulterating foreign substance.

Based upon this precedent, along with other cited cases, the court determined that a pharmacist has a "common law duty to use due and proper care in filling a prescription and that the failure to do so may give rise to an action for negligence." It further noted that this duty of care may involve more than simply filling the prescription as written. A breach of the duty of care may result even if the pharmacist filled the prescription in accordance with the physician's instruction if the prescription is unreasonable on its face. Such a "robotic compliance" will not shield a pharmacist from potential liability.

Under relevant legal standards, motions to dismiss are analyzed as if the allegations are accepted as true in an attempt to ensure the plaintiff is not unfairly denied its day in court. Following this standard, the Court of Appeals resolved inferences in favor of the executor and held that filling the prescribed concentration of hydromorphone may be determined to be negligent under the cognizable duty standard and, therefore, the dismissal of those counts was in error. Thus, the appellate court reversed the dismissal of those counts and sent the case back to the trial court.

Regarding the negligence per se counts, the executor argued that failure to be licensed to fill the prescription constitutes unlicensed practice by a health care provider and that resulting injuries are compensable under negligence theories. The lower court held that failure to be licensed merely constitutes evidence of negligence relevant only after the law has imposed a duty of care that has been breached. The court noted that legislative intent is the primary factor in considering whether a cause of action exists when the statute does not expressly provide for one. Referencing the pharmacy practice act and the statute addressing health care providers in general (of which a pharmacist is included), the court distinguished between laws that establish civil liability and laws that secure the general health, safety, and welfare of the public. The Florida pharmacy practice act, as a statute intended to protect the general public and without a reference to a private cause of action, did not exhibit the legislative intent to establish this private right. The court cited previous case law to buttress this conclusion relative to the practice act. Thus, the court affirmed the lower court dismissal of the counts alleging negligence per se based upon unlicensed activity.

One justice dissented in the opinion, focusing on the fact that the Defendant had no prior dealings with the decedent and that, although negligence can be found related to filling of prescriptions as per the physician's order, the record in this case did not support such a finding.

A pharmacist's duty to warn, as well as the duty to use professional judgment when filling a prescription, has been argued and litigated for many years. This case affirms the obligations of a pharmacist to use professional judgment and not engage in "robotic compliance." At the same time, this case affirms that in Florida a violation of the practice act, including failure to be duly licensed, may be considered evidence of negligence, but does not give rise to an independent cause of action in a civil matter.

Sorenson v. Professional Compounding Pharmacists of Western Pennsylvania, Inc. 2016 Fla App LEXIS 7136; 41 Fla L Weekly D 1119. ■

"A pharmacist's duty to warn, as well as the duty to use professional judgment when filling a prescription, has been argued and litigated for many years. This case affirms the obligations of a pharmacist to use professional judgment and not engage in 'robotic compliance.'"

Executive Officers to Gather for October Interactive Forum; Interactive Member Forum to Follow

This fall, the NABP Interactive Forums will return and focus on the theme "Stand Up and Be Counted to Advance Our Shared Mission."

Set to take place October 4-5, 2016, the upcoming 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 includes discussions of timely and relevant topics developed directly from suggestions submitted by the board of pharmacy executive officers. In addition, NABP support services available to boards of pharmacy will be reviewed. Invitations to attend the Executive Officer Forum were sent in August.

Following the Executive Officer Forum, NABP will hold another forum on November 30 and December 1, 2016, tailored specifically to board of pharmacy members. Invitations for the NABP Interactive Member Forum will be sent to board of pharmacy executive officers in late October. Executive officers will be asked to designate one member as the board's attendee.

There is no registration fee to participate in the NABP Interactive Forums. Travel, hotel accommodations, and meals will also be paid by NABP.

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. The next Executive Officer Forum as well as a forum for board compliance officers and legal counsel are scheduled for fall 2017. ■

NABP Webinar Draws Members From Across the Continent to Learn About Investigating and Prosecuting Diversion

Board of pharmacy executive officers, legal counsel, compliance officers, and staff from 23 boards located in the United States and Canada participated in NABP's educational webinar "Tales From the Front: Board Investigation and Prosecution of Drug Diversion Cases" on July 19, 2016. Presented by State of Ohio Board of Pharmacy Director of Compliance and Enforcement Eric Griffin and Chief Legal Counsel Nicole Dehner, the speakers educated participants on drafting plans to investigate and prosecute pharmacy drug diversion incidents and identifying evidentiary issues. During the live webinar, the speakers also described the fundamental evidence-gathering procedures in pharmacy diversion cases.

In particular, Griffin provided insight on the actions that are taken during a drug diversion investigation, such as gathering evidence in drug loss cases, using collected information, and defining significant loss. Griffin also reviewed the specific tasks that are performed during an investigation, including conducting daily counts, auditing selected drugs, obtaining a list of employees with access to the diverted drugs, and reviewing background information on employees. Griffin noted that as part of an investigation, covert cameras may be installed and the videos may be utilized. Common schemes encountered during an investigation were also addressed.

Providing the prosecution's perspective, Dehner offered participants guidance in reviewing investigative reports for administrative and criminal violations as well as evidentiary and proof issues in administrative cases. Dehner presented examples of the types of information obtained through the investigation that can be used as evidence in a case. For instance, in the event of theft from the pharmacy drug stock, audits and timesheets are offered as evidence; or, in cases of theft from the will-call area, interviews with technicians and other staff on duty are used. Wholesale records, audits, witness statements, and videos are key components in theft cases involving ordering and receiving. In the event that false prescriptions are created, statements from physicians and interviews with suspects are important pieces of the prosecution's case.

At the end of the webinar, participants were able to interact with the presenters during a question-and-answer session. Participants had an opportunity to earn continuing pharmacy education credit for participating in the webinar. To learn more about the webinar or obtain a recording, please contact NABP's Legal Affairs department at 847/391-4406. ■

Through e-Profile Connect, VPP Offers Boards Timely Information on Pharmacies Operating in Multiple States

The Verified Pharmacy Program® (VPP®) is currently being used by the majority of state boards of pharmacy in some manner. Many state boards require the program or recognize it as meeting a component of their state licensing requirements, while others review the inspection reports for findings that could have a negative impact on the public health.

Through NABP e-Profile Connect, the same platform the boards use for other NABP services, boards have access to comprehensive licensing, inspection, and disciplinary data for a pharmacy. The NABP e-Profile Connect system is accessible 24 hours a day, seven days a week, and offers a means for state boards to share their own critical pharmacy information with other states. The exclusive availability of quality information pertaining to a pharmacy's operations and activities helps state boards of pharmacy make informed licensing decisions—ultimately, increasing patient safety.

When making licensure decisions for nonresident pharmacies, the information contained in each e-Profile can be of significant value to the boards. The information includes details on the pharmacy's scope of practice, inspection reports by NABP and/or the resident state board of pharmacy, pharmacy license verification data for all states in which the facility holds a license, pharmacist-in-charge license verification data for all states in which the individual holds a license, and disciplinary data for the pharmacy and pharmacist-in-charge. NABP continues to offer the boards of pharmacy timely information about pharmacies operating in multiple states through VPP.

At press time, at least 494 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. This verified data is provided to the member boards in an effort to further support them in making informed licensure decisions for their nonresident pharmacies. Of the 494 VPP pharmacies, more than 79 have reapplied for a more current inspection, having previously been inspected through the program. Additionally, of approximately 494 pharmacies:

- 238 pharmacies engage in only nonsterile compounding;
- 50 pharmacies engage in only sterile compounding (two of which are also registered as outsourcing facilities);
- 141 pharmacies engage in both sterile and nonsterile compounding (four of which are also registered as outsourcing facilities);
- 62 pharmacies are general retail or mail-order pharmacies with no compounding; and
- 3 pharmacies are nuclear pharmacies.

Developed by NABP in partnership with member boards of pharmacy, VPP facilitates the communication of important inspection and licensure information between the state boards of pharmacy and serves as an information hub that provides verified data to support boards' licensure processes for nonresident pharmacies.

For more information about VPP or the inspection sharing network, visit the Programs section of the NABP website.

Newly Accredited VAWD Facilities

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

Allied 100, LLC, dba AED Superstore
Woodruff, WI

Ceva Animal Health, LLC
Kansas City, MO

Dental Health Products, Inc
New Franken, WI

A full listing of more than 560 accredited VAWD facilities is available on the NABP website.

Updates to NABP *Model Act* Address Evolving Pharmacy Practice

NABP recently amended the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to provide the state boards of pharmacy with model language that may be used for developing state laws or board rules for purposes of protecting the public health. Amendments to the *Model Act* were incorporated as a result of the NABP Executive Committee-approved recommendations suggested by the Task Force on Pharmacist Prescriptive Authority, Task Force on the Regulation of Pharmacist Care Services, and the 2015-2016 Committee on Law Enforcement/Legislation. The following is a summary of the *Model Act* changes.

> **"as health care evolves and pharmacists move beyond the community pharmacy as the epicenter of pharmacist care, the state boards of pharmacy should regulate the expanded function of and services provided by pharmacists."**

Broader Collaborative Practice Laws

Based on discussion that collaborative practice statutes and regulations are highly variable between states, the Committee on Law Enforcement/Legislation agreed with the Task Force on Pharmacist Prescriptive Authority's decision to amend the definition of "Collaborative Pharmacy Practice Agreement" to remove restrictions that currently exist in the *Model Act*. The committee also agreed with the task force that state collaborative practice laws and rules should be broad in scope to allow varying degrees of collaboration and should not interfere with the extent of collaboration between a pharmacist and other health care providers.

Defining the Practice of Pharmacy

The Task Force on the Regulation of Pharmacist Care Services noted that, as health care evolves and pharmacists move beyond the community pharmacy as the epicenter of pharmacist care, the state boards of pharmacy should regulate the expanded function of and services provided by pharmacists. The task force further noted that the practice of pharmacy can occur outside of the pharmacy and in settings that previously would not have been recognized as acceptable settings for practice. Therefore, the Committee on Law Enforcement/Legislation agreed with the task force to change the definition of the "Practice of Pharmacy" in the *Model Act* to make it more general and relevant to the evolving practice. Further, it was determined that in the future any specific practice changes or additions can be made to the comment section of the definition, rather than to the definition itself. The Executive Committee also streamlined the comment section regarding the practice of pharmacy by removing pharmacist-specific job functions.

Pharmacist Care Services

As recommended by the Task Force on the Regulation of Pharmacist Care Services, the *Model Act* was updated to change the term "Pharmacist Care" to "Pharmacist Care Services," and the definition was updated to make pharmacist clinical services more tangible and to include more than the dispensing of prescription drugs. In addition, the Committee on Law Enforcement/Legislation added language to specify that pharmacist care services outside of the premises of a licensed pharmacy should ensure the confidentiality of records and patient-specific information while still being readily retrievable. The committee members noted that each requirement for confidentiality of records and record maintenance was equally important and should be a separate requirement to stress the distinction. Regarding security of records, they concluded that the language "similar to or equivalent to those in place for a licensed pharmacy" was contradictory and therefore was deleted from the *Model Act*.

Addressing the DQSA

After reviewing the recommended amendments to the *Model Act* that align with federal requirements outlined in the Drug Quality and Security Act (DQSA), members of the Committee on Law Enforcement/Legislation agreed to add and revise definitions to mirror those in the Drug Supply Chain Security Act (DSCSA). Also, the term "Drop Shipment" was deleted from the *Model Act* to stay current. For example, the committee noted that the Licensing of Facilities section should not include a separate licensure requirement for pharmacies that compound sterile pharmaceuticals. However, a comment was added to clarify that some states may have additional licensing requirements.

As part of this review, the Model Rules for Compounded or Repackaged Pharmaceuticals and the Model Rules for Outsourcing Facilities sections were updated. The committee noted that state laws and rules should reference United States Pharmacopeial Convention (USP) General Chapters whenever possible, especially in regard to policies, procedures, and quality assurance control programs. Also, the Patient Education and Training section as well as the Pharmacist Care Outcomes section were deleted since the material is covered in other sections in the *Model Act*. Furthermore, the Good Compounding Practices Applicable to State Licensed Pharmacies section and its corresponding comments that were located in Appendix B were deleted since these sections were outdated.

For the Model Rules for the Licensure of Manufacturers, Repackagers, Third-Party Logistics Providers, and Wholesale Distributors section, definitions associated with the Prescription Drug Marketing Act were removed from the *Model Act* and replaced with definitions outlined in the DSCSA. The committee members supported the recommended reference to the Verified-Accredited Wholesale Distributors® (VAWD®) program as a board-designated third party to conduct inspections for initial licensure and/or verification of regulatory compliance. Third-party logistics providers are also included as a separate category for VAWD inspection and accreditation.

Additional Updates

Members of the Committee on Law Enforcement/Legislation agreed that the Model Inspection Form for Nuclear Pharmacies that was located in Appendix A of the *Model Act* was outdated, since Verified Pharmacy Program® (VPP®) surveyors use an updated nuclear pharmacy inspection form instead. To achieve universal inspection forms among state boards and VPP, the old nuclear pharmacy inspection form was removed from the *Model Act*.

In addition, the Multistate Pharmacy Inspection Blueprint is now included in the *Model Act* for the pharmacy community to have full access to such standards. After the blueprint, contact information was added to the *Model Act* to direct pharmacy boards to VPP staff for inquiries regarding inspection forms, since VPP inspection forms are continually updated over time.

The updated *Model Act* is now available for free download in the Publications section of the NABP website. ■

PCOA Successfully Administered to 128 Schools of Pharmacy During the First Two Testing Windows of 2016

During the first two testing windows of 2016, 128 schools and colleges of pharmacy administered the Pharmacy Curriculum Outcomes Assessment® (PCOA®) to 17,005 students. NABP is in its first year of providing the PCOA at no cost to schools and colleges of pharmacy for students nearing the completion of their didactic curriculum. This provides the schools and colleges the opportunity to comply with the Accreditation Council for Pharmacy Education's (ACPE) requirement that schools and colleges utilize the PCOA as one of their assessment strategies.

The PCOA is the only independent, objective, and national examination that enables schools and colleges of pharmacy in the United States to assess student performance in the curriculum and also provides school level data that can be compared to national outcomes.

"NABP is pleased to announce that student performance for the first two windows of the 2016 PCOA remains consistent compared to previous years despite the large growth in administrations," says NABP President Hal Wand, MBA, RPh. "Steady results support the validity of the assessment and the reliability with which it evaluates students from a formative and summative standpoint. We commend the schools' and students' efforts to implement the PCOA prior to ACPE's July 1, 2016 deadline."

The PCOA is a computer-based assessment with 225 questions that cover four major content areas: basic biomedical sciences, pharmaceutical sciences, social/behavioral/administrative pharmacy sciences, and clinical sciences. NABP data shows that first-year students score higher in basic biomedical sciences compared to other content areas and, as expected, third- and fourth-year students score higher in advanced content areas like clinical sciences. This observed educational growth shows that the PCOA is a valuable and integral education tool for measuring knowledge in pharmacy curricula while helping schools and students target student progression. The PCOA can be administered all four years, during any singular year, or any combination of years.

New PCOA items are written during item-development workshops throughout the year. Subject matter experts and pharmacy educators review and edit items, then select items for the various forms of the PCOA. To accommodate the increase in participating schools and students, as well as the variety of academic calendars, the PCOA administrations expanded from three to four windows in 2016. In addition, student registration moved online to allow students to register for the PCOA after creating an NABP e-Profile. Schools/colleges are able to confirm the roster of examinees prior to the scheduled assessment date. The administration of the PCOA has been standardized, and all proctors receive a test administrator guide to ensure that testing sessions are comparable across administrations.

To learn more about the PCOA, visit the Programs section of the NABP website.

Redesigned NABP Website to Launch on .Pharmacy Domain Soon

The newly designed NABP website will soon launch at *www.nabp.pharmacy*.

At this time, NABP's email addresses will change from .net to .pharmacy as well. More details are available in the August issue of *Innovations*.

Content and Administration Changes Coming to the NAPLEX in November 2016

Revisions to the test assembly format, length, and administration time of the North American Pharmacist Licensure Examination® (NAPLEX®) are on schedule to become effective in November 2016. The changes are a result of an evaluation process that started in 2014 and are intended to accommodate more content covering the diversity of pharmacy practice. The following changes will take place:

- The number of examination items will increase from 185 to 250, 200 of which will be used to calculate a score for the NAPLEX. The remaining 50 will be non-scored or pretest items. The increase in the number of questions accommodates an increase in the number of case-based items. As of November 2015, NABP has included more clinical-based, patient-centered test items.
- The testing time for the examination will increase from four hours and 15 minutes to six hours. The appointment time with the vendor, Pearson VUE, will be six and a half hours to allow candidates time to read and agree to the confidentiality/non-disclosure agreement and to take the tutorial and post-exam survey.
- The examination assembly format will change from a computer-adaptive exam (test assembled as candidate is taking the exam) to a linear form exam (preassembled exam form).
- NABP online registration for the new NAPLEX begins October 24, 2016, and the registration fee will increase from $505 to $575.

Candidates who wish to take the exam before the changes become effective are encouraged to register by October 3 and must schedule an appointment to take the exam by October 22. Administration of the current NAPLEX through Pearson VUE will be closed October 24-31, 2016. Students who graduate in 2017 are not eligible to take the current exam; these students may register with NABP for the new NAPLEX beginning October 24, 2016.

NABP has sent email notifications to the boards of pharmacy, as well as candidates and schools and colleges of pharmacy, informing them of the NAPLEX's upcoming changes as well as registration and scheduling deadlines. Details are listed on the NABP website and in the *NAPLEX/MPJE Registration Bulletin*. Additionally, boards and deans received notices in March and July 2016 notifying them of the changes.

NAPLEX Modifications Two Years in the Making

As part of an ongoing development process, the NAPLEX is continuously reviewed and evaluated to ensure the examination tests the necessary knowledge, skills, and abilities expected of an entry-level pharmacist. Two years ago, NABP conducted the national NABP Pharmacy Practice Analysis Survey, to which over 4,700 pharmacy regulators, practitioners, and academicians responded. They agreed that entry-level candidates should be tested on a variety of patient-centered, clinically based topics necessary for safe and effective practice. Following the survey, a panel evaluated the passing standard for the NAPLEX. The panel recommended to increase the depth and breadth of content tested on the NAPLEX, which also meant amending the competency statements. The new competency statements went into effect on November 1, 2015.

For questions regarding the updates to the NAPLEX program, please contact the competency assessment senior manager at 847/391-4406. ■

Newly Accredited VIPPS Facility

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

Park IRMAT Drug Corp, dba IRMAT Pharmacy
www.irmatpharmacy.com

A full listing of the accredited VIPPS pharmacy sites representing more than 12,000 pharmacies is available on the NABP website.

Professional Designations: Do New Licensees Understand the Value of the RPh?

The pharmacy profession has engaged in a recurrent debate over the last decade or more: What professional designation should pharmacists use? Pharmacists are frequently referred to as the most accessible members of the health care system – and yet, there is no consistent method by which they communicate their qualifications to the public they serve or even to potential employers. A couple of decades ago, most practicing pharmacists followed their names with the "registered pharmacist" designation, or RPh. More recently, many pharmacists, particularly those who have entered the profession in the last decade, use only the "doctor of pharmacy," or PharmD, abbreviation. Can the two be used interchangeably, the debate seems to ask? Should the profession settle on a standard professional designation?

Terminology Confusion

To some observers, the debate's existence demonstrates a fundamental misunderstanding of what the two credentials mean. "[The PharmD] is a degree conferred on all graduating pharmacy students," says Anita Young, EdD, RPh, director of continuing pharmacy education at Northeastern University Bouvé College of Health Sciences School of Pharmacy and a strong proponent of licensed pharmacists using the RPh designation. "But it does not assume licensure." A PharmD is an academic credential, she emphasizes, the current entry-level educational degree for those who wish to become pharmacists. RPh – along with other, less common licensure abbreviations determined by the state boards of pharmacy, such as RP, DPh, or PD – indicates that a pharmacist has not only achieved the necessary academic grounding, but is also licensed to practice pharmacy, a higher bar. A licensed pharmacist, at a minimum, must have passed the North American Pharmacist Licensure Examination® (NAPLEX®) and other state-mandated evaluations, such as the Multistate Pharmacy Jurisprudence Examination®. Moreover, a license "requires upkeep," Young points out. "You will always have your degree," she says. "The degree is given for life." A license, on the other hand, indicates that the pharmacist maintains his or her professional standing and development through continuing professional education, required by all states as part of the regular licensure renewal process. A license also requires ethical behavior, Young notes. "If a pharmacist doesn't act in a trustworthy, ethical manner, the board of pharmacy can take it away," she says.

Despite these distinctions, there does seem to be confusion as to the meaning of the designations – or at least disagreement as to their appropriate usage, even among pharmacists. An editorial published in *U.S. Pharmacist* in 2008 complains that the "[PharmD] really has nothing to do with whether or not the pharmacist is licensed to practice pharmacy. On the other hand, if you really think about it, neither does the RPh credential . . . [C]onfusion apparently reigns over the exact title for a pharmacist who has passed a licensing exam and holds a degree to practice pharmacy. The bottom line is that there is no universal designation for pharmacists . . ." Others seem to feel that the use of RPh is redundant, even if the pharmacist in question understands the distinction between the credentials. "If, suppose I didn't apply for a license to practice pharmacy (and pass the requisite board exams), I would not be an RPh, I would only have my Pharm.D. degree," wrote one pharmacist who chimed into an "RPh v. PharmD" discussion on a Student Doctor Network forum. But, the contributor continued, "I suppose I can use either, or both a Pharm.D. and the RPh, but to do so would be superfluous. I just use Pharm.D." This does not appear to be an uncommon attitude. Several years ago, the Oregon State Board of Pharmacy felt it necessary to remind licensees of the difference between RPh and PharmD. "The Board's compliance staff has run across several examples of improper use of the titles PharmD and RPh," the Board wrote in its August 2007 quarterly newsletter for licensees. "[A] person may hold the doctor of pharmacy degree and still not be licensed by the state as a registered pharmacist. This person could use the title PharmD, could perform a variety of research and other activities, but could not independently practice pharmacy, or use the titles pharmacist or RPh."

A Decade-Old Problem

Young dates the RPh designation's fall from near-universal usage to the initiation of the all-PharmD program. In the latter 1990s, the Accreditation Council for Pharmacy Education (ACPE) re-evaluated the existing standards for entry-level pharmacists, given the evolution of the pharmacy profession in specific and medical care in general and taking into account recommendations for health care provider competencies identified by the Institute of Medicine (now the Health and Medicine Division). ACPE adopted the resulting new accreditation standards and guidelines for the doctor of pharmacy as the sole entry-level degree for the pharmacy profession in 1997, with required implementation in 2000 for entering classes. By 2005, the transition to the all-PharmD program was complete.

The shift from a bachelor's degree to the PharmD as the entry-level pharmacy degree raised several new issues among pharmacists, including concerns about workplace discrimination against experienced pharmacists with "only" a bachelor's degree, and arguments about the suitability of using the title "Doctor" when referring to a pharmacist. And about this same time, Young says, "RPh fell out of favor." Historically, licensed (or registered) pharmacists had used RPh after their names instead of BSPharm or some other indication of their academic credential, much the same way registered nurses use RN. But for some reason – "I have no idea why," says Young – pharmacists began using PharmD instead of, not in addition to, the RPh designation. Moreover, Young says, some pharmacists do not seem to realize the importance of their RPh credential. She receives résumés, she says, in which applicants "list [their licensure status] down by their CPR certification."

Young finds this trend disturbing in part because licensure is an important aspect of what distinguishes pharmacy as a profession. In general, Young notes, five main attributes help to define what might be termed a "profession." These consist of a unique body of knowledge or theory, represented in pharmacy by achieving a PharmD, as well as any later specialization; professional authority and credibility, such as patients' trust and dependence on pharmacists for their specialized knowledge; community sanction or regulation, including licensing of pharmacists by the boards of pharmacy and ACPE accreditation of pharmacy schools and continuing education courses; a code of ethics, defining appropriate behavior; and a professional culture, including values and norms common to pharmacists. Pharmacists who use the RPh (or state-designated equivalent) credential after their names therefore help announce their professionalism to patients, colleagues, prospective employers, and other health care providers, among others.

Indeed, the Massachusetts Board of Registration in Pharmacy, for one, considers use of the licensure credential of sufficient importance as to mandate its use by licensees. Draft regulations updating the state's Code of Professional Conduct state that "A pharmacist shall wear a name tag with at least his/her first name and the title 'Registered Pharmacist' or "R.Ph.'"

Significance of RPh Designation

PharmD and RPh signify different things: PharmD denotes a level of educational achievement, while RPh signifies current licensure in the profession. While both are important achievements, only RPh can convey to patients that the holder is in fact licensed to practice pharmacy and in compliance with all current regulations and requirements. Ultimately, this is something all pharmacists – even those who choose to display only the PharmD – already know. As Young puts it, "Ask anyone who doesn't pass the NAPLEX or who loses their license. They understand how much that RPh means to them then." ■

NABP *Member Manual* Addresses Key Requirements of a Pharmacist

The *NABP State Boards of Pharmacy Member Manual* addresses many key topic points of what it means to be a pharmacist. Information related to licensure is highlighted, including general statutory requirements for licensure, the processes followed when a board of pharmacy denies a candidate for licensure, how scope of practice is defined, and the requirements for licensure transfer. Also included is information related to the requirement for pharmacists to have and maintain good moral character.

Updated once per year, the *Member Manual* is intended to serve as a guide to help support board members and executive officers better serve in their roles and meet new challenges that may arise in their day-to-day duties and responsibilities of protecting the public health. It includes information on understanding the examination development process, rulemaking, issuing declaratory statements, adjudication proceedings, and understanding investigatory processes. General information on board meetings, including guidance on sunshine laws, a summary of parliamentary procedure, and a sample of a typical meeting agenda, is also included. In addition, the *Member Manual* describes what boards can do in anticipation of sunset laws and provides information on additional legal topics in a collection of Legal Briefs articles reprinted from the Association's newsletter.

The *Member Manual* is available in the Member Services section of the NABP website. ■

Annual Program Review and Training Enables Board Staff to Network and Learn About 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 June 28-29, 2016, at NABP Headquarters.

Eighteen participants representing 17 state boards of pharmacy attended the two-day interactive session, which provided information about NABP's examinations, licensure transfer, accreditation programs, and more. In addition, these informational sessions provided attendees with a unique opportunity to network with other board of pharmacy staff.

The event began with a group dinner on June 28, which provided the board of pharmacy staff the opportunity to network with each other and NABP staff. On June 29, the group convened for breakfast before beginning the educational portion of the session, which provided an overview of the following NABP programs and services:

- Electronic Licensure Transfer Program® (e-LTP™) and license verification
- NABP Clearinghouse/National Practitioner Data Bank (NPDB) reporting
- Verified Pharmacy Program® (VPP®) and inspection sharing network
- North American Pharmacist Licensure Examination® (NAPLEX®)
- Multistate Pharmacy Jurisprudence Examination® (MPJE®)
- Pharmacist Assessment for Remediation Evaluation® (PARE®)
- NABP e-Profile Connect: NAPLEX/MPJE eligibility; score reporting and Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification; and online reporting to candidates
- FPGEC Certification Program, including information on the application, examination, and certification process
- Pharmacy Curriculum Outcomes Assessment® (PCOA®)
- Verified Internet Pharmacy Practice Sites® (VIPPS®)
- Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®)
- Verified-Accredited Wholesale Distributors® (VAWD®)
- Durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation
- NABP e-Advertiser Approval℠ Program
- Community Pharmacy Practice Accreditation
- .Pharmacy Top-Level Domain Program and Internet Drug Outlet Identification program.
- AWAR$_x$E® Prescription Drug Safety Program
- CPE Monitor® and the continuing pharmacy education (CPE) reporting tool for the boards
- NABP PMP InterConnect®
- Member Relations and Government Affairs
- Professional Affairs
- Communications

The training sessions are offered each summer. Information about the 2017 sessions will be in future issues of *Innovations.*

(Above) Participants representing 17 state boards of pharmacy attended the two-day NABP Program Review and Training in June. Attendees were given a tour of NABP Headquarters and learned about the Association's competency, licensure, accreditation, and inspection programs. Lawana Lyons (standing), NABP licensure programs senior manager, provided attendees with an overview of NABP's licensure programs.

PMPs From 38 States Discuss Governance and Policy Direction at PMP InterConnect Committee Meeting in July

Forty state attendees, representing 38 states, and six guests were among those present at the NABP PMP InterConnect Steering Committee meeting, held July 20-21, 2016, in Northbrook, IL. The committee convened to provide governance and policy direction as it relates to the implementation of the program.

Since approximately 17 members of the group were new to the Steering Committee meeting, the event began with a brief history of NABP PMP InterConnect®, including an explanation of the relationship between the Steering Committee and the NABP Executive Committee. The two-day agenda also featured discussions on interstate interoperability, software enhancements, third-party access to prescription monitoring program (PMP) data, barriers to interstate data sharing, and more.

The Future of PMP InterConnect

NABP staff informed meeting attendees that, in continuing to work with the Bureau of Justice Assistance (BJA), NABP met with BJA staff in March 2016 to discuss collaboration in the Prescription Monitoring Information Exchange architecture. Meeting attendees also discussed the current and future status of PMPs. Steering Committee members noted that there are still some challenges for PMPs. However, the Steering Committee stated that few, if any, political leaders are talking to the state PMPs. Members stressed that this lack of education and understanding is causing unrealistic expectations of PMPs to address the complex issue of prescription drug abuse.

After some discussion, motions were made to direct the Policy Subcommittee to develop PMP messaging to assist the states and to direct NABP staff to collaborate with other PMP stakeholder groups, including National Association of State Controlled Substances Authorities, National Alliance for Model State Drug Laws, National Governors Association, Brandeis University, and Association of State and Territorial Health Officials, to help develop the message.

Participant Worksheet Revisions

Steering Committee attendees also discussed its state participant worksheet – a document used to help states facilitate data sharing. The PMP InterConnect Participant Worksheet Subcommittee advocated recent revisions that will enhance its usability. The subcommittee further recommended that each state complete or review the worksheet annually; however, the group decided that if a PMP program or legislation changes, an updated worksheet must be submitted to NABP staff. This document is available to all PMP InterConnect participants so that they may use it as a guide to help make decisions on whether their PMP can share prescription drug data with another state.

Technical Updates

Appriss, Inc, NABP's technology provider for PMP InterConnect, provided attendees with an overview of the software utilized by PMP InterConnect participants, including API Version 4. The majority of states transitioned to Version 4 in 2015. However, some states are still using Version 3, which will be sunset on October 1, 2016.

Attendees also requested that Appriss provide guidance on integration of PMP Gateway, the service that facilitates integration of interstate PMP data into the health care workflow of third-party entities. Appriss informed attendees that it has developed an integration guide to assist PMP InterConnect participants in the future.

In addition, Mike Menkhaus, RPh, EPRN project manager at The Kroger Co, Louisville, KY, provided an overview of the security provided by Kroger and other health care entities to ensure that PMP data is safeguarded when accessed via PMP Gateway.

Committee Overview

Composed of representatives of PMPs that have agreed to participate in the PMP InterConnect program, the Steering Committee serves as the governing body of the program. The committee is tasked with discussing and making recommendations related to the operation of the program, including strengthening the network, best practices for state PMPs to facilitate data sharing, integrating PMP data into the health care workflow, and other policy matters. The committee meets at least once per calendar year, in person or by teleconference. The next meeting is scheduled for July 19-20, 2017.

More information about PMP InterConnect, including the most up-to-date information on state participation, is available on the NABP website.

Rogue Internet Drug Outlets Distribute CS, Contribute to Opioid Abuse Epidemic, Reports NABP

In July 2016, NABP issued a report exploring the connection between the dangers of rogue internet drug outlets and the risk of overdose from illegally dispensed prescription controlled substances (CS), as well as possibly tainted counterfeit medicines. As detailed in the *Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: July 2016*, some patients using prescription opioids non-medically may be obtaining them from sources other than or in addition to their doctors. Prescription opioids obtained from illegal sources may be counterfeit or may contain powerful substances other than what the user expects, leading to unintentional overdose. As overdoses and fatalities related to the abuse of prescription opioids continue to rise, regulators and enforcement agencies have issued warnings about deadly counterfeit prescription opioids on the street. What is often overlooked, however, is that they are also readily available over the internet without a prescription from rogue internet drug outlets.

Over the past eight years, NABP has worked to identify illegally operating websites to keep consumers safe and to try to decrease the overdoses and fatalities related to prescription drug misuse and abuse. As stated in the July report, 11,299 online drug outlets that sell prescription medications have been reviewed by NABP, and 95.79% have been classified as Not Recommended given that the websites are selling prescription medications out of compliance with state and federal laws and/or Association patient safety and pharmacy practice standards (see Figure A, right). However, as quickly as NABP is able to identify unsafe online drug outlets, more continue to appear.

Since its last report in April 2016, the Association has identified additional Not Recommended sites that offer medications from foreign sources or that are not approved by Food and Drug Administration, that dispense CS, and that lack a requirement for a valid prescription. These factors stress the need for NABP's .Pharmacy Top-Level Domain (TLD) Program, which enables consumers to see if a website is safe simply by looking for the .pharmacy domain name in the website address. Unlike logos and seals, the .pharmacy domain name cannot be faked by rogue websites. In order to obtain a .pharmacy domain, pharmacies and pharmacy-related entities must be vetted by NABP to confirm that they meet all applicable regulatory standards (including pharmacy licensure and valid prescription requirements) in the jurisdictions where they are based and where they serve patients.

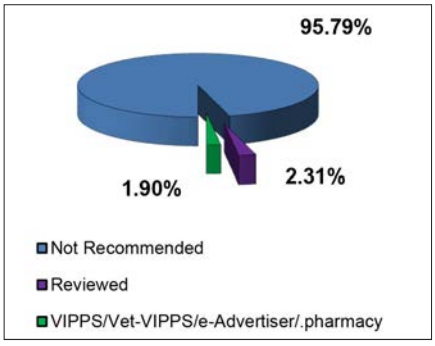
NABP's efforts to create a safe online environment for consumers started more than 15 years ago with the Verified Internet Pharmacy Practice Sites® accreditation program, followed by the Veterinary-Verified Internet Pharmacy Practice Sites® and the e-Advertiser Approval℠ programs. The .Pharmacy TLD Program is the evolution of the Association's ongoing efforts. Currently, 232 .pharmacy domain names have been registered for use. Among them, top pharmacies like CVS and Rite Aid have registered for the trusted .pharmacy domain.

The NABP report points out that, despite the perception that illegal purchases of prescription opioids only take place with drug dealers on the street, rogue internet drug outlets serve as dealers hiding behind sleek websites that look safe to people trying to purchase CS medications. For those struggling with drug abuse, finding a Not Recommended website can seem like an easy way to buy prescription medicines illegally, but NABP warns that many of these rogue websites sell counterfeit and tainted substances that can increase the risk of overdose and death. Utilizing unknown and unapproved sources selling medication online is dangerous.

NABP's report also details the findings of a study by the students of Fisher College Criminal Justice Division in Boston, MA, about opioid availability online and points out government agency warnings about counterfeit opioids. Both issues further reinforce concerns about the illegal sales of prescription opioid drugs and their link to the opioid epidemic. Pills with hidden lethal ingredients and websites that provide easy access to opioids without a prescription are only part of the dangers that consumers are facing when purchasing medications from unknown and unapproved sources online.

NABP continues to work with regulators and stakeholders to help shut down rogue internet drug outlets and eliminate the risks they pose to public health. The Association has been accrediting legitimate internet pharmacies since 1999, and the .pharmacy domain name now makes it easy to identify verified websites simply by looking to the right of the dot in a web address. For the full report, visit the Not Recommended Online Pharmacies page in the Acquire Safely section of *www.AWARErx.pharmacy.*

Figure A: Internet Drug Outlets Reviewed by NABP



NABP .Pharmacy TLD Program and Verified Registry Operators Partner to Strengthen TLD Space

Given the persistent dangers presented by rogue online drug sellers and other fraudulent website operators, NABP, as the registry operator for the .Pharmacy Top-Level Domain (TLD), continues to work with other registry operators on establishing guidelines to enhance public safety online. NABP, fTLD Registry Services (operator of domain names for the banking and insurance communities), and Medistry (operator of domain names for the medical community) shared information about the challenges and opportunities facing verified TLDs during a meeting with the United States Intellectual Property Enforcement Coordinator and several US government agencies in March 2016. Soon after, NABP helped establish the Verified Top Level Domains Consortium along with eight other registry operators for 15 verified TLDs. To solidify the group, the *Verified Top Level Domains Consortium Charter* was drafted and ratified in May 2016.

Consortium *Charter*

The Consortium provides a unifying set of principles that defines the group, such as a shared commitment to building trust online and supporting global public safety. The *Charter* outlines the elements of a verified TLD, which include verification of registrants prior to their use of a domain name, a requirement that registrants adhere to the verified TLD's standards, the autonomy to take back a name for violation of registration policies, and ongoing verification to ensure registrants' continued eligibility.

In addition, the *Charter* describes the benefits of Consortium membership, which include raising awareness for verified TLDs, impacting policies of the Internet Corporation for Assigned Names and Numbers on issues affecting verified TLDs, building trust on the internet, and educating consumers about the value of domain names that are part of verified TLDs.

Consortium Member

NABP and the other founding members of the Consortium are united in their shared commitment to raise awareness of verified domain name extensions as trusted channels for products, services, and communications online. New members must be approved by the group and are called on to agree with the Consortium's mission and to meet the components of a verified TLD as defined by the *Charter*. Further, advisors may also join the Consortium. Although advisors are not members of the Consortium, they too must be approved by the founding members.

Open generic TLDs (eg, .com, .net, or .org) do not offer consumers the security of a safe online space like verified TLDs such as .pharmacy do. NABP remains committed to offering consumers around the globe a place where they can be sure the medications and related services they obtain online are legitimate. The .pharmacy website (*www.safe.pharmacy*) provides information on the types of businesses that are eligible to apply for approval to register a .pharmacy domain name. All registrants within the .pharmacy TLD are verified prior to registration to confirm that they meet all applicable regulatory standards, including, where applicable, pharmacy licensure and valid prescription requirements in the jurisdictions where they are based and where they serve patients.

For information about the .Pharmacy TLD Program, including a list of approved .pharmacy sites, visit *www.safe.pharmacy*. To obtain additional information about the *Verified Top Level Domains Consortium Charter,* contact .pharmacy staff at info@safe.pharmacy. ■

Around the Association

Board Member Appointments

- **Kay Jessen, RN,** has been appointed a member of the Iowa Board of Pharmacy. Jessen's appointment will expire April 30, 2019.
- **Neal Dungan, RPh,** has been appointed a member of the New Mexico Board of Pharmacy. Dungan's appointment will expire July 1, 2020.
- **J. Andrew "Andy" Bowman, PharmD, RPh,** has been appointed a member of the North Carolina Board of Pharmacy. Bowman's appointment will expire May 1, 2021.

Board Member Reappointments

- **Fran Gronberg** has been reappointed a public member of the North Dakota State Board of Pharmacy. Gronberg's appointment will expire May 8, 2021.
- **Robert Hubbard, RPh,** has been reappointed a member of the South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy. Hubbard's appointment will expire June 30, 2022. ■

New Kentucky Laws Address Biosimilar Substitution, Other Practice Matters

New laws were passed in Kentucky that address biosimilar substitution, administrative functions, and home medical equipment. Governor Matthew Bevin signed the following bills into law during the 2016 Legislative Session.

Senate Bill (SB) 134 requires the automatic substitution of a Food and Drug Administration-approved interchangeable biosimilar product, but requires notice by a phone call, fax, or electronic communication to the prescriber or office personnel except when the prescription indicates "do not substitute."

House Bill (HB) 527 allows a pharmacy to engage in newly specified administrative functions that may be performed outside the pharmacy. These tasks include billing patients, entering patient insurance information, opening faxes, and setting up patient profiles. The bill also includes a new classification of protocols authorized by the Kentucky Board of Pharmacy as "prescription drug orders."

HB 562 creates the Kentucky Board of Durable Medical Equipment Suppliers under the authority of the Office of Occupations and Professions rather than the Board of Pharmacy.

Additional details on these and other bills are available on the Kentucky Legislature website at *www.lrc.ky.gov.*

North Dakota Board Finalizes Rules Granting Naloxone Prescribing Privileges to Pharmacists

The North Dakota State Board of Pharmacy finalized rules (North Dakota Administrative Code 61-04-12) implementing the authority given by SB 2104, which granted prescriptive privileges for naloxone to pharmacists in North Dakota. The process for a pharmacist to prescribe naloxone is available on the Board's website at *www.nodakpharmacy.com/naloxone.asp*, along with information that can be provided to patients and patients' loved ones. The process for pharmacists involves reviewing the context of the rule, completing one of the educational programs, and informing the Board of their intentions to prescribe this lifesaving drug. The Board will make the locations to which pharmacists are prescribing naloxone available to the public for their information.

Idaho Passes Laws Related to the State's PMP

The following pharmacy-related bills were passed by the Idaho legislature and signed into law by Governor Butch Otter with an effective date of July 1, 2016.

HB 337 updates the list of authorized individuals who can receive Idaho Prescription Monitoring Program (PMP) data by allowing access to coroners and medical examiners for the purposes of determining a cause of death.

A resolution passed at the NABP 112th Annual Meeting stresses the importance of such PMP access. Resolution 112-3-16 encourages PMPs to provide reports and other analytical information to appropriate prescribers, pharmacists, and entities that serve as sources of data impacting the identification and reporting of prescription drug injuries and deaths, such as, but not limited to, coroners' offices, to help address the prescription drug epidemic and improve patient care.

HB 374 provides pharmacists with a new tool to streamline access to the PMP. Specifically, pharmacists who are already registered with the PMP will be able to designate up to four registered pharmacy technicians who are under their supervision to access the PMP on their behalf. A technician may access information to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing any controlled substances, or for the purposes of a pharmacist providing pharmaceutical care as defined in law.

Full details of the bills may be found on the state legislature's website at *www.legislature.idaho.gov/legislation/2016/minidata.htm.*

Tennessee General Assembly Enacts Legislative Changes Affecting Pharmacy Practice

The Tennessee Board of Pharmacy reported the following 2016 legislative changes that affect the practice of pharmacy.

Public Chapter (PC) 596 authorizes the chief medical officer of the Tennessee Department of Health to implement a statewide collaborative pharmacy practice agreement for opioid antagonist therapy with pharmacists. PC 596 was signed into law March 10, 2016, and can be accessed at *http://share.tn.gov/sos/acts/109/pub/pc0596.pdf*.

PC 656 permits a pharmacist to dispense medication in a quantity that varies from the prescription under certain circumstances, provided that the units dispensed do not exceed a 90-day supply. PC 656 does not supersede the current regulation for the dispensing of opioids or benzodiazepines as stated in Tennessee Code Annotated 53-11-308(e): "No prescription for any opioids or benzodiazepines may be dispensed in quantities greater than a thirty-day supply." PC 656 was signed into law March 29, 2016, and can be accessed at *http://share.tn.gov/sos/acts/109/pub/pc0656.pdf.*

PC 942 permits a pharmacist to provide hormonal contraceptives, as defined in the PC according to a valid collaborative pharmacy practice agreement that contains a "[non-patient-specific] prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescribers." PC 942 was signed into law on April 27, 2016, and can be accessed at *http://share.tn.gov/sos/acts/109/pub/pc0942.pdf.*

More information about the 2016 legislative changes affecting pharmacy practice for Tennessee licensees can be found in the Tennessee Board's June 2016 newsletter available at *www.nabp.net/publications/newsletters/tennessee-board-of-pharmacy.*

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

1. Read and follow the label.
2. Know which medicines contain acetaminophen.
3. Take only one medicine at a time that contains acetaminophen.
4. Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org.*

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

Food and Drug Administration (FDA) is alerting health care providers that PharmaTech, LLC, of Davie, FL, is voluntarily recalling all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia*, a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and Centers for Disease Control and Prevention (CDC) continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

FDA Offers CE Webinars for Students and Clinicians About Drug Information Resources

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm.* ■

Health care providers and patients are encouraged to report adverse events or quality problems to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch.*

INNOVATIONS

National Association of Boards of Pharmacy
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Mount Prospect, IL 60056

UPCOMING EVENTS

October 4-5, 2016
NABP Interactive
Executive Officer Forum
Rosemont, IL

October 14, 2016
FPGEE Administration

November 2-4, 2016
NABP/AACP District 4 Meeting
Chicago, IL

November 29-December 10, 2016
PARE Administration

November 30-December 1, 2016
NABP Interactive Member Forum
Rosemont, IL