National Reports Raise Questions About Oversight of Drug Compounding in Physicians’ Offices

4 Legal Briefs: Professional Judgment Does Not Trump Law

9 NABP Accreditation Programs Continue to Help Protect Public Health

19 Interact and Network During Optional Events at the NABP 113th Annual Meeting
Interview With a Board Executive Director

Malcolm J. Broussard
Executive Director, Louisiana Board of Pharmacy

How long have you served as executive director of the Louisiana Board of Pharmacy? What was your role prior to working with the Board?

I have been serving as executive director since June 1999. Prior to working with the Board, I practiced pharmacy in community and hospital pharmacy settings for 21 years. The last position before transferring to the Board was as staff pharmacist in a community hospital in the New Orleans area for about five years.

What is one of the most significant challenges or issues your board addressed in the past year or so?

In the past year, the Board’s biggest project has been drafting rules to implement legislation for a statewide medical marijuana program, which was adopted by the state legislature. Unlike most states, Louisiana’s legislation places the dispensing of medical marijuana in pharmacies that are licensed by the Board. The Board is also writing standards for the packaging and labeling of the medical marijuana product, which is a topic managed on the federal level by the Food and Drug Administration and rarely on the state level.

What actions were taken by the Board to address the issue?

The Board has collaborated with a lot of interested stakeholders to finalize our financial impact statements. In addition, as part of the rulemaking process, the Board published a notice of intent and will hold hearings on March 2 to receive public comments and testimony. The Board will then evaluate and determine if any changes are necessary to the original rule proposal. If no changes are necessary, the Board will submit a comprehensive report to the state legislature, and hopefully the final rule will become effective by August 2017. The Board will then begin developing the permit and application forms and start inviting applicants.

What other key issues has the Board been focusing on?

One issue is related to the Board’s internal operations. The Board has been receiving a steady growth in the number of credentials/licenses managed by the Board, averaging 3-5% per year for the last several years. Since we cannot just keep buying more file cabinets, the Board is getting ready to start a scanning project to digitize our licensure files. We have about 46,000 files, so it’s a pretty big undertaking. The other issue is related to the opioid crisis. Like many other states, Louisiana has commissioned a study group on this issue – the Louisiana Commission on Preventing Opioid Abuse. The Commission is convening stakeholders across all sectors of state government, as well as citizens, law enforcement, health care providers, and consumers to discuss the issue. The commission is looking for ways to try to reduce, prevent, and examine different strategies to adopt, and the Board has been placed in the leadership role of this initiative. The Board plans to develop recommendations for the state legislature to consider when they convene in April 2017.

What insights do you have for other states that may be facing similar challenges?

I think it’s important to network with other states and work with other boards and other health care agencies within the state to determine what your sister states and other state entities may be dealing with or have gone through. There is no need to start from the beginning on an issue if others may have paved the way for you. These are valuable relationships especially as health care regulation continues to change. Historical silos are starting to give way as delivery of health care changes in order to increase patient access, and what used to be very clear lines separating scopes of practice for providers and scopes of authority for boards and other agencies are becoming very blurred.

Louisiana Board of Pharmacy

Number of Board Members: 16 pharmacist members and 1 public member
Number of Compliance Officers/Inspectors: 5
Rules and Regulations Established by: Board of Pharmacy
Number of Pharmacist Licensees: 8,441
Number of Pharmacies: 2,000 (in-state)
Professional Judgment Does Not Trump Law

The role of a pharmacist involves many significant factors that implicate the health, safety, and welfare of patients. As such, pharmacists are subject to licensure by the state board as a prerequisite to the lawful practice of pharmacy. The issuance of a license by a state board of pharmacy indicates to the public that such a licensee has met the relevant eligibility criteria for a state-issued credential. That pharmacist is, thus, allowed to practice the profession under the authority of the license. At times, pharmacists are allowed to “delegate” certain aspects of the practice to technicians or other personnel, so long as sufficient oversight is exercised. What may be delegated and what constitutes sufficient oversight can create legal issues for the licensee, permit holder, and patient care. Consider the following.

A licensed pharmacist (Licensee) was also the owner, facility permit holder, and pharmacist-in-charge of a pharmacy in Missouri. In addition to filling and dispensing retail prescriptions to patients, the pharmacy compounds drug products. In April 2011, the Licensee was attending a continuing education seminar in Chicago, IL. In his absence, the Licensee arranged for another pharmacist to work at the pharmacy. However, due to his wife’s illness, the other pharmacist was unable to report to work. When informed by the pharmacy technician of the absence of the relief pharmacist, the Licensee instructed the technician to close the pharmacy but leave the doors open so staff could explain to customers that there was no pharmacist on duty and that prescriptions could not be picked up.

The technician also notified the Licensee that a physician had called the pharmacy seeking the immediate compounding and dispensing of chemotherapy medication. After initially telling the technician not to prepare the drug, the Licensee instructed the technician to compound the chemotherapy medication and deliver it to the physician’s office. The technician followed the Licensee’s instructions, and the medication was administered to a patient. No harm or adverse effect of the compounded medication was reported.

The Missouri Board of Pharmacy (Board) was notified that the unlicensed practice of pharmacy may be occurring at the pharmacy. The Board undertook a preliminary investigation of the pharmacy and, based upon the results, filed separate complaints with the Administrative Hearing Commission (AHC) seeking adverse actions against both the Licensee and the pharmacy permit. A consolidated hearing was held wherein the AHC found cause to render discipline against both credentials. The bases for the disciplinary actions were premised upon assisting one to violate the provisions of Missouri law related to pharmacy practice, assisting in the unlicensed practice of pharmacy, and violation(s) of state and federal drug laws.

A formal hearing was held before the Board. At the hearing, the Licensee stated that he thought he did the right thing for the benefit of the patient. He also admitted that he knew he was breaking the law and that if he were presented with the same situation, he would “break the law again.” In his defense, the Licensee argued that he used his professional judgment in determining the best interests of patients.
the patient. Upon conclusion of the hearing, the Board issued orders placing the pharmacist license and the pharmacy permit on probation for one year, subject to terms and conditions. The Licensee, on behalf of both his license and permit (collectively referred to as Respondents), appealed the matter to the circuit court, which affirmed the findings of the Board. The Licensee appealed.

On appeal, the court first noted that the finding of cause by the AHC and the determinations of the Board after the formal hearing are treated as one decision. The Court of Appeals will affirm the administrative decision unless the agency action violates one (or more) of seven principles. They include:

- A violation of constitutional provisions;
- An action in excess of statutory authority;
- An action unsupported by competent and substantial evidence;
- An action unauthorized by law;
- An action made upon unlawful procedure(s) or without a fair trial;
- An action that is arbitrary, capricious, or unreasonable; or
- An action that involves an abuse of discretion.

The Respondents argued three points on appeal. First, they argued that they did not violate any drug laws and that the AHC erred in finding cause to proceed with the complaint. Second, the Respondents argued that the issuance of discipline was unsupported by substantial and competent evidence, was arbitrary and capricious, was an abuse of discretion, and violated the Licensee’s right to due process. Third, they argued that the Board erred in that it did not comply with Missouri law related to the issuance of findings of fact and conclusions of law supporting the decision.

Addressing the first point, the court summarized the Respondents’ arguments as an attempt to use professional judgment to trump state law. The court noted that no laws or cases were cited to support such a contention and that, simply put, “the regulations in question are not suggestions for use, they are mandatory rules established and designed to protect the public.” The Licensee admitted that he was not present during the compounding of the medications, and therefore the acts were unsupervised. The court stated that the Licensee’s “decision to pick and choose which mandatory regulations he believes himself to be bound by in his expertise is nothing short of the sort of arrogance that the regulations are designed to guard the public against.” Based upon the law and lack of cited authority that may contradict any logical interpretation, the court rejected the Respondents’ first arguments.

In their third point on appeal, the Respondents argued that the Board and AHC did not follow the appropriate procedural processes related to the proceedings and specificity of the final order. Specifically, the Respondents argued that the final orders did not contain the necessary detail to allow for a meaningful review of the proceedings and determinations. As shown by the court, administrative proceedings in Missouri are bifurcated whereby a board with sufficient evidence may file a complaint with the AHC. If after a hearing the AHC finds cause for disciplinary action, the matter is

continued on page 12
Compounding oversight has come a long way in the last four years. The deadly 2012 fungal meningitis outbreak stemming from contaminated injections traced to a compounding center caused a national re-examination of regulations addressing such activities. The Drug Quality and Security Act (DQSA) of 2013 was the centerpiece of the federal response and formed the framework for many state changes in regulation and oversight.

Food and Drug Administration (FDA) continues to issue final rules and industry guidance on implementing its responsibilities under the DQSA. Further, while there remains variability among states, overall regulation and oversight of compounding by pharmacists have increased substantially since 2012. This increased oversight and regulation has included both patient-specific drug compounding taking place in pharmacies (falling under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) and non-patient-specific compounding “for office use” and institutional settings occurring in FDA-registered outsourcing facilities (under FD&C Act Section 503B). But patient-specific compounding is not solely the province of pharmacies; it may also take place in other health care settings, including physicians’ offices, and the status of its oversight outside the pharmacy setting is much less clear. State boards of medicine regulate the practice of medicine, but whether that regulation includes physicians’ compounding activities can vary, and state compounding laws often do not specifically address nonpharmacist compounders.

Lack of Understanding Laws, Regulations by Nonpharmacists

Two reports issued in 2016 studying the compounding regulatory environment – the United States Government Accountability Office’s (GAO) Report to Congressional Committees titled “Drug Compounding” and the Pew Charitable Trusts’ “National Assessment of State Oversight of Sterile Drug Compounding,” both of which incorporated extensive surveys of the state boards of pharmacy, among other sources – noted the lack of clarity in state compounding laws as they pertain to physicians or other nonpharmacy personnel and uncertainty about oversight. “[R]espondents in some states were unsure which entity, if any, in their state had oversight responsibility for compounding by physicians and other nonpharmacists,” the GAO report
stated. It continued, “For example, respondents in 17 states reported that they did not know if their state had any laws, regulations, or policies specific to drug compounding by nonpharmacists.” Similarly, when Pew researchers asked pharmacy boards how their state provided oversight of physician offices or clinics that perform sterile compounding to ensure compliance with applicable standards, more than half of responding boards (24 of 43) indicated that there was “no oversight system to ensure compliance.”

However, physicians are expected to follow FDA guidance, United States Pharmacopeia (USP) standards, and state guidelines regarding good compounding practices, and many states do regulate such physician practices. For example, nine states reported to GAO researchers that their state did have laws, regulations, or policies “specific to compounding by physicians or other nonpharmacist health care practitioners,” while other states report that they handle compounding issues as they arise, using laws with more general practice standard language. In at least one state, North Carolina, the state board of medicine has issued a position statement on physician compounding to establish its policy on compounding standards and inform its licensees. In a few states such as Idaho and Ohio, the board of pharmacy is responsible for oversight of physician compounding. Nonetheless, the GAO and Pew reports indicate that, overall, physician office compounding is not regulated in the same manner as compounding pharmacies operating under 503A, and that the oversight mechanisms are not broadly understood, even by those responsible for overseeing drug safety in their states.

**Scope of Physician Compounding**

Even the scope of physician compounding is uncertain. In gathering information for their report, GAO researchers “did not find any sources of data specific to the extent to which [physician compounding] occurs.” Indeed, researchers spoke to medical board officials in more than one state who did not know whether physician compounding in their states was minimal or widespread; one official noted that since that state’s board investigated or inspected practitioners only if a complaint was filed, the board is only aware of compounding activity that gives rise to complaints. The GAO report cites two different national medical associations as being likewise uncertain about the extent of physician compounding; one of these associations even noted “that they would not know how to go about gathering information on the extent of compounding by physicians.”

In fact, physician-supervised compounding appears to vary widely by specialty. A general practitioner might perform no in-office compounding at all, whereas an allergist might treat hundreds of patients with individualized compounds. A 2016 resolution proposed to the American Medical Association (AMA) House of Delegates listed a number of physician specialties that would be particularly affected by FDA compounding guidance and USP compounding rule changes; these specialties included allergy, dermatology, immunology, otolaryngology, oncology, ophthalmology, neurology, and rheumatology.

Even among these specialties, the likelihood of compounding occurring in-office appears to vary widely. For example, ophthalmologists may use repackaged biologics such as bevacizumab (Avastin®) to treat age-related macular degeneration or other conditions for which FDA-approved treatments are rare or nonexistent, but compounding pharmacies generally supply these drugs. Physician groups representing these specialties have advocated for the availability and quality of the compounded drugs, rather than expressing concerns to FDA about physicians’ ability to compound them in-office. Similarly, oncologists may use patient-specific compounded drugs in chemotherapy, and neurologists in infusion treatments for multiple sclerosis or for intrathecal injections for neuropathic pain management. But again, these are not necessarily compounded in-office. Also, an area of concern to at least one related association was that USP should be clear in its language that certain reconstitution or dilution of manufactured products would not be considered “compounding.” The association referenced, for example, adding a single oncology drug to a bag of normal saline for administration to a patient. In other specialties, the frequent occurrence of day-to-day, in-office compounding is more evident. Allergists, immunologists, and otolaryngologists performing immunotherapy, for whose practices in-office allergen extract compounding is common, have argued that proposed changes in USP/FDA compounding standards would affect their ability to provide such treatments as subcutaneous immunotherapy; however, new draft guidance recently published by FDA addresses these concerns. Associations representing dermatologists have also indicated that physicians in that specialty perform in-office compounding frequently and have expressed concerns to regulators that changing standards would negatively impact activities such as pain control for removal of moles, skin lesions, or carcinomas. For these procedures, physicians often minimize lidocaine-related injection pain by using a dilution of sodium bicarbonate. Diluting steroids for intraliesional injections and reconstituting or diluting botulinum toxin type A prior to administration to a patient are other examples.

Somewhat complicating the issue, compounding in at least some cases has become a lucrative business. A 2015 report from Express Scripts

**continued on page 8**
Compounding in Physicians’ Offices
continued from page 7

estimated that compounded prescriptions made up less than 1% of total prescription volume in 2014, a market share that had stayed roughly constant since the early 2000s – yet by 2014, amounts spent on compounded drugs had “skyrocketed.” A 2016 review performed by the US Department of Health and Human Services Office of Inspector General found that Medicare Part D spending for compounded drugs shot up from $70.2 million in 2006 to $508.7 million in 2015, an increase attributed at least in part to high-cost compounded topical creams and ointments. A number of companies – including those touting controversial topical pain creams – exist to facilitate medical practices’ entry into compounding. Their services include providing physicians’ offices with the tools, materials, and training to begin their own compounding, stressing improved patient care and convenience as well as a major new source of income for practices.

Increasing Adherence to Compounding Practice Standards

Both FDA and the US Centers for Disease Control and Prevention (CDC) have raised concerns about adverse events occurring as a result of physician-office compounding and have encouraged greater monitoring of the practice. FDA included physician in-office compounding in its definition of “compounding facilities” (and encouraged state regulators to inspect such facilities) in its draft guidance “Insanitary Conditions at Compounding Facilities,” issued in August 2016, and included “licensed physician” alongside “licensed pharmacist” throughout its final guidance “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act,” released in December 2016. CDC noted during FDA’s September 2016 Inter-governmental Working Meeting on Pharmacy Compounding that “[o]utpatient settings (including physician offices and other clinic settings) are being increasingly identified as sources of healthcare outbreaks linked to breaches in infection control and sterile compounding.” CDC points to a lack of a clearly established authority for managing adherence to compounding standards as one factor that could increase the difficulty of preventing outbreaks. Other challenging factors include some offices’ lack of appropriate infrastructure to perform sterile compounding and inadequately trained personnel.

A number of physician groups, including the AMA, have indicated disagreement with putting physician in-office compounding on the same footing as compounding pharmacies and, in particular, using the same sterile compounding standards for all sterile compounding situations. They cite a lack of widespread adverse events resulting from individually compounded medications prepared in physicians’ offices, and they point particularly to treatments such as subcutaneous immunotherapy (as mentioned above), the vials for which currently may be prepared to less stringent standards than current USP Chapter <797> standards on sterile compounding. (These groups have also objected to the proposed revisions to USP Chapter <797> that would eliminate existing special criteria for such treatments as allergen extracts.) Unfortunately, it is difficult to assess the safety record of in-office, patient-specific compounding due to a lack of standardized reporting. The Pew report on sterile compounding found that only 5% of survey responders could answer a definite “yes” when asked if their state had a regulatory body with the ability to track adverse events associated with sterile compounded products made in a physician office or clinic; the remaining 95% either answered “no” (31%) or “don’t know” (64%).

In a second compounding-related report issued in 2016, “Best Practices for State Oversight of Sterile Drug Compounding,” the Pew Charitable Trusts reaffirmed its conclusion that “quality standards must be the same wherever compounding occurs.” The report noted the importance of having a mechanism to identify and oversee physician office compounding, whether that should occur through the board of medicine or the board of pharmacy. The report’s authors recommended collaboration between NABP and the Federation of State Medical Boards to “identify appropriate oversight systems, whether through state medical boards, state boards of pharmacy, or other appropriate entities.”

As Pew noted in its “National Assessment of State Oversight of Sterile Drug Compounding,” this remains a time of transition for compounding regulation, and the influx of new and changing laws and rules will likely continue for some time. NABP will continue to report on new developments.

“Both FDA and the US Centers for Disease Control and Prevention (CDC) have raised concerns about adverse events occurring as a result of physician-office compounding and have encouraged greater monitoring of the practice.”
NABP Accreditation Programs Continue to Help Protect Public Health, See Steady Number of 2016 Applicants

With the Association’s mission to protect the public health at the forefront, NABP’s accreditation and approval programs help to ensure that patients receive quality care and products. In 2016, entities including durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) providers, pharmacies with an internet presence, and wholesale distributors continued to seek the appropriate accreditation or approval status to comply with state and federal requirements and to distinguish their companies as providers of high-quality products and services.

As a means to help protect the public from the threat of counterfeit drugs infiltrating the United States medication supply chain, Verified-Accredited Wholesale Distributors® (VAWD®), launched in 2004, verifies suppliers’ compliance with criteria based on state and federal laws and best practices for wholesale distributors. By December 31, 2016, a total of 581 wholesale facilities were actively accredited by the VAWD program. As entities continue to seek VAWD accreditation or reaccreditation each year, the number of states requiring or recognizing VAWD has grown to three and 24, respectively.

Since 2009, the DMEPOS accreditation program has assisted numerous pharmacies seeking to meet the Centers for Medicare & Medicaid Services DMEPOS requirements. At the program’s peak in 2009, the DMEPOS program had accredited over 1,000 companies representing over 30,000 facilities. Despite legislative changes made in 2010 that exempt certain pharmacies from having to obtain DMEPOS accreditation, the DMEPOS program continues to receive a steady number of applications, resulting in 87 new accreditations and reaccreditations in 2016. Today, the program has nearly 350 accredited DMEPOS companies representing almost 26,000 facilities.

Since 1999, the Verified Internet Pharmacy Practice Sites® (VIPPS®) program has accredited pharmacies offering a full range of pharmacy services over the internet that meet a comprehensive set of criteria, including compliance with state and federal laws and regulations. As patients’ use of the internet to obtain prescription medications continues to increase, NABP consistently monitors the VIPPS program standards to keep pace with rapid technological advancements in medication access.

In 2016, VIPPS and Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) accredited 12 and four pharmacies, respectively. In addition, 12 VIPPS pharmacies were reaccredited. By the end of 2016, a total of 51 pharmacy sites were VIPPS accredited and 24 pharmacies were Vet-VIPPS accredited.

The NABP e-Advertiser ApprovalCM Program targets internet advertisers that offer only limited pharmacy services or other prescription drug-related services online. There are currently 138 entities approved through the program, 49 of which were newly approved in 2016 and 62 that were reapproved.

In August, NABP announced its intention to begin streamlining its accreditation and approval programs, including incorporating Vet-VIPPS and e-Advertiser into the .Pharmacy Verified Top-Level Domain (TLD) Program. At that time, NABP ceased accepting new applications and renewal applications for Vet-VIPPS and e-Advertiser. 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 request a .pharmacy domain and seamlessly transition to the .Pharmacy TLD Program.

The VIPPS program will remain; however, VIPPS-accredited pharmacies must register and use a .pharmacy domain by September 1, 2017 to maintain their accreditation. All VIPPS-accredited sites are automatically eligible to register a domain name through the .Pharmacy TLD Program. VIPPS-accredited pharmacies are exempt from the .pharmacy application fee and are automatically approved to register .pharmacy domains for their accredited websites. However, the annual domain name registration fee charged by registrars still applies.

More information can be found in the Programs section of the NABP website at www.nabp.pharmacy.
Electronic Licensure Transfer Program Request Volume Remains Consistent for Third Consecutive Year

The number of license transfer requests submitted through the NABP Electronic Licensure Transfer Program® (e-LTP™) remained fairly stable from 2015 to 2016, with a total of 20,715 requests in 2016. This figure represents an increase of 1.1% compared to the 20,492 requests made in 2015.

Transfers to the State

Continuing the trend from the past several years, Texas had the highest number of requests to transfer licensure to the state, with a total of 1,819 requests submitted in 2016. This represents a 54.3% increase compared to the 1,179 requests to transfer a license to Texas made in 2015.

The continuous increase in Texas requests is consistent with overall licensure trends reported in the NABP 2017 Survey of Pharmacy Law. According to the 2017 Survey, Texas reported a total of 32,680 licensed pharmacists, making it one of the top five states in terms of the number of licensed pharmacists.

Additional states with the highest number of license transfer requests to the state in 2016 include:

- Virginia – 867 requests, an increase of 6% when compared to the 818 requests in 2015;
- Maryland – 840 requests, an increase of 3.6% when compared to 811 requests in 2015;
- Florida – 801 requests, a decrease of 7.5% when compared to 866 requests in 2015; and
- Tennessee – 740 requests, a decrease of 8.1% when compared to 805 requests in 2015.

In addition, while not among those states with the greatest number of license transfer requests in 2016, some states did show significant change in overall percentage growth when compared to 2015 data. For example, South Dakota reported 83 requests in 2016, an increase of 29.7% when compared to 2015 data. Other states with significant percentage growth from 2015 to 2016 were Maine (27.4%), California (25.1%), and Washington (23%).

Transfers From the State

The e-LTP data also show the trends in requests to transfer from states, with Florida, Texas, Pennsylvania, New Jersey, and Illinois showing the highest number of such requests. The total number of requests to transfer licenses from these states is as follows:

- Florida – 834 requests, an 8.4% decrease since 2015, when there were 911 requests;
**e-LTP Requests by State**

Shaded areas denote states where the number of applications for transfer from the state is greater than the number of applications requesting transfer to the state.

- Texas – 699 requests, a 9% increase since 2015, when there were 641 requests;
- Pennsylvania – 687 requests, a 10.8% decrease since 2015, when there were 770 requests;
- New Jersey – 605 requests, a 2.6% decrease since 2015, when there were 621 requests; and
- Illinois – 589 requests, a 3% decrease since 2015, when there were 607 requests.

**National Trends**

The 2016 request totals correlate slightly with trends in data on the demand for pharmacists nationally and in certain states, as tracked by the Pharmacy Manpower Project, Inc. This project tracks the data through the monthly Aggregate Demand Index (ADI) report, with a ranking of 1 indicating little need or a surplus of pharmacists and a ranking of 5 indicating a great need for and difficulty in filling pharmacist positions. A ranking of 3 indicates that the demand for pharmacists is in balance with the supply.

Pharmacy Manpower Project data through March 2016 reported a national average at that time of 2.94, indicating that the nationwide demand for pharmacists is fairly in balance with supply. Only one of five states with a high number of license transfer requests in 2016 had a March 2016 ADI ranking above this national average – Texas (3.33).

Further, the ADI report also tracks demand by region. States in the West have the highest level of unmet demand at 3.25. This trend may correlate with the increase in requests to transfer license to California. Following the West is the South with a demand of 3.04. These statistics are in line with trends seen in the top five states with the highest number of requests to transfer licensure to the state. Texas, Virginia, Maryland, Florida, and Tennessee are all located in divisions of ADI’s South region.

The reported data mentioned in this article include all applications for license transfers to and from the states in March 2016, including requests that may not have been completed or fulfilled.

In 2016, the average processing time for e-LTP requests was four days. Approximately 11,978 applications were processed in 2016. For more information about e-LTP, visit the NABP website at www.nabp.pharmacy.
VPP Shows Growth in Number of Pharmacies Applying, Making More Verified Licensure Data Available to Boards

In 2016, 185 pharmacies applied to the Verified Pharmacy Program® (VPP®) as new applicants, which is an increase of 36% compared to 2015’s total of 136 VPP applications. An additional 76 pharmacies chose to keep their profiles up-to-date by requesting a current inspection. These trends may be due to additional states requiring compounding pharmacies to demonstrate compliance with United States Pharmacopeia Chapter <795> and/or <797> in order to obtain or renew a pharmacy license.

Further, NABP continues its partnership with FocusScript (formerly United Compounding Management), which requires an inspection through VPP as a component of its United Credentialing and Accreditation Program.

At press time, at least 545 pharmacies have applied to VPP and currently, or soon will, have verified data available for the boards to view. Of these, more than 111 have been inspected through VPP more than once (see table for inspection totals). This verified data is provided to the member boards through the secure NABP e-Profile Connect in an effort to further support them in making informed licensure decisions for nonresident pharmacies. In addition to providing this data to the states, NABP continues work with boards of pharmacy to provide inspection training and tools through existing VPP processes when requested. For more information about VPP or the inspection sharing network, contact the NABP Accreditation department at vpp@nabp.pharmacy. Additional details are also available in the Programs section of the NABP website at www.nabp.pharmacy.

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*The inspection totals above represent inspections in 2016 and do not include applicants who are awaiting an inspection or who recently submitted an application.

Legal Briefs

referred to the board for a second hearing to determine the appropriate sanction(s).

In the current case, the Board incorporated into its order the AHC findings of fact and conclusions of law. The substantiation for imposing sanctions was justified, and the Board had broad discretion to determine the appropriate form of discipline. As noted, the regulations do not require the Board to make additional findings to justify the sanctions imposed. However, the Board did indeed make additional findings justifying the sanctions. All such findings support the conclusions of wrongdoing and the sanctions imposed. Thus, the court rejected the Respondents’ third arguments. Consequently, the Court of Appeals affirmed the lower court and upheld the findings of and sanctions rendered by the Board.

This Missouri Court of Appeals decision contains important language recognizing and deferring to the expertise of the members of the Missouri Board of Pharmacy. The need for expertise on boards of pharmacy is necessary for the effective and efficient administrative processes contained in a regulatory structure. These characteristics are sometimes lost or ignored in the current reactionary political climate focusing on deregulation and economic growth. In the wake of the North Carolina State Board of Dental Examiners United States Supreme Court decision, boards of pharmacy and their professional and public members must be tuned in to the public protection roles that regulatory boards play and dispel the notion of self-regulated professions.

Jefferson City Apothecary, LLC v. Missouri Board of Pharmacy, 499 S.W.3d 321 (App Ct MO 2016)
Commending 14 returning members, NABP is pleased to announce the 2017-2018 Multistate Pharmacy Jurisprudence Examination® (MPJE®) Review Committee.

Dedicated to reviewing and safeguarding the integrity and validity of the MPJE, the committee is composed of experts in pharmacy law and regulation who are representative of the diversity of pharmacy practice and share the responsibility for developing and reviewing the items in the MPJE. This team of dedicated volunteers acts under the policy and planning guidance of the Advisory Committee on Examinations (ACE) and the NABP Executive Committee. Responsibilities include reviewing the examination questions to ensure compliance with pharmacy law as it applies to contemporary practice and participating in meetings.

NABP appreciates the assistance of these committee members as they evaluate examination content and ensure that it meets the specified competency assessment statements, which, in essence, determine the question pool. ACE recommends appointments to the committee, and the NABP Executive Committee approves the appointments. Committee members, whose terms began February 1, 2017, are as follows:

**MPJE Review Committee**
- Mark Brown, MBA, RPh, Lahaina, HI
- Katie Busroe, RPh, Kentucky Board of Pharmacy
- Grace Cheung, RPh, Kenmore, WA
- Mark T. Conradi, JD, RPh, Clanton, AL
- Randy Jones, RPh, Sioux Falls, SD

Guam is the latest NABP member board to require NABP's Multistate Pharmacy Jurisprudence Examination®, raising the number of jurisdictions utilizing the examination to 50. On January 16, 2017, administration of Guam's MPJE began at Pearson VUE test centers throughout the United States.

According to Guam Board of Examiners for Pharmacy Board Member Angie Eustaquio, PharmD, BCPS, the Board decided to adopt the MPJE into its licensure process to formalize and standardize the exam process for its candidates. In the past, Guam’s examination was offered on a candidate-to-candidate basis and relied on a Guam Board member’s availability to proctor exams. In addition, prior to the MPJE, candidates had to travel to Guam to sit for an exam.

Eustaquio noted, “Now, thanks to the assistance of NABP and the efforts by Board members, we are pleased to be the first territory (aside from District of Columbia) to accept the MPJE as part of our licensure process. It removes the barrier of having to travel thousands of miles away, formalizes and standardizes the process to be in line with the vast majority of other Boards, and allows the Board flexibility to focus on updating rules, addressing complaints, and collaborating with the pharmacy community to promote safe pharmacy practice on our island.”

The MPJE combines federal- and state-specific questions to test the pharmacy jurisprudence knowledge of prospective pharmacist licensees. It serves as the pharmacy law examination in participating jurisdictions. Specifically, the MPJE tests candidates on:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients;
- Licensure, registration, certification, and operational requirements; and
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors.

NABP develops and administers the MPJE at no cost to the participating boards. Annually, the boards are required to develop items that address laws and regulations relevant to practice in their jurisdiction; review the MPJE pool to ensure accuracy and relevancy of content; select new items among the submissions from other MPJE-participating states; and notify NABP of any laws or regulatory changes that would impact MPJE test items. In addition to evaluating items, boards of pharmacy are responsible for approving candidate eligibility and providing candidates with score reports. To assist boards in meeting these requirements, NABP provides guidance and training.
Number of Administrations for All NABP Examinations and Assessments Increased in 2016

In 2016, there was an increase in administrations of all of NABP’s examinations and assessments, reflecting various changes in the practice of pharmacy.

Showing a consistent increase from year to year, the number of North American Pharmacist Licensure Examination® (NAPLEX®) administrations rose again in 2016. The increase of pharmacy school graduates throughout the United States continues to positively impact the number of candidates who sit for the NAPLEX annually. From January 1, 2016, to December 31, 2016, there was a total of 18,127 NAPLEX administrations compared to 16,661 administrations in 2015, representing an increase of 8.8%.

Currently, there are 129 Accreditation Council for Pharmacy Education (ACPE)-accredited schools and colleges of pharmacy in the US that have graduating classes. Of the candidates who sat for the 2016 administration, 83.81% were first-time test takers.

There was a significant increase in the number of Pre-NAPLEX® administrations between 2015 and 2016. The Pre-NAPLEX, which serves as the practice examination for the NAPLEX, had a total of 12,347 administrations in 2016, an increase of 23.3% when compared to the 2015 administrations.

The number of Multistate Pharmacy Jurisprudence Examination® (MPJE®) administrations showed an increase in 2016. The MPJE had a total of 31,352 administrations, an increase of 10.7% compared to 2015. This increase is likely associated with the increase in the number of students graduating in the US as well as the steady number of license transfer requests. Also, Virginia joined the MPJE in July 2016, bringing the total number of jurisdictions requiring the MPJE for initial licensure and license transfer in 2016 to 49.

The Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®) had a total of 1,528 candidates who sat for the 2016 spring and fall administrations, a 2.1% increase when compared to 2015.

Over 18,000 students from 134 schools and colleges of pharmacy participated in the 2016 testing windows for the Pharmacy Curriculum Outcomes Assessment® (PCOA®). NABP continues to cover the cost of one-time PCOA administrations to students nearing the completion of their didactic curriculum for compliance with ACPE Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (Standards 2016). Details about the 2016 PCOA testing windows will be provided in the April 2017 issue of Innovations.

More information on NABP examinations and assessments is located on the NABP website at www.nabp.pharmacy.

Committee on Law Enforcement/Legislation Convenes

In January 2017, the Committee on Law Enforcement/Legislation convened in Rosemont, IL, to review and comment on existing legislation and rules for the practice of pharmacy. Pictured are (left to right) Gay Dodson, RPh, NABP Executive Committee liaison; Steven W. Schierholt, Esq, executive director, State of Ohio Board of Pharmacy; Jody H. Allen, PharmD, FASHP, member, Virginia Board of Pharmacy; Tom Van Hassel, RPh, member, Arizona State Board of Pharmacy; Alice G. Mendoza, RPh, member, Texas State Board of Pharmacy; Debbie Chisolm, RPh, member, Connecticut Commission of Pharmacy; Larry L. Pinson, PharmD, RPh, executive secretary, Nevada State Board of Pharmacy (chairperson); Diane Halvorson, RPhTech, CPhT, member, North Dakota State Board of Pharmacy; and Lemrey “Al” Carter, PharmD, RPh, member, Illinois Department of Financial and Professional Regulation, Division of Professional Regulation – State Board of Pharmacy.
More than 55 million people from Massachusetts, New Hampshire, New York, and Texas are now covered by NABP PMP InterConnect®. The addition of these states to the network brings the total to 37 states sharing prescription monitoring program (PMP) data to combat the abuse of prescription drugs, with additional states expected to join the system in 2017.

Over the past few months, these states have updated their PMP software and tested their systems to ensure full functionality with PMP InterConnect and compliance with their own data standards.

“As states continue to join this system, authorized physicians and pharmacists will have access to more comprehensive information about prescription histories allowing them to make more informed medical decisions,” said NABP President Hal Wand, MBA, RPh. By enabling the secure exchange of data in state PMPs, Wand further noted that “PMP InterConnect is a unique system that can help health care practitioners identify potentially problematic trends with prescription drugs so problems can be addressed early.”

The new participants will also be represented on the governing body, which determines the strategic, technical, and operational evolution of PMP InterConnect. Each state is able to use the system free of charge in full compliance with their own laws to provide the greatest benefit to their citizens. Massachusetts, for instance, sent more than 625,000 requests to 21 states in just the first month of operation with PMP InterConnect.

“The fight against prescription drug abuse is one of our top public health concerns,” said Allison Vordenbaumen Benz, MS, RPh, director of professional services, Texas State Board of Pharmacy. “We have joined the InterConnect program because it will ensure our public health professionals secure access to information that can have a positive impact on the health of our local communities.”

PMP InterConnect was designed to allow authorized health care professionals to obtain multistate information about their patients’ controlled substance prescriptions. The initiative delivers health care providers a more complete view of patient records to combat drug diversion and drug abuse nationwide. Through a comprehensive collaborative approach, PMP InterConnect delivers a practical solution that processes prescription data for millions of patient encounters each year.

“We’re excited about the growth and response to PMP InterConnect,” said Wand. “Our goal is to reach every state with a PMP to guarantee a true connection across our country in an effort for greater medical knowledge and our patients’ safety.”

### Spreading the Word About PMP InterConnect

Educating state boards of pharmacy and pharmacists about PMP InterConnect and its benefits to stakeholders and consumers is one way NABP continues to grow the initiative.

This spring, NABP staff will give two presentations focusing on PMPs at the 2017 American Pharmacists Association (APhA) Annual Meeting and Exposition, to be held March 24-27 in San Francisco, CA. On March 24, during the Association’s new APhA Pain Institute, themed “Pharmacists on the Frontlines of the Opioid Epidemic,” NABP will discuss the current state of PMPs, their benefits and limitations, and how to use the information on a day-to-day basis. On March 26, NABP will co-present in an educational session at the meeting titled “Identification and Prevention of Drug Diversion in the Pharmacy” with Bob Parrado, past chairman, Florida Board of Pharmacy, and president/chief executive officer of Parrado Pharmacy Consultants. The session will explore how to address legal concerns so patients can access legally prescribed controlled substances.

For more information about the APhA Annual Meeting and Exposition and APhA Pain Institute, visit http://aphameeting.pharmacist.com.

For more information about PMP InterConnect, visit the Initiatives section on the NABP website at www.nabp.pharmacy.
As interest in the .Pharmacy Top-Level Domain (TLD) Program has grown among Canadian entities and organizations, the program sought to raise consumer awareness about the TLD via TV public service announcements (PSAs).

In January 2017, NABP distributed a PSA on the global .Pharmacy TLD Program to 210 major television stations throughout Canada. The 60-second “.Pharmacy: Buying Safely” PSA, which was previously distributed in the United States in May 2016, highlights how difficult it can be for consumers to know what they are receiving when buying medications from illegal online drug sellers and encourages consumers to use internet pharmacies with a .pharmacy domain. Consumers can find the PSA as well as a list of helpful tips for spotting rogue sites on the .pharmacy website at www.safe.pharmacy/buying-safely.

The PSA is intended to raise awareness about the risks of buying medicine online from illegal drug outlets, which often distribute dangerous counterfeits to unsuspecting consumers as detailed in the Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators: January 2017. In previous versions of its report, NABP has provided information on how many websites presenting themselves as licensed Canadian pharmacies are in fact rogue drug sellers wanting to make a profit from US citizens seeking lower-cost medicines.

In June 2016, the National Association of Pharmacy Regulatory Authorities (NAPRA) signed an agreement with NABP to assist with reviewing .Pharmacy TLD Program applications for pharmacies located or doing business in Canada, and since that time interest in the .pharmacy TLD by Canadian sites has grown. NAPRA’s members, most of whom represent associate members of NABP, have a key role in the .Pharmacy TLD Program. Some of NAPRA’s representatives support the .Pharmacy TLD Program by serving as members on the program’s Executive Board and on its Regulator Advisory Committee.

NABP is committed to working with stakeholders globally to ensure .pharmacy operates in a manner consistent with international laws and standards. NABP continues to form relationships with countries around the world to work toward creating a more widespread program.

“As interest in the .Pharmacy Top-Level Domain (TLD) Program has grown among Canadian entities and organizations, the program sought to raise consumer awareness about the TLD via TV public service announcements (PSAs).”
Schedule of Events

Saturday, May 20, 2017
10 AM - 5 PM
Registration/Information Desk Open

1:30 - 3:30 PM
Pre-Meeting CPE
Expanded Scopes of Practice – No More Mickey Mousing

4 - 5 PM
From District Meeting to Annual Meeting – Learning About NABP

6 - 9 PM
President’s Welcome Reception
Honoring NABP President
Hal Wand, MBA, RPh
Dinner will be served. Dress: Business casual

Sunday, May 21, 2017
7:30 AM - 4:45 PM
Registration/Information Desk Open

7:30 - 8:30 AM
NABP AWAR,E Fun Run/Walk

8:30 - 11:30 AM
Hospitality Brunch and Educational Table Top Displays

8:30 - 11:30 AM
Joint CPE
Educational Poster Session – Imagineering for the Protection of Public Health

Noon - 3:15 PM
First Business Session
• Welcome Remarks
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
• Presentation of Colors
• National Anthem
• Keynote Address, Howard Fineman, Global Editorial Director, Huffington Post Media Group
• Call to Order
• Greetings From the Host State Florida Board of Pharmacy
• Report of the Executive Committee
  Edward G. McGinley, MBA, RPh, DPh, Chairperson, NABP Executive Committee
• President’s Address
  Hal Wand, MBA, RPh, NABP President
• Report of the Treasurer
  Susan Ksiazek, RPh, NABP Treasurer
• Announcement of Candidates for Open Executive Committee and Member Positions
• Open Microphone Session
  (Time permitting)

3:45 - 4:45 PM
Joint CPE
Specialty Pharmacy – The Future of Pharmacist Care?

Monday, May 22, 2017
7:30 AM - 12:30 PM
Registration/Information Desk Open

7:30 - 9 AM
USP Update and Breakfast
Plated breakfast served from 7:30 - 8 AM

9:15 - 10:15 AM
Joint CPE
Telehealth – Another Epcot Experiment?

10:30 AM - Noon
Second Business Session
Presiding: Hal Wand, MBA, RPh, NABP President
• Report of the Executive Director/Secretary
  Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary
• Report of the Committee on Resolutions
  Jeanne D. Waggener, RPh, NABP Treasurer
  Susan Ksiazek, RPh, NABP Treasurer
• Report of the Committee on Constitution and Bylaws
  L. Suzan Kedron, JD, Chairperson, Committee on Constitution and Bylaws
  - First Reading of Resolutions
• Report of the Committee on Amendments to the Constitution and Bylaws
  - Presentation of Proposed Amendments to the Constitution and Bylaws
• Candidate Speeches for Open Executive Member Officer and Member Positions

Noon - 12:30 PM
Informal Member/Candidate Discussion

Free Afternoon: No programming

continued on page 18
The continuing pharmacy education (CPE) sessions presented at the Annual Meeting are developed specifically for the Association’s member boards of pharmacy, which are composed of executive officers, board staff, board members, compliance staff, and board counsel. Sessions are also relevant to other attendees in the practice of pharmacy. By actively participating in the meeting’s CPE programming, at the conclusion of the Annual Meeting, participants should be able to:

- Identify the latest legislative and regulatory issues being addressed by the state boards of pharmacy.
- Explain how the changing regulatory environment impacts the state boards of pharmacy and the practice of pharmacy.
- Identify gaps in regulatory oversight and best practices for state pharmacy boards to overcome them.
- Discuss emerging roles of pharmacists and pharmacy technicians with respect to the public’s access to quality health care.
- Discuss how poster session research findings further the protection of the public health.
- Describe best practices for regulating pharmacist care services in a changing health care environment.
- Analyze licensing standards between state boards of pharmacy.

Contact NABP Professional Affairs staff at 847/391-4406 or via email at Prof-Affairs@nabp.pharmacy for more details.

NABP and NABP Foundation® are accredited by the Accreditation Council for Pharmacy Education (ACPE) as providers of CPE. ACPE provider number: 0205. Learning objectives and descriptions for each CPE session are available on the CPE page at NABPAnnualMeeting.pharmacy. Instructions for claiming CPE credits, including continuing legal education credits, are also provided.
Looking for opportunities to share information and network with fellow state board of pharmacy members and other pharmacy professionals at the NABP 113th Annual Meeting? Look no further than the optional events taking place throughout the meeting.

**Orientation Session**

Attendees new to the Annual Meeting, including recently appointed board of pharmacy members, are encouraged to attend “From District Meeting to Annual Meeting – Learning About NABP,” on Saturday, May 20. During this session, attendees will learn details about how member decisions at the district meetings set the stage for the business session agenda of the NABP Annual Meeting. In addition, they will learn details on the Annual Meeting processes for discussing and voting on resolutions, amendments to the NABP Constitution and Bylaws, and Executive Committee open member and officer positions. Attendees will also have the opportunity to meet and network with their fellow district members.

**NABP AWARX® Fun Run/Walk**

Get a head start on the day’s Annual Meeting activities by participating in the NABP AWARX® Fun Run/Walk. The 2.5-mile Fun Run/Walk course will take participants through the nearby shopping and resort area before looping back through the grounds of the Orange County Convention Center. To participate, select the Fun Run/Walk Session when completing the online meeting registration process. Participants and other attendees may order a Fun Run/Walk t-shirt for $20 during the online registration process. All proceeds from the Fun Run/Walk t-shirts sales will go to NeedyMeds, Inc, a national charity selected by the Florida Board of Pharmacy.

**Hospitality Brunch and Table Top Displays**

The Hospitality Brunch offers attendees an opportunity for informal discussions and networking while partaking in a full buffet brunch. In addition, educational table top displays from NABP, NABP/American Association of Colleges of Pharmacy districts, the NABP Executive Committee and NABP Past Presidents, federal regulatory agencies, and other associations highlighting important issues and programs will be displayed nearby. Representatives will be on hand to answer questions about their organizations. Attendees will also have the opportunity to meet members of the Florida Board of Pharmacy and get a local perspective on the must-see sights of Orlando at the host state’s table top display.

**Educational Poster Session**

This year’s Educational Poster Session addresses the theme “Imagineering for the Protection of Public Health.” Posters will include information on timely legislative, regulatory, and policy issues from a variety of organizations and stakeholders. Poster Session participants have the opportunity to earn up to one contact hour (0.1 CEU) of Accreditation Council for Pharmacy Education-accredited continuing pharmacy education (CPE) credit by spending at least 60 minutes discussing the displays with presenters and passing an online post-session test.

**Networking Session**

Attendees seeking to network further with their regulatory colleagues are encouraged to attend “Expanding on Forum Discussions – The Magic of Networking on Shared Topics,” on Tuesday, May 23, from 10:30 AM to noon. Continuing the momentum begun at the fall interactive forums, this session will include topics selected by forum attendees as key issues faced by their boards, as well as new topics from Annual Meeting attendees.
Still Time to Request a Travel Grant

Are you an active board of pharmacy member or administrative officer who is attending the NABP 113th Annual Meeting?

NABP has travel grant opportunities available for qualified individuals to cover costs for needed expenses. Eligible individuals may receive up to $1,500 to cover the costs of travel, hotel rooms, meals, taxis, parking, and tips. The grant does not include Annual Meeting registration fees.

- One grant will be awarded to a current board member or administrative officer of each active NABP member board of pharmacy, as designated by the board’s administrative officer.
- Active member boards of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.

To obtain a grant application, board administrative officers may contact the NABP Executive Office at ExecOffice@nabp.pharmacy.

Important Deadlines

- Early Registration Rate – April 7
- Early Hotel Reservation Rate – April 20
- Voting Delegate Submissions – April 21

Exploring Orlando

Attendees can explore the Sunshine State through its many exciting theme parks, museums, and gardens during a free afternoon on Monday, May 22. Several parks and museums were highlighted in the January 2017 issue of Innovations, including Lake Eola Park and the Orange County Regional History Center.

Attendees may also contact the hotel concierge for recommendations on things to do while in Orlando. Please note, no other functions are scheduled on Monday afternoon. The final meeting event is the Annual Awards Dinner on Tuesday, May 23.

Orlando Links

- City of Orlando
  www.cityoforlando.net
- Harry P. Leu Gardens
  www.leugardens.org
- Lake Eola Park
  www.cityoforlando.net/parks/lake-eola-park
- Orlando Eye
  www.officialorlandoeye.com
- Orlando Museum of Art
  www.omart.org
- Loch Haven Park
  www.cityoforlando.net/parks/loch-haven-park
- Orange County Regional History Center
  www.thehistorycenter.org
NABP Renovates Headquarters to Better Address Members’ Needs, Prepare for Future Growth

NABP began an extensive renovation of its headquarters in Mount Prospect, IL, in October 2016. Purchased by the Association in 2003, the one-story, approximately 57,000-square-foot building is being reconfigured and updated to provide efficiencies and resources that better address the needs of NABP’s member boards of pharmacy. Among the many improvements to the building’s interior are larger meeting rooms, which will enable NABP to house more of its regularly scheduled meetings onsite throughout the year.

The redesigned building will also provide space for additional staff that may be needed to support existing and future NABP programs and services, such as the Verified-Accredited Device Integrity Program™ (VDIP™), which launched in September 2016. In planning the renovation, staff analyzed various options to accommodate future change and determined that the renovation was the most cost-effective solution and use of NABP resources. After review and further analysis, the NABP Executive Committee approved the current plan.

During the renovation, NABP staff have temporarily relocated to an unoccupied building situated near the Association’s headquarters. NABP anticipates returning to its updated headquarters in April 2017.

Around the Association

Board Member Reappointments

- **Kevin Desmond, RPh**, has been reappointed a member of the Nevada State Board of Pharmacy. Desmond’s appointment will expire October 31, 2019.
- **Tallie Pederson, PharmD, RPh**, has been reappointed a member of the Nevada State Board of Pharmacy.
- **Candace Bouchard, PharmD**, has been reappointed a public member of the New Hampshire Board of Pharmacy. Bouchard’s appointment will expire October 22, 2021.
- **Michael Bullek, RPh**, has been reappointed a member of the New Hampshire Board of Pharmacy. Bullek’s appointment will expire September 6, 2021.
- **Franklin LaDien, RPh**, has been reappointed a member of the Wisconsin Pharmacy Examining Board. LaDien’s appointment will expire July 1, 2020.
Illinois Requires Pharmacy or PIC to Submit Pharmacy Personnel Termination Report

In Illinois, a pharmacy or pharmacist-in-charge (PIC) is required to file a report within 60 days to the Illinois Department of Financial and Professional Regulation (IDFPR) any time a pharmacist, a registered certified pharmacy technician, or a registered pharmacy technician licensed by the IDFPR is terminated for actions that may have threatened patient safety. The new law (Public Act 099-0863) signed by Governor Bruce Rauner provides protection from criminal prosecution or civil damages when such report is made in good faith. The Pharmacy Personnel Termination Report may be obtained on the IDFPR website at www.idfpr.com/profs/pharm.asp.

Illinois Makes Pharmacy Citation Program Permanent to Reduce Resources Spent

The IDFPR designed a pilot pharmacy citation program, which is now permanent, to reduce the amount of resources spent by both the IDFPR and licensed pharmacists when dealing with minor infractions. The IDFPR will continue with the same fine structure ($100 for one offense, $250 for two offenses, and $500 for three) that will only be applied to minor violations.

During approximately six months of the pilot program, more than 80 tickets were issued. Each pharmacy that was issued a ticket had the option of choosing not to pay the nominal fine amount of no more than $500. If the pharmacy did this, the infraction would be litigated through the system normally. Out of the tickets issued, no pharmacies chose to fight their fine. The IDFPR views this as a great success. The pharmacy citation program is one of the many steps that the IDFPR is taking to reduce regulatory burdens without compromising patient care.

New Mexico Revises Controlled Substances Regulations

New Mexico Regulation 20, Controlled Substances, was recently revised. Regarding new controlled substance (CS) prescription orders, wording was clarified to state that a telephone order for a new therapy for an opiate listed in Schedule III, IV, or V shall not exceed a 10-day supply, based on the directions for use, unless a written prescription is on file at the pharmacy from any practitioner for the same opiate within the past six months. A telephone order for this new opiate therapy may not be refilled.

Ohio Updates Rules on Pharmacist Consult Agreements With Physicians

In March 2016, Ohio House Bill 188 took effect and made the following modifications to pharmacist consult agreements with physicians (Ohio Revised Code 4729.39):

- Authorizes one or more pharmacists practicing under a consult agreement with one or more physicians to (1) manage a patient’s drug therapy for specified diagnoses or diseases and (2) order and evaluate blood and urine tests.
- Creates a single process for establishing a consult agreement, in place of separate processes that were based on whether the patient’s drug therapy was being managed within or outside a hospital or long-term care facility.
- Grants certain immunities from civil liability to pharmacists and physicians practicing under consult agreements.


Ohio Enacts New Requirements for Reporting DEA Registration Number Suffixes by Hospitals

As of October 2016, Rule 4729-17-13 requires all hospitals to submit electronically to the State of Ohio Board of Pharmacy an initial list of the internal codes that are used as a suffix to the hospital Drug Enforcement Administration (DEA) registration number within 30 days. Furthermore, the rule requires that all additions, deletions, or changes to the list be submitted to the Board within five business days of any such addition, deletion, or change. Additional information is available at www.pharmacy.ohio.gov/reporting.
DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

• If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.

• DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.

• Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at www.deadiversion.usdoj.gov/drugreg/index.html.

FDA Issued Guidance for Industry on the Implementation of the DSCSA, Requested Comment on a Section

In December 2016, Food and Drug Administration (FDA) issued a final guidance for industry related to the Drug Supply Chain Security Act (DSCSA) to aid trading partners (manufacturers, repackagers, wholesale distributors, and dispensers) in identifying a suspect product as defined by the Federal Food, Drug, and Cosmetic Act and terminating notifications. FDA also requested comments regarding the portion of the guidance that describes when manufacturers should notify FDA if there is a high risk that a product is illegitimate.

The guidance, “Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification Guidance for Industry,” identifies specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain; provides recommendations on how trading partners can identify a product and determine whether a product is a suspect product as soon as practicable; and sets forth the process by which trading partners should notify FDA of illegitimate product or products with a high risk of illegitimacy, and how they must terminate the notifications, in consultation with FDA. The guidance is available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf. Additional information may be found online in the Federal Register at www.federalregister.gov/documents/2016/12/09/2016-29588/drug-supply-chain-security-act-implementation-identification-of-suspect-product-and-notification.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the continuing education (CE) course “Internet Drug Sellers: What Providers Need to Know” to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were “very aware” counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, “After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm.”

For more information about the campaign, visit www.BuySafeRx.pharmacy.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.
UPCOMING EVENTS

Committee on Constitution and Bylaws
April 12, 2017
Teleconference

FPGEE Administration
April 25, 2017

NABP 113th Annual Meeting
May 20–23, 2017
Orlando, FL

PARE Administration
June 5–16, 2017

2017 Tri-Regulator Symposium
July 25–26, 2017
Chicago, IL