

INNOVATIONS



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INNOVATIONS

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Innovations

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National Association of Boards of Pharmacy

1600 Feehanville Drive, Mount Prospect, IL 60056 • 847/391-4406
www.nabp.pharmacy • help@nabp.pharmacy

Carmen A. Catizone
Executive Director/Secretary

Amy Suhajda
Communications Manager

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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.

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Feature News

Prevalence of Rogue Online Pharmacies Pushes Regulators to Raise Awareness, Continue the Fight Against Counterfeits

Vet-VIPPS and e-Advertiser Transition to .Pharmacy

VIPPS-Accredited Pharmacies Must Register for .Pharmacy Domain Names

As of September 1, 2017, websites that are accredited or approved under NABP's Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®) and NABP e-Advertiser Approval^{CM} programs will be fully transitioned into the .Pharmacy Verified Websites Program if they wish to maintain the benefits of those programs. By this date, Vet-VIPPS and e-Advertiser will no longer be available. Also by this date, pharmacies accredited through the Verified Internet Pharmacy Practice Sites® (VIPPS®) program must register and use a .pharmacy domain name through the .Pharmacy Program to maintain their accreditation status.

NABP began consolidating its online accreditation programs into the .Pharmacy Program in August 2016, with the first being Vet-VIPPS and e-Advertiser; shortly thereafter, the new requirements for VIPPS were announced. Since that time, NABP ceased accepting new applications and renewal applications for the Vet-VIPPS and e-Advertiser programs and notified

program participants that they would be able to maintain their program status through August 31, 2017, enabling them to transition to the .Pharmacy Program. Vet-VIPPS and e-Advertiser customers now must go through the application process to maintain their approved status. VIPPS-accredited pharmacies are automatically approved to register .pharmacy domains without having to complete an application. To date, 95% of Vet-VIPPS and approved e-Advertiser websites and 37% of VIPPS websites have requested a .pharmacy domain.

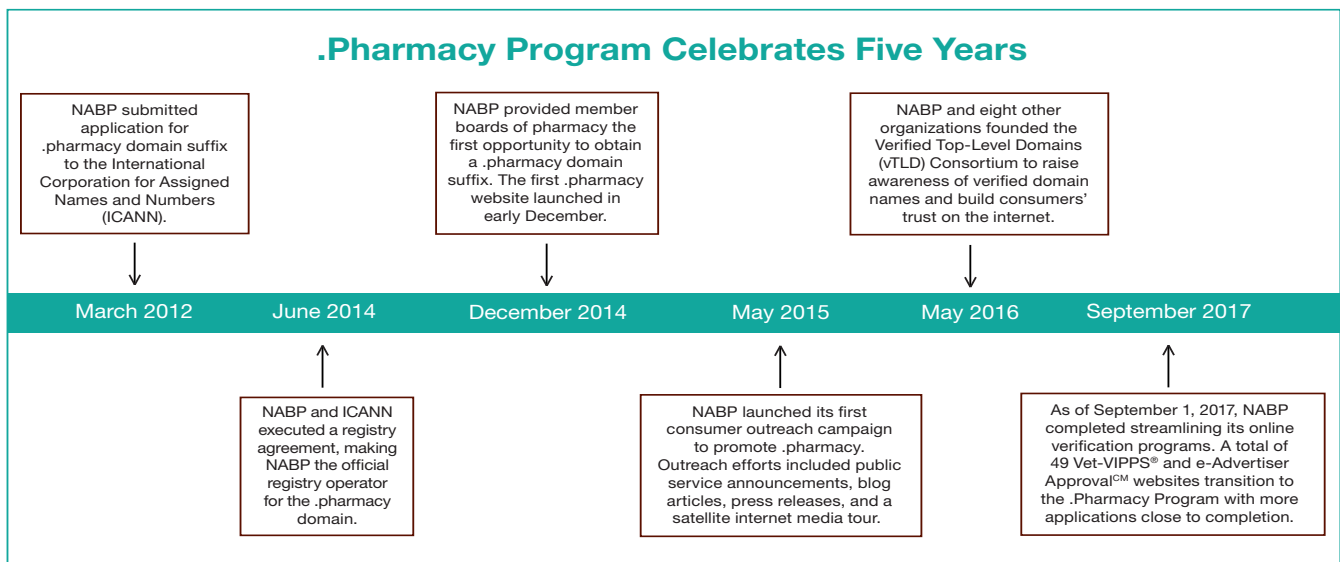
NABP has been encouraging businesses with accredited and approved sites to obtain a .pharmacy domain name before the aforementioned end date to maintain ongoing NABP approval and ensure uninterrupted online program privileges. The Association conducted several webinars throughout the year to help customers transition their websites to .pharmacy and to learn about digital marketing.

As online safety and security challenges evolve, NABP recognizes that its



online accreditation programs must also evolve and progress to protect public health. The .Pharmacy Program offers a superior means of identifying legitimately operating pharmacies and pharmacy-related entities for consumers, advertisers, and search engine companies. NABP believes the .pharmacy domain is the way to turn the tide against sophisticated criminals who can easily duplicate verification logos and seals on authentic-looking sites to trick unsuspecting consumers.

More information about the .Pharmacy Program, including how to register for a .pharmacy domain, is available at www.safe.pharmacy. ■



What's in a Name?



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

“Distinguishing between substantive information subject to confidentiality protections and other information deemed not to be within the sphere of what is protected can present interesting legal questions.”

Certain patient and practitioner identifying information related to medical care and prescription activities are subject to significant privacy legislation, both at the state and federal levels. The Health Insurance Portability and Accountability Act is federal legislation designed to provide such layers of confidentiality. In addition, the states also provide for the protection of this type of sensitive information. However, state legislation providing confidentiality protections differs from jurisdiction to jurisdiction. Consider the following:

An estate through surviving children filed a lawsuit against an emergency room physician alleging negligence in the form of medical malpractice following the death of a patient, their father. The physician was represented by a law firm in the civil matter. Before the case proceeded to trial, the parties settled the dispute for a monetary payment of \$450,000.

Thereafter, the physician sued the law firm for legal malpractice, arguing that the case should not have been settled. As part of defending itself, the law firm sought information related to the physician's access to the prescription monitoring program (PMP). A concurring appellate court judge provided further clarification to the facts of the malpractice case and the relevance of the information requested by the law firm. The cause of death of the father was a narcotic overdose, not from the medical treatment of the physician. During his deposition, the physician gave conflicting testimony of when he learned of the decedent's prescription history. The physician first stated that he learned of the

narcotic prescription history almost one year after the death of the patient when he accessed the records on the Board's PMP. He thereafter stated that he learned of the decedent's prior prescription history through the PMP in the course of examination and treatment in the emergency room, prior to the time of settlement of the medical malpractice case.

The PMP is a repository of information collected by the Louisiana Board of Pharmacy (Board) related to the dispensation of controlled substances and other drugs of concern in the state. The law firm requested the physician's login and search history of the PMP, believing there were inconsistencies with the dates and times claimed by the physician to have accessed the PMP databank relative to the settlement of the medical malpractice claims.

The Board refused to provide the requested information and the law firm filed motions to compel with the trial court. Specifically, the law firm requested that the Board "disclose the date, time and portal location of [the physician's] access of the online database concerning [the patient] for the time period of 2013 through the present date." The trial court granted the law firm's petition and the Board appealed.

The Court of Appeals of Louisiana identified the issue as whether a physician's login time, portal location, and search history of an individual patient qualifies as "prescription monitoring information" subject to the limitations of disclosure under Louisiana law. The applicable Louisiana law titled Access to Prescription Monitoring Information provides (emphasis added as set forth in judicial opinion):

A. Except as provided in Subsections C, D, E, F, G, H, and I of this Section, *prescription monitoring information submitted to the board shall be protected health information*, not subject to public or open records law, including but not limited to R.S. 44:1 et seq., and not subject to disclosure. *Prescription monitoring information shall not be available for civil subpoena from the board nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding nor shall such records be deemed admissible as evidence in any civil proceeding for any reason.* Notwithstanding this provision, law enforcement and professional licensing, certification, or regulatory agencies may utilize prescription monitoring information in the course of any investigation and subsequent criminal and administrative proceedings, but only in accordance with federal and state law and the requirements of this Part.

B. The board shall maintain procedures to ensure that *the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons or entities except as in Subsections C, D, E, F, G, H, and I of this Section.*

The exceptions to confidentiality involve Board notice to occupational and licensing boards where there is reasonable suspicion of wrongdoing, aggregated information for education purposes without identifying participants, notice to certain specified state agencies, notice to certain law enforcement and prosecution personnel, notice to other

PMPs, and notice to authorized users of PMPs.

Prescription monitoring information is defined as “data submitted to and maintained by the prescription monitoring program.”

The Board argued that a physician’s login and search history is data submitted to and maintained by the PMP and, thus, not subject to disclosure. The appellate court disagreed. It held that a timestamp, portal location identifier, and search history is not data “submitted” to the PMP. It interpreted the term submitted to include “input of the listed information into the database.” Such listed information included prescriber information, patient information, prescription information, drug information, and dispenser information. Further buttressing its opinion, the court noted that the plain language of the statute defines prescription monitoring information to include data submitted and maintained. The use of the word “and” does not indicate a basis for broad interpretation. It held that login, time access, portal, and search history is not submitted to the PMP.

The court also noted that the intent of the legislation encompassed the protection of substantive PMP information. As noted by the Board in its brief filed with the court, the privilege from disclosure “fosters the legislative purpose of collecting prescription monitoring information to use to combat doctor shopping and thus ultimately combat drug use and addiction.” Citing this language, the court noted that access to a physician’s login time and search history “is not information submitted to the database and it serves no

purpose in combating doctor-shopping or drug abuse.”

The court conceded that prescription monitoring information is not available for any reason related to civil lawsuits to promote participation in and, where appropriate, access such information. But, the information requested by the law firm in this case is not prescription monitoring information subject to the disclosure protections.

Finally, the Board argued that a search of a person’s name constitutes revealing patient identity. Again, the court disagreed, holding that the search of a particular name reveals nothing about the person or his/her prescription drug use. Indeed, the court noted that nearly every citizen has been a patient sometime between birth and death and that revealing one’s status as a patient is neither significant nor a revelation. Accordingly, the court affirmed the ruling of the trial court and upheld the order to compel production of the information requested by the law firm.

Distinguishing between substantive information subject to confidentiality protections and other information deemed not to be within the sphere of what is protected can present interesting legal questions. Such an analysis likely differs from state to state and will be dependent upon the language of the applicable law.

Dean v. St Mary Emergency Group, LLC, 2017 La App LEXIS 878 (App Ct LA 2017) ■

Proposed Legislation Brings **Risk of Imported Counterfeit Medications**, Bypasses Regulatory Safeguards



“At present, there is no way for consumers to be certain that all websites purporting to be legitimate, Canadian-based pharmacies are in fact based in Canada – or are even pharmacies.”

Illinois retiree Joseph Smith, like many senior citizens, has several chronic health conditions, which he manages with a prescribed drug regimen. Due to his fixed income and limited mobility, Smith likes the convenience of ordering his prescription medications from an online pharmacy. Recently, he found an online site claiming to be based in Canada that sells the pharmaceuticals he needs at a significant discount over similar United States sites. “It’s Canada,” he explains. “Their drug safety regulations are equal to [Food and Drug Administration (FDA)] standards.”

According to a September 2016 poll conducted by the Kaiser Family Foundation, 71% of Americans agree with Smith and favor legislation that would allow them to purchase prescription drugs imported from Canada. This groundswell of support has, in turn, led Senators Bob Casey (D-PA), Bernie Sanders (I-VT), and Cory Booker (D-NJ) to introduce Senate Bill (SB) 469: The Affordable and Safe Prescription Drug Importation Act, which would amend the Federal Food, Drug, and Cosmetic Act and “allow for the importation of affordable and safe prescription drugs from pharmacies located in Canada by US wholesale distributors, pharmacies, and individuals.”

The genesis of this legislation appears firmly rooted in concerns regarding the cost of prescription drugs purchased from store front and online pharmacies based in the US. In a news release to his constituents, Casey wrote, “In Canada and other major countries, the same medications, manufactured by the same companies, in the same factories are available for a fraction of the price compared to the United States. In 2014, Americans spent \$1,112 per person on prescription drugs while Canadians spent \$772 and Danes spent \$325.” Casey further stated that despite record profits accruing for drug manufacturers, “nearly 1 in 3 Americans are unable, at some point in their lives, to afford their prescribed medications.”

NABP, its member boards of pharmacy, and a number of US and Canadian regulatory agencies and pharmacy organizations have warned that the proposed legislation focuses on drug pricing without fully considering the complexities of verifying the national origin and authenticity of websites selling medication online, the implications for patient safety, or the international regulatory quagmire that could result if the bill is passed in its current state.

Real Online Pharmacy? Canadian Pharmacy?

At present, there is no way for consumers to be certain that all websites purporting to be legitimate, Canadian-based pharmacies are in fact based in Canada – or are even pharmacies. The Internet Drug Outlet Identification program, which has reviewed over 11,000 websites selling medications, has found that in 2016, nearly 96% were operating out of compliance with state and federal laws and/or NABP patient safety and pharmacy practice standards.

The Alliance for Safe Online Pharmacies (ASOP Global) estimates that there are between 30,000 to 35,000 online pharmacies operating at any one time, with 20 new illegal online pharmacy sites being launched every day.

Speaking at a program sponsored by the Partnership for Safe Medicines (PSM), NABP Executive Director/Secretary Carmen A. Catizone, MS, RPh, DPh, warned that “illegal internet pharmacies simply slap a maple leaf on their website, but can’t sell products that have been approved in Canada to US patients.”

Apprehension about the risks to patient health and safety posed by the proliferation of unlicensed and unregulated off-shore online pharmacies are not new. As far back as December 2005, a “bait and switch” operation conducted by FDA at New York’s JFK International Airport, examined nearly 4,000 parcels thought to contain pharmaceuticals sent from four countries: Costa Rica, India, Israel, and Vanuatu. Approximately 43% of these drugs had been advertised as being manufactured in Canada and sold by “Canadian” online pharmacies. Only 15% of the “Canadian” drugs examined were actually Canadian in origin.

Then Acting FDA Commissioner Dr Andrew von Eschenbach said, “This operation suggests that drugs ordered from so-called ‘Canadian’ internet sites are not drugs of known safety and efficacy. These results make clear there are internet sites that claim to be ‘Canadian’ that, in fact, are peddling drugs of dubious origin, safety, and efficacy. We believe that these ‘bait and switch’ tactics are misleading to patients and potentially harmful to the public health.”

Canadian Pharmacies Do Not Fill US Prescriptions

Concerns about the proposed bill are not limited to the national origin and/or verification of online Canadian pharmacies. The College of Pharmacists of Manitoba, the Newfoundland and Labrador Pharmacy Board (NLPB), and the National Association of Pharmacy Regulatory Authorities have advised US Congress that Canadian law prohibits Canadian pharmacists from filling prescriptions written by US practitioners. In an April 10, 2017 letter, the Manitoba regulatory authority further notes that Canada’s supply of pharmaceuticals is limited and cannot accommodate the needs of Canadian and US patients.

They also point out that there is no way to effectively monitor and regulate the thousands of pharmacy sites purporting to be based in Canada. “Sending consumers online to look for Health Canada-approved medicines is reckless,” they warn, “as US patients are likely to receive unapproved, substandard and counterfeit drugs from unknown foreign sources, posing a risk to patient safety.”

Importation Bypasses Safeguards

The US drug supply chain is known to be among the safest in the world. The combined efforts of numerous state and federal agencies, pharmaceutical manufacturers, and health care organizations, including NABP and its member boards of pharmacy, strive to protect the nation’s drug supply from such threats as counterfeiting, diversion, and importation of substandard drugs. As proposed, SB 469 could imperil the integrity of this system by allowing consumers to bypass the established safeguards and consequently open the door to counterfeit, substandard, and potentially dangerous products.

Alarmed by the implications for the US drug supply chain and patient safety, Catizone enumerated for the PSM audience the current protective measures that could be circumvented by an enacted SB 469. “Besides FDA oversight, every pharmacy in the United States, whether it is on your corner or a mail order pharmacy, is inspected by state officials, the members of NABP,” he stated. “Every pharmacist, every technician has to be licensed. Those safeguards would be completely undermined by importation.”

Catizone is not alone in his concerns. Several regulatory agencies and organizations, including the Arizona, Kentucky, Louisiana, Oklahoma, Virginia, and West Virginia state boards of pharmacy, the American Pharmacists Association, and former FDA commissioners, have joined NABP in expressing to US Congress their reservations about the provisions of the proposed legislation.

Canadian regulators are also alarmed. In its April 21, 2017 letter to US Congress, the NLPB advised that, “There is currently no

regulatory system, nor any mechanisms or jurisdictional guidelines in place to address how any concerns, complaints, medication errors, or other patient safety issues arising from the proposed method of sale of medications would be handled.”

Signaling their opposition to the bill, ASOP Global and The Pew Charitable Trusts jointly conducted a Capitol Hill briefing regarding “The Security of the Drug Supply Chain, Patient Safety and the Importation of Prescription Drugs from Canada and Other Countries” and other key elements of SB 469.

For several years, the Pew Charitable Trust’s Drug Safety Project has strived to ensure the reliability and safety of the US pharmaceutical manufacturing and distribution system. The unintended consequences of SB 469’s online drug importation provisions encouraged them

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The following sources provide additional information or access to the materials referenced in this article:

SB 469: The Affordable and Safe Prescription Drug Importation Act:

<https://www.congress.gov/bill/115th-congress/senate-bill/469/text>

NLPB’s April 21, 2017, letter to Congress: buysaferx.pharmacy/wp-content/uploads/2017/04/nlpb_letter_to_congress.pdf

College of Pharmacists of Manitoba’s April 10, 2017, letter to Congress: www.safemedicines.org/wp-content/uploads/College-of-Pharmacists-of-Manitoba-Letter-to-Congress.pdf

Leona Aglukkaq’s Washington Post Op-Ed column, May 12, 2017: www.washingtonpost.com/news/global-opinions/wp/2017/05/12/dear-bernie-sanders-canada-is-not-americas-drug-store/?utm_term=.d799b22cfe81

US Senate Committee on Health, Education, Labor and Pensions: www.help.senate.gov/about/members

Where Will You Find Pharmacy Regulation Experts This Fall? At the NABP Interactive Forums!

Save the Date and Join Your Colleagues to Discuss Today's Important Issues

Interactive Executive Officer Forum
October 3-4, 2017

Interactive Compliance Officer and Legal Counsel Forum*
November 29-30, 2017



- Network with colleagues
- Participate in discussions on topics submitted by fellow attendees
- Discover solutions for shared challenges
- No registration fee
- Travel, hotel, and meal expenses paid by NABP
- Held at NABP Headquarters

Executive officers will receive registration information for the Executive Officer Forum in August and the Compliance Officer and Legal Counsel Forum in October. For more information about the forums, contact ExecOffice@nabp.pharmacy.

** One compliance officer and one legal counsel per board may attend at no charge. Prior to the start of the forum, compliance officers will have the opportunity to attend an educational session on compounding facility inspections presented by Food and Drug Administration. This session will begin the afternoon of November 28 and conclude the morning of November 29.*

Proposed Legislation

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to join ASOP Global in presenting the recent briefing.

Dubious Origin of Medications from Online Drug Outlets

With concerns regarding the proposed legislation mounting on both sides of the US-Canadian border, there is one issue that everyone agrees upon – the vast majority of the drugs purchased through websites claiming to be online Canadian pharmacies do not come from Canada.

Speaking at the PSM event, George Karavetsos, former director of FDA's Office of Criminal Investigations, addressed the issue of online drug sites claiming to be licensed Canadian pharmacies. "Let me state this loud and clear," he affirmed, "none of these drugs are coming from Canada. Time and time again, the investigations of the FDA's Office of Criminal Investigations revealed that these drugs were coming from anywhere but Canada."

Leona Aglukkaq, former Canadian Minister of Health from 2008 to 2013, shared these concerns and took them a step further in an op-ed column that appeared in the May 12, 2017 *Washington Post*. She noted that under SB 469, "Canada would simply serve as an intermediate transshipment point for unapproved drugs heading to the US." She also worries that an unintended consequence of the proposed legislation could be a potential worsening of the opioid epidemic that is raging in both the US and Canada.

.Pharmacy Program Supports Patient Safety

Since 1999, NABP has served as a front-line defender in the effort to protect the public from fraudulent online pharmacies purportedly domiciled in the US, beginning with the Verified Internet Pharmacy Practice Sites® (VIPPS®) program and most recently with the .Pharmacy Verified Websites Program. Online pharmacies that apply for and meet the 10 core safety standards for this new program may be identified by the ".pharmacy" addition to their URL. To date, the program includes online pharmacies in both the US and Canada.

NABP encourages all stakeholders to promote the new initiative to the public and to build awareness of the potential danger of indiscriminately buying medications online.

Legislation Status; Member Action Encouraged

At present, SB 469 is in the early stages of Congressional consideration. Sanders introduced the bill on February 28, 2017, at which time it was referred to as the Senate Committee on Health, Education, Labor and Pensions. The state boards of pharmacy and interested individuals are urged to write to members of the Committee and their state senators regarding the dangerous implications for the public health and patient safety posed by SB 469: The Affordable and Safe Prescription Drug Importation Act.

NABP will continue to monitor the progress of this bill and keep its members apprised of developments. For additional information or assistance contacting a member of Congress, please contact NABP Member Relations and Government Affairs via email at GovernmentAffairs@nabp.pharmacy. ■

vTLD Consortium Continues to Engage With Governmental and International Agencies to Encourage Online Safety

NABP and other founding members of the Verified Top-Level Domains (vTLD) Consortium are united in their shared commitment to raise awareness of verified domain name extensions and build consumers' trust on the internet. Since the group's inception, the Consortium has engaged in various efforts to improve universal awareness and recognition of vTLDs by collaborating with various stakeholders and sharing best practices for operating verified domains with governmental agencies. Unlike registry operators of open Top-Level Domains (TLDs) in which anyone can register a domain name, members of the vTLD Consortium have policies in place to verify the eligibility of registrants before they are allowed to activate a website.

Since May 2016, when the *Verified Top Level Domains Consortium Charter* was ratified, the Consortium has been advocating for safer policies online. One way the group does this

is through its involvement with the Internet Corporation for Assigned Names and Numbers (ICANN), a not-for-profit partnership of stakeholders from all over the world dedicated to keeping the internet secure, stable, and interoperable. Specifically, in May 2017, NABP responded to two ICANN working groups' calls for public comments related to consumer trust and subsequent procedures for new generic TLDs. In its comments to ICANN, NABP indicated its support for the creation of a trusted online environment that is free of bad actors and cybercrime.

In March 2017, during the 58th ICANN international conference in Copenhagen, Denmark, NABP and members of the Consortium met with the Public Safety Working Group (PSWG), a subgroup of the ICANN Governmental Advisory Committee composed of law enforcement and national regulators from multiple countries, to discuss best practices for achieving consumer safety

online. NABP also presented to the PSWG and the ICANN community on behalf of the Consortium during the 59th international conference in Johannesburg, South Africa. The Consortium intends to continue its involvement with ICANN at upcoming meetings.

Previously, along with members of the Consortium, NABP met with agents from the United States Department of Justice Computer Crime and Intellectual Property Section in August 2016 and discussed how vTLDs, like .pharmacy, can help keep consumers safe online. NABP also met with agents of the US Drug Enforcement Administration Office of Investigative Technology and Diversion Control Division in November 2016 to discuss .pharmacy and vTLDs.

To learn more about the vTLD Consortium, visit www.vtld.domains. For additional information on NABP's involvement in the Consortium and its efforts to build trust on the internet, contact info@safe.pharmacy. ■

Tri-Regulator Collaborative Approves Two Position Statements on Protecting Public Health

The Tri-Regulator Collaborative, the governing boards of the three organizations representing the state boards that license physicians, nurses, and pharmacists – the Federation of State Medical Boards (FSMB), National Council of State Boards of Nursing (NCSBN), and NABP – has drafted and approved two position statements that highlight the organizations' shared commitment to protecting public health, as well as the common issues faced by the three groups.

The "Tri-Regulator Collaborative Position Statement on Electronic Health Records" (EHRs) calls for improving interoperability and uniformity of use, declaring that the seamless transfer of this data is essential to the delivery of high-quality health care and to patient safety. The multiple systems that comprise today's health care network provide little or no interoperability and present serious concerns for practitioners and regulators. The Collaborative is urging that steps be taken by all

stakeholders to bring uniformity and interoperability to EHRs across all practice settings.

Practitioner wellness is a patient safety issue and is increasingly affecting practitioners in the medical, nursing, and pharmacy professions. In the "Tri-Regulator Collaborative Position Statement on Practitioner Wellness," the Tri-Regulator Collaborative expresses its commitment to identifying and preventing practitioner burnout. Today, knowledge overload, numerous technology innovations, social media pressures, and a rapidly changing practice environment create numerous challenges.

The Collaborative meets periodically to discuss issues of mutual concern, exchange ideas, and share resources to better protect patients and improve the quality of care. In July, members from the three organizations met at the 2017 Tri-Regulator Symposium in Chicago, IL, to discuss current and future opportunities for interprofessional cooperation and collective challenges faced by each group. ■

Prevalence of Rogue Online Pharmacies Pushes Regulators to Raise Awareness, Continue the Fight Against Counterfeits



“With as many as 34,000 illegal online pharmacies active at any moment and more and more consumers turning to the internet for less expensive drugs or to avoid doctors’ appointments, efforts to reduce patient harm from this global threat have been at the forefront for regulators – both in the US and Canada.”

The proliferation of rogue online drug outlets and the increase of counterfeits entering the United States drug supply chain continue to threaten public health. Drug products sent by such sites also exacerbate the opioid epidemic, which has led governors in several states, including Alaska, Arizona, Florida, Maryland, and Virginia, to declare statewide public health emergencies. With as many as 34,000 illegal online pharmacies active at any moment and more and more consumers turning to the internet for less expensive drugs or to avoid doctors’ appointments, efforts to reduce patient harm from this global threat have been at the forefront for regulators – both in the US and Canada.

Uncovering False Canadian Claims

While a consumer may order medicine from what appears to be an online Canadian pharmacy, the product delivered may not be what the consumer ordered. Such rogue online drug outlets market themselves as Canadian internet pharmacies, but sell medications that do not come from Canada and are not approved to sell in Canada or the US.

Health Canada, the federal department responsible for Canadians’ public health, seized almost 5,500 packages of counterfeit drugs, mostly for sexual enhancement (eg, fake Viagra®), on their way into the country between April 2016 and March 2017. Within one week last year, \$2.5 million worth of counterfeit pharmaceuticals – mainly for erectile dysfunction – were seized by Health Canada at the border, reports the National Post in the June 12, 2017 article “Canada fights influx of fake Viagra, as erectile dysfunction creates ‘perfect storm’ for counterfeiters.” These drugs are commonly bought from online drug outlets or social media sites because people do not want to go to their doctors. Pfizer’s North American Director of Global Security, Brian Donnelly, told the National Post, “The problem is significant,” and “I think most people believe that they’re getting something . . . that is approved by Health Canada or approved by [Food and Drug Administration (FDA)].”

Additionally, wholesale quantities of counterfeit prescription drugs entering the US is a growing problem for regulators and law enforcement. For example, US federal prosecutors have accused Kristjan Thorkelson, *CanadaDrugs.com*, and affiliated companies and associates in the United Kingdom and Barbados of illegally importing and selling \$78 million worth of unapproved new drugs, misbranded drugs, and counterfeit drugs to American doctors between 2009 and 2012. Thorkelson is the president and founder of *CanadaDrugs.com*, a Winnipeg-based company.

According to court documents obtained by *CBCNews Manitoba*, Canada Drugs allegedly bought its inventory from questionable sources and sold fake versions of the drugs Altuzan® and Avastin® to US doctors. The fake Avastin was found to contain cornstarch and acetone, and no active ingredients. In addition, Canada Drugs’ UK affiliate, River East Supplies, is accused of falsifying customs documents to hide the product. Further, River East Supplies and several US companies are accused of not keeping

the medications at the cold temperatures required to keep them safe.

Trafficking Opioids Directly to Consumers

Online sales of prescription opioids also continue to be a problem, and have become more alarming with the distribution of dangerous synthetic drugs, such as fentanyl and carfentanil, into the US via international mail. Alliance for Safe Online Pharmacies – Global Executive Director Libby Baney notes that the websites selling these products exploit a global postal system incapable of sufficiently screening the materials within its shipments.

Drugs bought online from the dark web have allowed synthetic opioids, such as fentanyl – the fastest-growing cause of overdoses nationwide – to be delivered to consumers in small packages by mail. Enough fentanyl to get approximately 50,000 people high can fit into a standard first-class envelope, in contrast to heroin and prescription drugs, which are bulky. Although authorities took down Silk Road – the online black market where buyers anonymously used special browsers and bought illegal drugs using virtual currencies like Bitcoin – since 2013, countless dark web markets have emerged, making synthetic opioids readily available to consumers. AlphaBay, the leading dark web market, was recently shut down and seized by the US Department of Justice for selling deadly drugs and other harmful goods for over two years. The investigation revealed that numerous vendors sold fentanyl and heroin, and several overdose deaths across the country have been attributed to purchases on the site.

In yet another scheme, fake prescription drugs made from fentanyl were distributed in Utah and throughout the US to customers who had ordered pills via the dark web. On May 31, 2017, six individuals, including the alleged ringleader, Aaron Shamo, were indicted for their involvement. These individuals purchased pill presses, dyes and stamps to mark pills to match those of legitimate pharmaceutical drugs, and inert pill ingredients, such as binding agents

and colors. Some bulk ingredients were purchased legally and others, such as fentanyl and alprazolam, were imported into the US illegally, including from China. Court documents indicate the enterprise sold hundreds of thousands of pills.

STOP Act

One effort to address such scenarios at the source is bipartisan legislation aimed at stopping dangerous synthetic drugs from being shipped into the US. The Synthetics Trafficking and Overdose Prevention Act (S.372) would require shipments from foreign countries arriving through the postal system to be subject to review by US Customs and Border Protection (CBP), and would require advance electronic information (eg, whom and where it is coming from, who it is going to, and what is in it) before the shipments enter the US.

Registrar-Level Solutions

A February 2017 report released by KnujOn.com, LLC, an independent online abuse handler and internet policy research organization, scrutinized several US registries' and registrars' responses to complaints of domains trafficking opioids online. More than 300 domains selling opioids were analyzed in the report, and approximately 50 different internet companies were contacted directly.

When contacted about internet domains that were promoting illegal activity (eg,

trafficking opioids), numerous US registries and registrars did not investigate, suspend, and/or report the illegal activity to law enforcement. The report, which is available at knujon.com/onlineopioidsUSfeb2017.pdf, further discusses which US-based registry companies had the most opioid domains and which registrars should be considered rogue.

NABP has been addressing the increasing prevalence of rogue online pharmacies at the registry level with the .Pharmacy Verified Websites Program. Part of the Association's motive for launching the .Pharmacy Program was to keep the .pharmacy domain out of the hands of a third party that may turn a blind eye to illegal activities.

As the registry operator for the .pharmacy domain, NABP is committed to ensuring that all businesses seeking a .pharmacy domain for their websites have been verified and hold applicable licenses in the jurisdictions where they are based and where they do business. These sites undergo continual monitoring and must apply for renewal of their domain registrations annually. In addition, NABP thoroughly vets the registrars that service .pharmacy registrants and continually monitors these registrars to ensure that they are adhering to the terms and conditions they agreed to when they became a .pharmacy registrar. ■



Task Force Recommends Amendments to NABP Constitution and Bylaws for International Membership

In response to 2016-2017 NABP President Hal Wand's initiative to strengthen and develop relationships with international member jurisdictions, the Task Force on Expanding International Membership was established. The task force met on November 8-9, 2016, and discussed the differences and commonalities of various international boards of pharmacy as well as the feasibility of allowing international boards to become active members.

The task force members recommended that NABP create a new international membership category that provides international members with rights and privileges to discuss and decide on international matters outside the current requirements of the NABP Constitution and Bylaws for issues regarding licensure transfer, competency assessment, and disciplinary actions. Members indicated that pharmacy regulators around the world have shared purposes and that there is a need for increased global cooperation; the essence and core principles of pharmacy regulation are not unique to any one country or jurisdiction. Currently, there is not one organization that brings them together to share and learn from one another. The members noted that this collaboration is especially important for such matters as competency assessment, discipline, and NABP's

.pharmacy initiative. The internet and other advances in technology have moved regulators from across the world closer together, leading to the realization that pharmacy regulation in one part of the world is likely similar to that in most other parts of the world.

In addition, the task force members recommended that NABP provide for an international member to be included on the NABP Executive Committee to allow for elected representation from jurisdictions outside of the states and territories of the United States who will be eligible to vote on international matters in a manner consistent with existing NABP Constitution and Bylaws. In order to garner input and benefit from international regulatory agencies, the task force determined that the Executive Committee should include representation from international member boards.

The NABP structure, as outlined by the NABP Constitution and Bylaws, only allows for active members and associate member boards. Therefore, the task force members recommended that the Constitution and Bylaws be reviewed and amended to expand international membership and participation within the NABP Executive Committee.

Task force members included Gayle D. Ziegler, RPh; Buford Abeltdt, Sr, RPh; Howard C. Anderson, Jr, RPh;

Malcolm J. Broussard, RPh; Richard Cieslinski, RPh; Bradley Hamilton, RPh; Cathy Lew, RPh; Gene Minton, RPh; Tejal Patel, RPh; Phyllis Stine, BS; Cynthia "Cindy" Warriner, RPh; Richard B. Mazzone, RPh, Executive Committee liaison; and Deeb Eid (Pharmacy Technician Certification Board), guest.

The task force report was accepted by the Executive Committee during its February 2017 meeting, and the proposed international membership amendment set was submitted in accordance with the recommendations of the task force. The Executive Committee continues to support the inclusion and expansion of international members. However, the Executive Committee withdrew the proposed amendment set after the Committee on Constitution and Bylaws convened in April and the notice of the proposed amendments was sent to the boards. The Executive Committee received additional information meriting further review and determined that withdrawing the amendment set will be beneficial and allow the Executive Committee to fully engage the membership and its international counterparts to study this key issue.

The task force report is available in the Publications and Reports section of the NABP website at www.nabp.pharmacy. ■

Task Force Charges

Task Force on Expanding International Membership met on November 8-9, 2016, and accepted the following charges:

1. Review the differences and commonalities of various international boards of pharmacy.
2. Explore the feasibility of allowing international boards to become active members.
3. Recommend, if necessary, amendments to the NABP Constitution and Bylaws for the Committee of Constitution and Bylaws to review.

Biennial NABP Survey Provides Overview of Board of Pharmacy Responsibilities and Actions

The NABP 2017 Resources and Responsibilities Survey results have been compiled, providing board of pharmacy employees and other stakeholders with a high-level overview of how the boards of pharmacy operate and some of their key differences. Conducted by NABP, the biennial survey also delivers insights into current trends and patterns among the Association’s 54 active member boards as they continue their efforts to protect the public health.

As part of the survey, member boards of pharmacy are asked to provide information on a variety of topics, including licensure, inspections, disciplinary activity, budgets and appropriations, emergency preparedness, and support staff. This year, NABP received responses from 42 member boards, resulting in a 78% participation rate.

General Structures and Responsibilities

Of the 42 responding boards, nearly half characterized their organization as “independent” – that is, operating independently of other professional boards, with an executive officer whose primary responsibility is to the board. An additional 19 boards indicated that they were part of an umbrella organization, with an executive officer whose primary responsibility is to the umbrella organization rather than the pharmacy board.

The majority of the responding boards of pharmacy also indicated that they are responsible for multiple licensing and disciplinary functions, either alone or in conjunction with another agency. All 42 responding boards specified that they had sole (36) or shared (6) responsibility for licensure of pharmacists, and sole (38) or shared (4) responsibility for discipline of pharmacists. Most boards also have sole (32) or shared (5) responsibility for licensing pharmacy technicians and disciplining (35 sole, 2 shared) pharmacy technicians. Fewer pharmacy boards reported sole (5)

or shared (11) responsibility for licensure of dispensing prescribers; while only three boards reported sole responsibility for discipline of dispensing practitioners. An additional 19 boards reported sharing this function with another agency.

Survey results also show that boards of pharmacy are typically responsible for handling the license, registration, or permit process for pharmacies and other entities that deal in the manufacture or distribution of prescription medications. As expected, the boards most frequently report having sole responsibility in this area for various types of pharmacies. More than 85% of responding pharmacy boards license or register:

- community pharmacies (35);
- long-term care pharmacies (35);
- infusion/home care pharmacies (35);
- nuclear pharmacies (34);
- sterile compounding pharmacies (34);

- nonsterile compounding (34);
- institutional pharmacies (32); and
- nonresident pharmacies (34).

While not all states issue separate licenses to each category, some states bundle multiple types of pharmacy practice into one license category. Most boards also license or register wholesale distributors and manufacturers, as well as internet pharmacies, veterinary pharmacies, specialty pharmacies, and telepharmacies. Nearly three-quarters of responding boards are also responsible for licensing or registering non-resident wholesale distributors, and more than half have sole responsibility for licensing or registration of reverse distributors.

A majority of the responding boards of pharmacy also indicated that they had sole responsibility for other functions, including:

- setting practice standards;
- evaluating the qualifications of candidates for licensure;

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Board of Pharmacy Responsibilities		
Function	Sole Responsibility of Boards	Shared Responsibility With Umbrella or Other Agency
Discipline of pharmacists	38	4
Licensure of pharmacists	36	6
Discipline of pharmacy technicians	35	2
Licensure of pharmacy interns	34	5
Discipline of pharmacy interns	34	3
Holds disciplinary hearings	34	6
Determines penalties	34	7
Evaluates qualifications of candidates for licensure	33	7
Makes final determination whether law/regulation violated	33	7
Licensure of pharmacy technicians	32	5
Sets practice standards	32	4
Receives complaints	30	8
Conducts investigations	29	9
Rulemaking	28	11
Issues examination scores	24	6
Administers examinations	18	7
Issues controlled substances licenses to pharmacy licensees	14	7
Issues controlled substances licenses to nonpharmacy licensees	11	9
Licensure of dispensing prescribers	5	11
Discipline of dispensing prescribers	3	19

The table above represents a select portion of reported board of pharmacy responsibilities. A total of 42, or 78% of active member boards, participated in the survey; however, not all 42 boards provided responses to every question.

Resources and Responsibilities Survey

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- making a final determination whether a law or regulation has been violated;
- determining penalties; and
- holding disciplinary hearings.

More than half the boards reported sole responsibility for conducting investigations, receiving complaints, and rulemaking. Some boards also issue examination scores or administer examinations.

Due to the continued opioid abuse and overdose epidemic, a continuing priority in many states is working to prevent abuse and diversion of prescription drugs. This priority can be seen in some of the other duties the boards of pharmacy report carrying out. Of the responding boards,

- 19 have sole responsibility for their state's prescription monitoring program;
- 27 boards have responsibility to enforce their state's wholesale drug distribution licensing act; and
- 13 boards enforce their state's methamphetamine precursor control act.

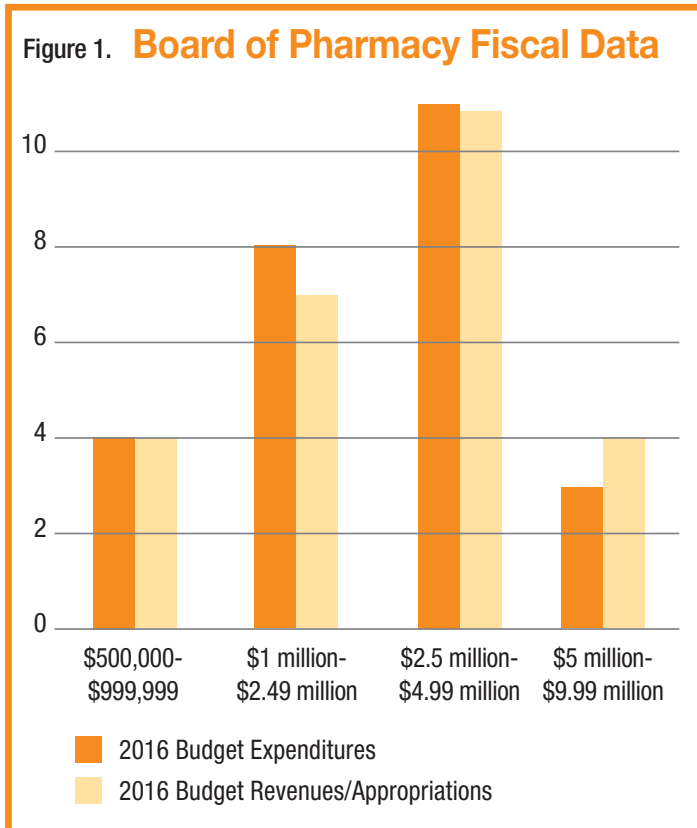
Slightly less than half of the responding boards (18) indicated that enforcement of the state controlled substances act (CSA) fell solely under board purview. Responsibility for the federal CSA falls to fewer boards, with 15 having sole responsibility. Fourteen boards reported issuing controlled substances (CS) licenses to pharmacy licensees, while 11 issue CS licenses to non-pharmacy licensees. Processing renewals of CS licenses, meanwhile, was the sole responsibility of 13 pharmacy boards for pharmacy licensees and 12 boards for non-pharmacy licensees.

Boards without sole responsibility for a licensing or disciplinary function often share that responsibility with an umbrella or other agency. The most commonly shared functions, according to survey respondents, include receiving complaints, conducting investigations, and issuing examination scores.

About 72% of 39 responding boards reported having a preparedness or response plan for external events or circumstances that would prevent the board from performing normal activities. Approximately two-thirds reported having a preparedness or response plan for internal disasters or emergencies that would similarly impair the board.

Fiscal Information

Thirty-seven boards provided information on the fiscal functions they perform. Of the responding boards, 78% reported that they are responsible for one or more of the following:



Twenty-six boards provided information on their 2016 budgets, expenditures, and revenues/appropriations. Of those 26 states, the most common range was between \$1 million and \$5 million for both 2016 budgets, expenditures, and budgeted revenues/appropriates.

- developing the board of pharmacy's budget (24)
- setting fines (29) and fees (24)
- collecting fines (25) and fees (27)
- making purchasing decisions (25)

Only 18 of the responding boards reported processing accounts payable and receivable. The remaining 19 respondents reported the responsibility falling to an umbrella agency, as was the case for most fiscal functions not fulfilled by the board. Some other boards report that such functions are handled jointly by both the board and another agency.

Of the 37 boards responding to the question, all but two have the ability to impose fines for infractions of laws or regulations. The maximum fine amount that boards could levy starts at \$500 per violation, with some states imposing no limit. Fifteen respondents reported that other state agencies (such as the state department of health, state attorney's office, or drug control agency) could impose fines for infractions of pharmacy or wholesale drug distributor laws or regulations; 60% reported that other agencies could not impose such fines. About 54% of 37 responding boards reported that their budget was fixed by legislative appropriation, a slight increase from 2015; 46% reported that the budget was not fixed. Twenty-six

boards provided information on their 2016 budgeted expenditures and appropriations. Of these,

- 4 boards reported budgeted expenditures under \$1 million,
- 19 boards reported budgeted expenditures between \$1 million and \$5 million, and
- 3 boards reported budgeted expenditures over \$5 million.

Twenty-two states provided details on their revenue sources. Of these, 18 states reported that anywhere from 60% to 100% of their budgeted revenues derived from permit or license fees, with more than half reporting 97% to 100% of their budgeted revenue came from this source. Other common revenue sources include examination and reciprocity fees, fines, and state appropriations. Of 36 responding boards, 72.2% reported that revenues were utilized by the board itself; about 8% reported that revenues were utilized by the state government or legislature.

Board of Pharmacy and Support Staff

The number of support staff utilized by boards of pharmacy varies widely, with the largest support staff comprised of 77, and three support staff for the smallest. Almost all reporting boards have a full-time executive officer (31 of 35), with four boards reporting an executive director assigned to the board less than full time. Nearly 95% of responding boards reported that they have administrative staff other than an executive officer or inspectors:

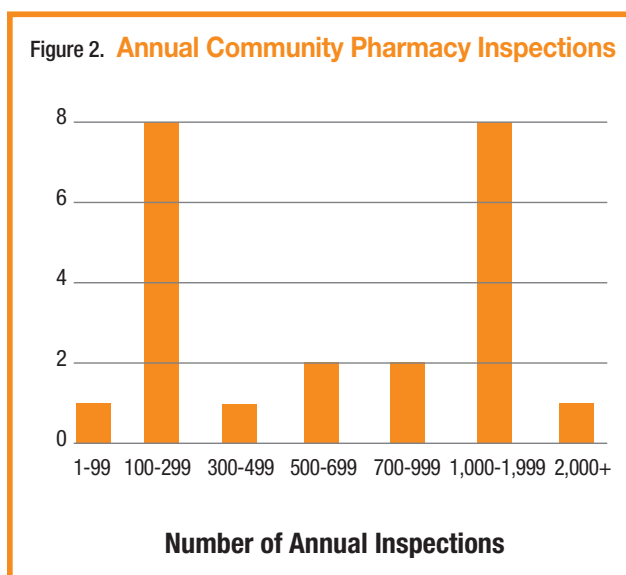
- 6 boards reported between one and four full-time support staff members;
- 13 boards reported between five and 10 full-time staff; and
- 8 boards reported 11 or more full-time staff.

Eight boards indicated that at least one of these support staff serves as an information technology specialist. Of 35 responding boards, most indicated that executive officers (34), board administrative staff (35), and inspectors (32) are eligible for state employment benefits.

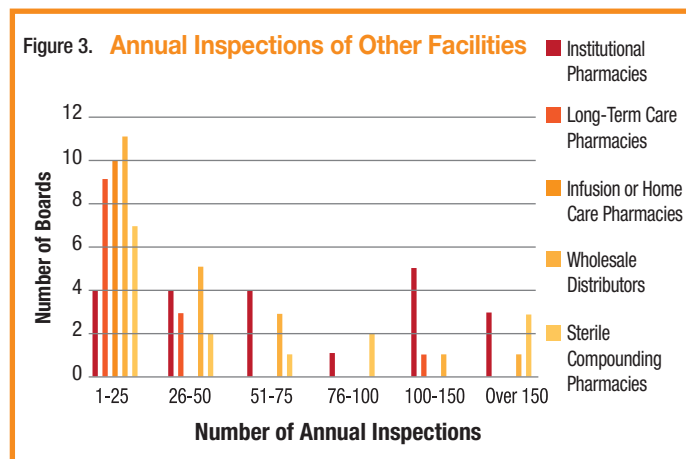
Benefits are most likely to include health insurance for self and family, life insurance, and a retirement plan with both employee and (somewhat less commonly) state contributions.

Disability insurance is also common, and reimbursement of traveling expenses is offered by nearly every state. Fourteen states indicated that inspectors have access to a state car or receive a car allowance to carry out inspections.

Of 34 responding boards, only three indicated that board of pharmacy members receive no compensation for their participation on the board. Most states provide at least some compensation to board members, most commonly in the form of per diem or per meeting payment, and in some cases travel or lodging reimbursement. Reported per diem rates vary from about \$30 to \$200. One state reported that board members also receive \$100 per month.



Two boards noted that they do not have separate categories for pharmacies and they inspected 915 and 1,074 pharmacies in 2016. These numbers are not reflected in Figure 2.



Inspectors and Inspections

The survey also sought details from the boards of pharmacy regarding their inspection functions. Of 33 responding boards, all reported having at least one full-time or full-time equivalent (FTE) inspector.

- 21% (7) reported having between one and three full-time or FTE inspectors supporting the board of pharmacy;
- 42% (14) reported having between four and six; and
- 36% (12) reported having seven or more.

Twenty-one boards reported that at least some inspectors are employed directly by the board of pharmacy, 12 boards

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Resources and Responsibilities Survey

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indicated that some inspectors are employed by an umbrella agency, and four boards stated that some were employed by another state agency. One board indicated that it also contracts with a private investigator to perform inspections.

Thirteen boards, or 37.1% of respondents, reported that they are legally required to hire pharmacists as inspectors; 22 boards (62.9%) were not. Twenty-nine of 34 responding boards, however, have one or more inspectors who are pharmacists.

Reflecting continuing concerns about compounding oversight, all 34 responding boards reported that their inspectors have training in pharmaceutical sterile and pharmaceutical nonsterile compounding. Less than 20% (6) of boards reported that their inspectors have training in current Good Manufacturing Practices.

Nine boards reported that they have one or more inspectors who are commissioned peace officers. Nearly a quarter of responding boards (8) stated that their inspectors are authorized by the state

to bear arms; though only four boards indicated that any of their inspectors do so.

Twenty-eight boards, or 82.4% of respondents, reported having procedures in place to monitor the effectiveness of their inspectors' field work; six boards (17.6%) do not. Monitoring methods include review of inspection reports and data, regular reports and/or quality reviews, and ride-alongs. Thirty-one boards provided details on the number of inspections performed in a typical year, though these numbers vary widely. For example, boards report performing from a low of zero to a high of 3,640 inspections of community pharmacies.

Reported numbers of institutional pharmacy inspections ranged from 0 to 386, long-term care pharmacy inspections ranged from 0 to 50, and infusion or home-care pharmacy inspections ranged from 0 to 30. Boards reported that they or their agency performed from 0 to 400 inspections of wholesale distributors.

A comprehensive report of the survey results will be provided to member boards of pharmacy executive officers in the third quarter of 2017. Any questions may be directed to NABP at ExecOffice@nabp.pharmacy. ■



Newly Accredited VAWD Facilities

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

**Cardinal Health 200, LLC, dba
Cardinal Health**
Solon, OH

**Central Admixture Pharmacy
Services, Inc**
Allentown, PA

Community Blood Center
Dayton, OH

Covidien Sales, LLC
Atlanta, GA

**Fisher Scientific Company,
LLC, dba Fisher Scientific and
Fisher Healthcare**
Chino, CA
Santa Clara, CA
Suwanee, GA

**HF Acquisition Co, LLC, dba
HealthFirst**
Mukilteo, WA

HLS Therapeutics (USA), Inc
Rosemont, PA

**Medline Industries, Inc, dba
Medline Industries**
Tracy, CA

**Priority Healthcare
Distribution, Inc, dba
CuraScript SD Specialty
Distribution**
Tempe, AZ

Smith Medical Partners, LLC
Carol Stream, IL

**The North Carolina Mutual
Wholesale Drug Company**
Durham, NC

**UPS Supply Chain Solutions,
Inc**
Louisville, KY

**Valley Wholesale Drug Co,
LLC**
Stockton, CA

A full listing of more than 580 accredited VAWD facilities is available on the NABP website at www.nabp.pharmacy.

NABP Returns to Renovated Headquarters

Reconfigured Floor Plan Addresses Members' Needs, Future Growth

NABP returned to its renovated headquarters in Mount Prospect, IL, in May 2017. Purchased by the Association in 2003, the one-story, 57,150-square-foot building was reconfigured and updated to 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 host more of its regularly scheduled meetings on site throughout the year; four furnished workspaces for use by visiting members and off-site staff; a larger cafe; and ecologically friendly features such as updated water fountains and a skylight.

The redesigned building also provides 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, and the specialty pharmacy accreditation program, which is anticipated to begin accepting applications in the fourth quarter of 2017.

In planning the renovation, staff analyzed various options to accommodate future changes and determined that renovating was the most cost-effective solution and use of NABP resources. After review and further analysis, the NABP Executive Committee approved the plan. During the renovation, NABP's staff worked in a leased building situated near the Association's headquarters. ■



NABP's newly renovated headquarters in Mount Prospect, IL, features larger meeting rooms and space for additional staff that may be needed to support existing and future Association programs and services.

NABP Receives Award for Newsletter Redesign

NABP received a 2017 EXCEL Award during Association Media & Publishing's (AM&P's) 37th Annual EXCEL Awards Gala, held June 26, 2017, at the DoubleTree by Hilton Hotel Washington, DC – Crystal City in Arlington, VA. AM&P's prestigious EXCEL Award program recognizes excellence and leadership in nonprofit association media, publishing, marketing, and communications.

NABP received the honor in the Newsletters: Redesign (Print) category for the redesign of its newsletter, *Innovations*. NABP received the Bronze award level.

AM&P's 2017 EXCEL Awards program drew nearly 830 entries in seven broad categories ranging from digital

publishing and magazines to books and promotional campaigns. Of those, the judges selected 235 entries to receive EXCEL Awards. During the Awards Gala, AM&P announced the award levels for each of the awards (Gold, Silver, and Bronze).

The 2017 EXCEL Award winners will be featured in the July/August issue of AM&P's *Signature* magazine. ■



Utah 2017 Legislature Passes Pharmacy-Related Bills

The Utah State Legislature passed the following pharmacy-related bills in its 2017 General Session:

- House Bill 61: Pharmacy Service for Discharged Hospital Patients allows a hospital pharmacy to dispense a limited supply of a prescription drug to a discharged patient under certain circumstances when the patient's regular retail pharmacy is not available, and requires the Utah Division of Occupational and Professional Licensing to make rules.
- Senate Bill 246 1 Sub: Pharmacy Practice Act Amendments amends the Pharmacy Practice Act. Specifically, it requires certain Utah-licensed nonresident pharmacies to submit to an inspection as a prerequisite for licensure, excludes drugs administered under certain conditions from certain drug-container labeling requirements, and permits certain pharmacists to administer long-acting injectable drugs intramuscularly under certain conditions. The bill also makes technical changes.

For additional details about these legislative changes, visit the May 2017 *Utah Board of Pharmacy Newsletter*, available in the Boards of Pharmacy section of the NABP website at www.nabp.pharmacy.

Oregon Introduces Online Pharmacist-in-Charge Change Forms

The Oregon State Board of Pharmacy is no longer accepting emailed, mailed, or faxed pharmacist-in-charge (PIC) change forms. Reporting of a PIC change must be done via online submission. Oregon is one of the few states to offer an online submission form for incoming and outgoing change of PICs. Previously, these forms were filled out and then mailed, emailed, or faxed. The online form went live in early March 2017 and is available on the Board website at www.oregon.gov/pharmacy/Pages/index.aspx, under the Forms tab.

Delaware Opioid Analgesics Prescribing Regulations Take Effect

Safe prescribing of opioid analgesics regulations went into effect in Delaware on April 1, 2017. The following materials explain the new regulations and why they were developed:

- Letter from David Mangler, Delaware Division of Professional Regulation (DPR) director, available at http://dprfiles.delaware.gov/controlledsubstances/Safe_Opiate_Prescribing_Letter.pdf, which explains new resources available to prescribers, as well as specific prescribing information. The letter also clarifies that with the new opioid prescribing regulations, there will more likely be prescriptions for more than a seven-day supply for acute instances. These regulations place no requirements on pharmacists beyond what a pharmacist's role has always been in filling prescriptions. The regulations allow a practitioner to write prescriptions for less than a seven-day supply, without taking any further action. A supply greater than seven days, either in the initial prescription or by subsequent prescriptions, requires additional actions by the practitioner.
- Delaware Prescription Opioid Guidelines for Health Care Providers, available at http://dprfiles.delaware.gov/controlledsubstances/Prescription_Opioid_Fact_Sheet-Providers.pdf.
- Delaware Prescription Opioid Guidelines for Patients, available at http://dprfiles.delaware.gov/controlledsubstances/Prescription_Opioid_Fact_Sheet-Patients.pdf.
- Full text of the regulations, available at <http://dprfiles.delaware.gov/controlledsubstances/20-DE-Reg-564-01-01-17.pdf>.

The above materials are also available on the DPR Controlled Substances website at www.dpr.delaware.gov/boards/controlledsubstances.

Ohio Authorizes Dispensing of Multiple Simultaneous Refills on Prescriptions

As of April 6, 2017, Section 4729.40 of the Ohio Revised Code authorizes a pharmacist who is filling or refilling a prescription that has one or more refills to dispense the drug in a quantity or amount that varies from the quantity or amount that would otherwise be dispensed. This authority is contingent on meeting conditions specified in the law, including conditions concerning the quantity or amount that may be dispensed and the type of drug prescribed. For more information on this law, visit www.pharmacy.ohio.gov/MultipleRefills. ■

Newsletters of state boards participating in the NABP State Newsletter Program are available on the NABP website. Five years' worth of issues are posted on each state's page.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at www.ama-assn.org/opioids-disposal. Options for disposing of medications safely are available in the Initiatives section of the NABP website at www.nabp.pharmacy under AWAR_xE®.

New CDC Guide Shows Link Between Physicians and Pharmacists Working Together to Improve Patient Outcomes

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and the AMA. The guide, *Creating Community-Clinical Linkages Between Community Pharmacists and Physicians*, discusses the importance of community-clinical linkages specific to community pharmacists and physicians, and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians, and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhdsppubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for

themselves. The definition of self-care that this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report demonstrates that pharmacists can provide valuable assistance in the goal of personal wellness through self-directed and pharmacist-assisted education and medication. The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch. ■



INNOVATIONS

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UPCOMING EVENTS

NABP/AACP Districts 1 & 2 Meeting

September 14-16, 2017
Groton, CT

NABP Interactive Executive Officer Forum

October 3-4, 2017
NABP Headquarters

NABP/AACP Districts 6, 7, and 8 Meeting

October 8-11, 2017
San Antonio, TX

NABP/AACP District 4 Meeting

November 1-3, 2017
Toledo, OH

NABP Interactive Compliance Officer and Legal Counsel Forum

November 29-30, 2017
NABP Headquarters