



Delaware State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Pharmacy Issues

Letter From the Board – Change of PIC

The Delaware State Board of Pharmacy has received a number of inquiries as to when a replacement pharmacist-in-charge (PIC) must be reported to the Board. The information below was taken from the Board Regulations. Section 3.1 of the Board's [Rules and Regulations](#) explains the requirements and responsibilities of the PIC. One of these requirements is that a new PIC who has never been a PIC in Delaware must appear before the Board for an interview. In addition, the PIC of a Delaware-licensed community pharmacy must complete a PIC self-inspection report within 30 days of first being designated as PIC, and by February 1 of each year while continuing as the PIC.

When a PIC of a Delaware pharmacy leaves his or her position, notify the Board office using the [Report of Pharmacist-in-Charge Change form](#) within 10 days (Section 3.1.2.6). The incoming PIC must sign the form to acknowledge his or her new responsibilities. In addition, the present (outgoing) and prospective (incoming) PICs must inventory all medications covered under 16 Del. C., Chapter 47. The Delaware Office of Controlled Substance (OCS) recommends that the incoming and outgoing PICs take the inventory at the same time, either at the start or the close of the business day. Forward a copy of this inventory to the attention of OCS in the Division of Professional Regulation. Retain another copy on the premises for a period of at least two years. The inventory must include the name and address of the registrant, the registrant's Drug Enforcement Administration number, the date and time that the inventory was completed, and the names of the pharmacists performing the inventory.

Title 24 §2545 Penalties states,

The Board may suspend or revoke a permit to operate a pharmaceutical establishment if the permit holder violated federal law or any state's law, any of the conditions of the permit, or any of the rules or regulations adopted by the Board relating to the operation of a pharmaceutical establishment. The Board may impose an administrative penalty of not more than \$50 for each day a violation occurs and/or continues

to occur . . . A person who commits the offense of operating a pharmaceutical establishment without a permit may be fined not more than \$50 for each day that the offense occurs and/or continues to occur.

PIC Board Review Request Process

The Board regulations require all new PICs or consultant pharmacists to attend an interview conducted by the Board. To request an interview, send the Board a written request at least 10 days prior to the next meeting. Include in your request your full name, the name of the pharmacy, and the address of the pharmacy. You can send this request by email to customerservice.dpr@state.de.us or via fax to 302/739-2711 to the attention of the Board. Your request will be added to the next available agenda.

Immunizing Pharmacist Requirements

In order to be an immunizing pharmacist in Delaware, the following educational requirements must be met per **Regulation 14.1 Educational Requirements:**

14.1.1 In order to administer injectable medications, biologicals, and adult immunizations a licensed pharmacist, a registered intern or a pharmacy student shall complete a Board approved academic and hands-on practical curriculum and maintain a current Cardio-Pulmonary Resuscitation (CPR) certificate acceptable to the Board of Pharmacy. CPR certification cannot be obtained through an on-line course.

14.1.1.1 An approved academic and practical curriculum includes, but is not limited to, disease epidemiology, vaccine characteristics, injection technique, emergency response to adverse events, and related topics.

14.1.1.2 Pharmacists successfully completing the above education and practical training shall notify the Board. The Board will record the successful training in Board database systems.

You must provide the Board a copy of the certificate of completion of the immunization program attended as well as a current copy of the hands-on CPR certificate in order to be recognized as an immunizing pharmacist in Delaware. In

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.Pharmacy Domain Signals Safety on the Web



With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: *www.safe.pharmacy*. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply*.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting *www.ismp.org*. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at *www.ismp.org*. Email: *ismpinfo@ismp.org*.*

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

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®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

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 AMA. The guide,

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

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/dhbsp/pubs/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 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 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.

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.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide*, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

addition, continuing education requirements for immunizing pharmacists must be completed as required in **Regulation 14.1.3 Continued competency shall be maintained and available for Board inspection:**

14.1.3.1 A minimum of two hours (0.2 C.E.U.) of the thirty hour requirement for continuing education for licensed pharmacists, every licensure period, must be dedicated to this area of practice.

14.1.3.2 A minimum of two hours of continuing education every two years for registered interns and pharmacy students must be dedicated to this area of practice.

If your current pharmacist license does **not** indicate “immunizing pharmacist,” you are not approved through the Board as such.

Rules and Regulations Changes to 1.4.1, 1.2.4, 17.0, and 5.1.7 – Effective June 11, 2017

Pursuant to 24 Del. C., Section 2506(a)(1), the following regulations changes took effect on June 11, 2017.

- ◆ **Subsection 1.4.1** adds the requirement that all licensees must complete two hours of continuing education in 1) the distribution, dispensing, or delivery of controlled substances, or 2) the detection and recognition of symptoms, patterns of behavior, or other characteristics of impairment and dependency resulting from the abusive or illegal use of controlled substances.
- ◆ **Subsection 1.2.4** has been revised to reflect new North American Pharmacist Licensure Examination® requirements for taking the licensure examination.
- ◆ The list of crimes substantially related to the practice of pharmacy, set forth in **Section 17.0**, has been updated to include amendments to the Uniform Controlled Substances Act.
- ◆ **Subsection 5.1.7**, pertaining to compounded medications for office use, has been revised to delineate standards for both human use and animal use. The proposed changes allow veterinarians to administer and dispense compounded preparations for animal patients subject to certain specified requirements.

Newly Licensed Pharmacists

80 Issued From April 1, 2017, to September 30, 2017

Veronica A. Crowder – A1-0005060; Juliette M. Fombi – A1-0005061; Meghan L. Schoenemann – A1-0005062; Nancy E. Mcilvaine – A1-0005063; Amy Susan Howard – A1-0005064; Nathalie R. Jones – A1-0005065; Hemang K. Shah – A1-0005066; Lauren A. Schmucker – A1-0005067; Agnes K. Sweileh – A1-0005068; Sohee Chang – A1-0005069; Luigi Anthony Mollichelli – A1-0005070; Philip P. Bruno – A1-0005071; Olubukola O. Akinwekomi – A1-0005072; Daniel John Desch – A1-0005073; Sarah E. Stieven – A1-0005074; Yassin Ahmed Nuru – A1-0005075; Irene Marie Lee – A1-0005076; Evelyn O. Fisher – A1-0005077; Yesha S. Amin – A1-0005078; Yong Eun Song – A1-0005079; Kailey E. Troutman – A1-0005080; Colleen J. Whyte – A1-0005081; Taryn L. Hinners – A1-

0005082; Ross Michael Broton – A1-0005083; Justin G. Simpkins – A1-0005084; Camyn H. Perry – A1-0005085; Rachel M. Lynch – A1-0005086; Tijo Jose Aikara – A1-0005087; Oyenike O. Adegoke – A1-0005088; Eric L. Souder – A1-0005089; Priya Panchal – A1-0005090; Kristen Michele Audley – A1-0005091; Christopher J. Cook – A1-0005092; Richard Taylor Mearhoff – A1-0005093; Michael Adolph Beyer – A1-0005094; Ashley Ward Robold – A1-0005095; Kara Elizabeth Anderson – A1-0005096; Samil Jagdishkumar Patel – A1-0005097; William Eli Mattioli – A1-0005098; Maria Fidelis Ilagan Romero – A1-0005099; Indira Beepin Jamnadas – A1-0005100; Willis M. Richardson – A1-0005101; Quynh Ngoc Vu – A1-0005102; Donna M. Rothrock – A1-0005103; Chukwuka S. Dimonye – A1-0005104; Jincy Philip – A1-0005105; Caryn Patricia Robinson – A1-0005106; Stephen Nicholas May – A1-0005107; Khiem Thien Huynh – A1-0005108; Gerald L. Knepp – A1-0005109; Patrick Mensah – A1-0005110; Jamie S. John – A1-0005111; Mason Henry Bucklin – A1-0005112; Ann Lee – A1-0005113; Eugene T. Kwachuh – A1-0005114; James Stanley Young – A1-0005115; Daoud Yousri Tawfik Daoud – A1-0005116; Amanda Rae Lehmann – A1-0005117; Hong A. Kim – A1-0005118; Jordyn C. Loy – A1-0005119; Alison E. Bukowitz – A1-0005120; Tam Bao Nguyen – A1-0005121; Shannon M. Adams – A1-0005122; Ejike Chukwukere – A1-0005123; Khoa Anh Bui – A1-0005124; Kinjal Mehul Desai – A1-0005125; Parth Jagdishbhai Patel – A1-0005126; Ikenna Anyanwu – A1-0005127; Elena Stambone – A1-0005128; Katherine Marie Lurk – A1-0005129; Alexander Scott Bimson – A1-0005130; Nguyet Anh Le – A1-0005131; Chioma Sandra Aigbedo – A1-0005132; Sara El-Baff – A1-0005133; Sean William Wolf – A1-0005134; Catherine Ronalder – A1-0005135; Maria del C. Chaar – A1-0005136; Michelle Sebok – A1-0005137; Rebecca C. Gordon – A1-0005138; Crystal R. Schnur – A1-0005139; Jessica Paulistin Marcelin – A7-0002451; Jagdishkumar N. Rabadia – A7-0002452; Reeves M. Ade – A7-0002453; Nitesh Ramanlal Darji – A7-0002454; Linda M. Hendrickson – A7-0002455; Victoria M. Urban – A7-0002456; Phuong Minh Nguyen – A7-0002457; Yunju Lee – A7-0002458; Shelby Chan – A7-0002459; Kayla M. Jones – A7-0002460; Dania Demashkieh – A7-0002461; Melissa Anh Dang – A7-0002462; Elizabeth M. Gleeson – A7-0002463; Jeel Dilipkumar Shah – A7-0002464; Gregory C. Hayes – A7-0002465; Shahrzad Barzin – A7-0002466; Amanda C. Sember – A7-0002467; Katherine Michelle Gibison – A7-0002468; Nguyet Anh Le – A7-0002469; Samil Jagdishkumar Patel – A7-0002470; Darshil D. Patel – A7-0002471; Todd Holden – A7-0002472

Distributor Permits

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FFF Enterprises, Inc – A4-0000244; ALK-Abello, Inc – A4-0001682; Bound Tree Medical, LLC – A4-0001925; Reliable Pharmaceutical Returns, LLC – A4-0002318; Nielsen BioSciences, Inc – A4-0002378; Imprimis NJOF,

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LLC – A4-0002399; Mallinckrodt Nuclear Medicine, LLC – A4-0002400; Cambridge Therapeutic Technologies, LLC – A4-0002401; TAGI Pharma, Inc – A4-0002403; Delhaize America Distribution, LLC – A4-0002404; Huvepharma, Inc – A4-0002405; Wholesalers Group, Inc – A4-0002406; Diamond Pharmacy Services – A4-0002407; Qualanex, LLC – A4-0002408; AstraZeneca Pharmaceuticals, LP – A4-0002409; AmerisourceBergen Drug Corporation – A4-0002410; McKesson Corporation dba McKesson Drug Company – A4-0002411; Rochester Drug Co-Operative, Inc, dba RDC – A4-0002412; PCCA – A4-0002413; Top Quality Manufacturing, Inc – A4-0002414; Glenmark Pharmaceuticals, Inc, USA – A4-0002415; PI Services, LLC – A4-0002416; Southern Anesthesia & Surgical, Inc – A4-0002417; Southern Anesthesia & Surgical, Inc – A4-0002418; The Procter & Gamble Distributing, LLC – A4-0002419; Patterson Medical Supply, Inc – A4-0002420; The Hibbert Group – A4-0002421; ICU Medical Sales, Inc – A4-0002422; Marnel Pharmaceuticals, LLC – A4-0002423; Upsher-Smith Laboratories, LLC – A4-0002424; RxC Acquisition Company – A4-0002425; Golden State Medical Supply, Inc – A4-0002426; Golden State Medical Supply, Inc – A4-0002427; FedEx Supply Chain, Inc – A4-0002429; Athenex Pharma Solutions, LLC – A4-0002430; ICU Medical Sales, Inc – A4-0002431; Granules

Pharmaceuticals, Inc – A4-0002432; Owens & Minor Distribution, Inc – A4-0002433; DermaRite Industries, LLC – A4-0002434; Foundation Care, LLC – A4-0002436; Global Pharmacy Wholesale – A4-0002437; Unit Dose Solutions, Inc – A4-0002439; Mercer Medical, LLC – A4-0002440; Marlex Pharmaceuticals, Inc – A4-0002441; Epic Pharma, LLC – A4-0002442; Emes 2 Pharmaceuticals, LLC – A4-0002443

In-State Pharmacy Permits

Four Issued From April 1, 2017, to September 30, 2017

Community, A Walgreens Pharmacy #16532 – A3-0001010; Weis Pharmacy #271 – A3-0001011; Careplus Pharmacy – A3-0001012; Saveway Compounding Pharmacy, Inc – A3-0001013

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