



Delaware State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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<http://dpr.delaware.gov/boards/pharmacy/index.shtml>

Pharmacy Issues

Letter From the Board

It has been brought to the attention of the Delaware State Board of Pharmacy that there have been cases where pharmacists have become accusatory with patients who are under the care of multiple prescribers concerning valid prescriptions for controlled substances (CS).

Because of the pressure to prevent the abuse of CS, pharmacists have become skeptical of some patients who have valid CS prescriptions. In such cases, attempts should be made to contact the prescribing practitioner and check the prescription monitoring program to ensure the patient under the care of multiple prescribers is not receiving multiple CS prescriptions that may lead to a drug reaction or be injurious to the patient. Of course, the final decision should be based on a pharmacist's professional judgment, with consideration of providing a temporary supply if the prescriber cannot be contacted in a timely fashion. At all times, patients should be treated with dignity, even patients with what seem to be suspicious intentions. Pharmacists should avoid accusatory insinuations that are unfavorable toward good patient care.

Pharmacy Technician Support Regulation 3.8

The Board has received several inquiries regarding the regulation changes that affected required pharmacy technician coverage. The regulation holds the pharmacy permit holder accountable for Pharmacy Regulation 3.8, which states:

Technician Support. The pharmacy permit holder shall ensure that, at all times that the pharmacy department is open for business, there shall be at least one fully trained technician immediately available in the facility to assist in the pharmacy at the pharmacist's request. A schedule of technician support shall be readily available to the pharmacists at all times.

Practitioner Self-Treatment or Treatment of Immediate Family Members

The Board sometimes receives calls from pharmacists regarding practitioner self-treatment or treatment of immediate family members. The following is from the American Medical Association *Code of Medical Ethics*, Opinion 8.19, regarding this issue:

Physicians generally should not treat themselves or members of their immediate families. Professional objectivity may be compromised when an immediate family member or the physician is the patient; the physician's personal feelings may unduly influence his or her professional medical judgment,

thereby interfering with the care being delivered. Physicians may fail to probe sensitive areas when taking the medical history or may fail to perform intimate parts of the physical examination. Similarly, patients may feel uncomfortable disclosing sensitive information or undergoing an intimate examination when the physician is an immediate family member. This discomfort is particularly the case when the patient is a minor child, and sensitive or intimate care should especially be avoided for such patients. When treating themselves or immediate family members, physicians may be inclined to treat problems that are beyond their expertise or training. If tensions develop in a physician's professional relationship with a family member, perhaps as a result of a negative medical outcome, such difficulties may be carried over into the family member's personal relationship with the physician.

Concerns regarding patient autonomy and informed consent are also relevant when physicians attempt to treat members of their immediate family. Family members may be reluctant to state their preference for another physician or decline a recommendation for fear of offending the physician. In particular, minor children will generally not feel free to refuse care from their parents. Likewise, physicians may feel obligated to provide care to immediate family members even if they feel uncomfortable providing care.

It would not always be inappropriate to undertake self-treatment or treatment of immediate family members. In emergency settings or isolated settings where there is no other qualified physician available, physicians should not hesitate to treat themselves or family members until another physician becomes available. In addition, while physicians should not serve as a primary or regular care provider for immediate family members, there are situations in which routine care is acceptable for short-term, minor problems. Except in emergencies, it is not appropriate for physicians to write prescriptions for controlled substances for themselves or immediate family members.

When faced with the above issue, pharmacists should speak to the practitioner about their concerns, focusing on the patient's care. While it is difficult to confront other health care professionals about their prescribing, patient safety is paramount.

DEA Changes Registration Renewal Process

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

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

- ◆ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- ◆ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- ◆ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

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

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

 *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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the

ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacap/Index.asp>.

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf.

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

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcphp.net>.

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

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

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

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

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed

to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at www.ptcb.org in the News Room section.

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

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

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

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

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

Controlled Substance Issues CS Regulation Amendments

Safe Prescribing of Opioid Analgesics regulations went into effect on April 1, 2017. To understand the new regulations and why they were developed, please review the following materials:

- ◆ Letter from David Mangler, director, Delaware Division of Professional Regulation, at <http://tinyurl.com/prescribeltr>, 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 virtue of subsequent prescriptions, requires additional actions by the practitioner.
- ◆ Delaware Prescription Opioid Guidelines for Health Care Providers at <http://tinyurl.com/providerfacts>
- ◆ Delaware Prescription Opioid Guidelines for Patients at <http://tinyurl.com/patientfacts>
- ◆ Full text of the regulations at <http://tinyurl.com/opioidregs>

The above materials are also available on the Division of Professional Regulation's CS website at <http://dpr.delaware.gov/boards/controlledsubstances/index.shtml>.

Newly Licensed Pharmacists

51 Issued From October 1, 2016, to March 31, 2017

Bragadeesh R. Iyer – A1-0005009; Dwan Dalton – A1-0005010; Katrina Evans Johnson – A1-0005011; Victor Ly – A1-0005012; Melissa Anne Urian – A1-0005013; Johnson Manoharan – A1-0005014; DongMin Kim – A1-0005015; Tyler R. Mullen – A1-0005016; Christopher D. Edmonds – A1-0005017; Harish Chhibba – A1-0005018; Kaci A. Coveleski – A1-0005019; Kenny Dong Kwack – A1-0005020; Sravya Nimmagadda – A1-0005021; Katarzyna Joanna Bandyk – A1-0005022; Gina Marie DeCarolis – A1-0005023; Michelle L. Maylie – A1-0005024; Edward Woo Suh – A1-0005025; Joshua S. Kim – A1-0005026; Anoiel Gevergizian – A1-0005027; Rina Rajesh Patel – A1-0005028; Joan Eunice Morillo – A1-0005029; Shidie Tang – A1-0005030; Danielle Claire Parmley – A1-0005031; Dianna Naree Kenner-Staves – A1-0005032; Nnamdi F. Ofoegbu – A1-0005033; Elizabeth E. Austin – A1-0005034; Kassahun Tsehay Bogale – A1-0005035; Farooq Adeyede Adetola – A1-0005036; Sarah Elizabeth Mangham – A1-0005037; Magued M. Saad – A1-0005038; Marian M.Y. Morcouc – A1-0005039; Hai N. Nguyen – A1-0005040; Anthonia O. Eruchie – A1-0005041; Justin Daniel Miller – A1-0005042; Robert Rudolf Svenson – A1-0005043; Chima Ihedigbo – A1-0005044; Kerri D. Bevacqua – A1-0005045; Stefan A. Kolodij – A1-0005046; Zishan S. Khan – A1-0005047; Messay Addis – A1-0005048; Eliezer N. Ayettey – A1-0005049; Meghana R. Fadadu – A1-0005050; Gunjan H. Kamdar – A1-0005051; Anh H. Vu – A1-0005052; Sarah J. Lim – A1-0005053; Levette A. Owusu-Ansah – A1-0005054; Scott Andrew Hoffman – A1-0005055; Krupa K. Patel – A1-0005056; Donna M. Kemp – A1-0005057; Joseph S. Crisafulli – A1-0005058; Zachary M. Rodgers – A1-0005059

Distributor Permits

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Seacoast Medical, LLC – A4-0000883; Sourceone Healthcare Technology, Inc – A4-0001171; HF Acquisition Co, LLC – A4-0001722; PharmaLink, Inc – A4-0002026; RxTPL, LLC – A4-0002343; Masters Pharmaceutical, LLC, dba River City Pharma – A4-0002344; HFC Prestige International US, LLC – A4-0002345; US Special Formulations, LLC – A4-0002346; Par Pharmaceutical – A4-0002347; PuraCap Laboratories, LLC – A4-0002348; HVO, Inc – A4-0002349; Larken Laboratories, Inc – A4-0002350; The Procter & Gamble Distributing, LLC – A4-0002351; Reckitt Benckiser, LLC – A4-0002352; Chesapeake Waste Solutions – A4-0002353; YS Marketing, Inc, dba NUMED – A4-0002354; Pharmeducence, Inc – A4-0002355; Cardinal Health 110, LLC, dba ParMed Pharmaceuticals – A4-0002356; The Wella Corporation – A4-0002357; SCA Pharmaceuticals Holding, LLC – A4-0002358; Anda Pharmaceuticals, Inc – A4-0002359; ANDA, Inc – A4-0002360; Attain Med, Inc – A4-0002361; MedArbor, LLC – A4-0002362; Healthsource Distributors, LLC – A4-0002363; Miller Veterinary Supply Co, Inc – A4-0002364; RxTPL, LLC – A4-0002365; Westminster Pharmaceuticals, Inc – A4-0002366; Nitrous Oxide Corp – A4-0002367; TQM, LLC, dba Two Rivers Medical – A4-0002369; Janssen Pharmaceuticals, Inc – A4-0002370; Solubiomix, LLC – A4-0002371; Central Admixture Pharmacy Services, Inc – A4-0002372; Lone Star Pharmaceuticals, Inc – A4-0002374; Advanced Pharma, Inc – A4-0002375; Ollin Pharmaceutical, LLC – A4-0002376; Mechanical Servants, LLC – A4-0002377; Nielsen Biosciences, Inc – A4-0002378; Valmed Pharmaceutical, Inc – A4-0002379; Masters Pharmaceutical, LLC, dba River City Pharma – A4-0002380; Graxcell Pharmaceutical, LLC – A4-0002381; Smith Drug Company, Division of J M Smith Corporation – A4-0002382; Pharmsource, LLC – A4-0002383; SterRx, LLC – A4-0002384; Cayman Chemical Company, Inc – A4-0002385; West-Ward Pharmaceuticals Corp – A4-0002386; Gavis Pharmaceutical, LLC – A4-0002387; Priority Healthcare Distribution, Inc, dba CuraScript SD Specialty Distribution – A4-0002388; Anutra Medical, Inc – A4-0002389; UPS Supply Chain Solutions, Inc – A4-0002390; Westminster Pharmaceuticals, LLC – A4-0002393; Nitrous Oxide Corp – A4-0002394; Nephron SC, Inc – A4-0002395; Kuehne + Nagel, Inc – A4-0002396; MediNatura, Inc – A4-0002397; Pharmaceutical Trade Services, Inc, dba Durbin USA – A4-0002398

In-State Pharmacy Permits

Four Issued From October 1, 2016, to March 31, 2017

JCPR, dba Glasgow Pharmacy – A3-0001006; Kent Pharmacy – A3-0001007; Concord Pharmacy – A3-0001008; Raajipo, LLC – A3-0001009

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