April 2017

New Jersey State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

PO Box 45013 • 124 Halsey St, 6th Floor • Newark, NJ 07101 • *www.njconsumeraffairs.gov/phar*

Message From the President – Thomas F.X. Bender, RPh

I would like to thank, at this time, the thousands of pharmacists who practice in New Jersey for their outstanding efforts in delivering quality health care to the residents of our state. An overwhelming majority of pharmacists provide the citizens of New Jersey, on a daily basis, with prescriptions and health services and the corresponding instruction and information necessary for positive patient outcomes to improve health and the quality of life. The pharmacists of New Jersey practice their profession with competence, compassion, and professionalism. It is because of them that the profession of pharmacy is held in such high regard by the public and is consistently cited as the most trustworthy and accessible of all professions.

All of us on the New Jersey State Board of Pharmacy would like to thank the pharmacists of New Jersey for your outstanding work and contributions to our society. You do not hear it often enough, but you are doing a remarkable job. When we consider the millions of prescriptions and medication orders dispensed and the thousands of immunizations administered on a yearly basis, the number of negative experiences, on a percentage basis, is relatively low. With that said, we recognize that even a small amount of dispensing errors or violations of rules and regulations is unsatisfactory as we strive for a perfection that we know can never be realistically achieved.

Most pharmacists know and recognize that the primary function of the Board is to **protect the public.** How the Board fulfills its obligation may be less obvious. The Board regulates the practice of pharmacy by promulgating rules and regulations and enforcing these rules and regulations. The Board ensures that all licensees and registrants are qualified and competent to practice and are properly licensed and registered to do so. The Board contributes to and reviews testing questions for the Multistate Pharmacy Jurisprudence Examination® and North American Pharmacist Licensure Examination®. Another function of the Board is to deal with consumer complaints relating to the practice of pharmacy. A major function of the Board is to review inspection reports compiled by the New Jersey Division of Consumer Affairs Enforcement Bureau to ensure that all Board rules and regulations are being met. The most distasteful function of the Board is dealing with licensees who knowingly violate rules and regulations or who practice incompetently or negligently. Fortunately, these individuals comprise a very small number of pharmacists. Some tools that the Board utilizes in imposing discipline include revocations, suspensions, warnings, and the imposition of monetary penalties. Benjamin Franklin was correct when he said, "Those things that hurt, instruct." Most of us learn from mistakes or errors and are less inclined to repeat transgressions or violations. Corrective actions then become the norm.

Future *Newsletter* articles will examine in more detail functions and decisions made by the Board. In closing, I would like to commend and thank the large plurality of pharmacists who consistently perform with the utmost of competence, honesty, and integrity and who are responsible for making the profession of pharmacy a respected and revered source of health care.

Continuing Education Requirements for New Jersey Pharmacists

A complete explanation of the continuing education (CE) requirements for New Jersey pharmacists can be found in N.J.A.C. 13:39-3A. Some important regulations to note are as follows.

CE credits must be completed every two years or each biennial period. Each applicant for biennial license renewal shall complete a minimum of 30 credits of CE during the preceding biennial period, except that the Board shall not require completion of CE credits for an applicant's initial license renewal.

At least 10 of the CE credits shall be obtained through didactic, or "live," instruction. Didactic "live" instruction means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction.

At least three CE credits shall be obtained in pharmacy law applicable to the practice of pharmacy in New Jersey.

Ten credits of CE may be carried over into a succeeding biennial period only if such credits were earned during the last six months of the preceding biennial period and were not previously reported. This means if the applicant has a total of 40 CE credits from the previous period, and 10 CE credits fall between November and April before the succeeding biennial period, 10 credits may be used for the succeeding period.

CE that may be used includes: programs or courses offered by Accreditation Council for Pharmacy Education (ACPE)-approved providers; programs and courses that have received prior Board approval (N.J.A.C. 13:39-3A.6); graduate coursework relevant to the practice of pharmacy taken at an accredited college or university (beyond that required for professional licensure); participation in teaching and/or research appointments; participation as a preceptor in externship or internship programs; and publication of an article related to the practice of pharmacy in a peer-reviewed professional journal.

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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/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

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://jcpp.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.

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A licensee seeking credit for attendance at a program or course that is not offered by an ACPE-approved provider and that has not been approved by the Board pursuant to N.J.A.C. 13:39-3A.6 shall submit for Board review and approval on a form provided by the Board along with a fee and verification of attendance.

CE credits are defined as one credit for each hour of attendance. Credit shall not be granted for programs or courses that are less than one contact hour in duration, which is defined as 50 minutes of actual attendance in a program or course of study. One half credit shall be granted for each 30-minute segment of a program or course that is more than one contact hour in duration. Completion of an entire program or course is required in order to receive any CE credit for the program or course. Successful completion of graduate coursework related to the practice of pharmacy at an accredited college or university beyond that which is required for professional licensure shall be granted three CE credits for each course credit awarded. Teaching and research appointments related to the practice of pharmacy shall be granted three CE credits for each new program or course taught or subject matter researched by a licensee to a maximum of six credits. "New," in this paragraph, means a program, course, or subject matter that the licensee has never taught or researched before in any educational or practice setting. A licensee who is employed as a teacher and/or as a researcher on a full-time basis shall not be eligible to obtain CE credit for such activities. Participation as a preceptor in an externship program, upon prior approval by a college of pharmacy, shall be granted three CE credits per student to a maximum of six credits. Participation as a preceptor in an internship program shall be granted three CE credits per 160 hours of work performed by the intern(s) and supervised by the licensee to a maximum of six credits. Publication of an article related to the practice of pharmacy in a peer-reviewed professional journal shall be granted three CE credits per article to a maximum of six credits.

The Board will not grant credit for, or approve as a component of a CE program, participation in the routine business portion of any meeting of a pharmaceutical organization or any presentation that is offered to sell a product or promote a business enterprise.

A licensee shall specify on his or her application for biennial license renewal that the required number of CE credits has been completed. Falsification of any information contained in the renewal application may result in an appearance before the Board and the assessment of penalties and/or license suspension pursuant to N.J.S.A. 45:1-21 et seq. A licensee shall maintain all documentation concerning the completion of CE requirements for a period of five years from the completion of the credit hours and shall submit such documentation to the Board upon request. Such documentation shall consist of: a certificate of completion from the course or program (for programs offered by ACPE-approved providers), the sponsors' written verification of attendance (for programs and courses approved by the Board), a statement from the chairperson of the department verifying completion of the assignment (for teaching or research appointments in an academic setting), a statement from the project coordinator verifying completion of the assignment (for research appointments in an industrial setting), a certificate from the college of pharmacy (for participation as a preceptor in an externship program), a certificate from the Board (for participation as a preceptor in an internship program), and submission of the published article (for publications in a peer-reviewed professional journal).

The Board may waive CE requirements on an individual basis for reasons of military service, hardship, illness, or disability. A licensee seeking a waiver of CE requirements shall apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as the Board may request in support of the application for waiver. A waiver of CE requirements granted shall be effective only for the biennial period in which such waiver is granted. If the condition(s) that necessitated the waiver continues into the next biennial period, a licensee shall apply to the Board for a renewal of such waiver for the new biennial period.

The Board will audit licensees on a random basis at the end of each biennial period to determine compliance with CE requirements. Fines and penalties will be assessed for licensees who fail to meet the educational requirements. Please note that a Board member or a Board representative may monitor an approved program or course without prior notification to the CE sponsor.

New Jersey Pharmacy Technician Law Review

The following is a summary of rules pertaining to pharmacy technicians. For complete information regarding pharmacy technicians practicing in New Jersey, please see N.J.A.C. 13:39.

To be eligible as a New Jersey pharmacy technician, applicants must be 18 years of age or older and possess a high school diploma or equivalent, must be proficient in written and spoken English, and submit to a criminal history background check. There must be no active alcohol or drug abuse within 365 days, no federal or state controlled dangerous substances (CDS) or habit-forming drug violation convictions, no criminal convictions involving moral turpitude, and no prior suspensions or revocations by any state board of pharmacy.

Pharmacy technicians must apply to the Board within 10 days of hire. Pharmacy technicians must receive registration within 180 days of application and must notify the Board of name change (with a certified copy) and address change within 30 days.

Please note that pharmacy technicians are registered, not licensed. All registrants must display their large blue registration prominently at their primary place of employment. Photocopying registration certificates is not permitted. Pharmacy technicians who work at two or more places of employment must carry their wallet-sized blue registration on their possession while at work and must present it to a Board investigator when requested.

Pharmacy technicians are permitted to perform the following tasks and duties: retrieve patient profiles and files; perform data entry of prescription information; collect patient demographic information; transcribe the prescription content into the patient record or profile; prepare labels; count, measure, and compound prescriptions, stock legend drugs, and refill automated medication systems; and accept authorization of an unchanged prescription for refill. Pharmacy technicians must identify themselves as a pharmacy technician and wear an identification badge with their last name, at least the first initial of their first name, and their employment title.

Pharmacy technicians may not perform the following tasks and duties: receive new verbal prescriptions, interpret prescriptions for therapeutic appropriateness, verify dose and directions of prescriptions and medications, perform prospective drug reviews, provide patient counseling, monitor prescription usage or the New Jersey Prescription Monitoring Program, transfer prescriptions from one pharmacy to another pharmacy, and violate patient confidentiality. Pharmacy technicians are required to sign confidentiality agreements that must be maintained on site at their place of employment.

The pharmacist to **uncertified** pharmacy technician ratio can be no greater than 1:2. Places of employment must have policies and procedures, tasks lists, and job descriptions of pharmacy technicians, and the pharmacist-in-charge (PIC) must ensure that

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each pharmacy technician has completed a job competency and has a full understanding of the policies and procedures and job descriptions with documentation. Training must be documented and may take no longer than 210 days. Pharmacy technicians may not exceed their job description. Pharmacists cannot train more than two pharmacy technicians at a time. Pharmacy technicians must have immediate direct supervision of a pharmacist at all times.

The pharmacist to pharmacy technician ratio may be greater than 1:2 if the pharmacy technicians are certified. Pharmacy technicians may be certified by meeting the requirements of N.J.A.C. 13:39-6.15, including: passing the Pharmacy Technician Certification Board's Pharmacy Technician Certification Exam and fulfilling the requirements to maintain this status, passing a Board-approved certification program and fulfilling the requirements to maintain this status; or completing a program that includes a testing component and has been approved by the Board. Completion of a program with a Board-approved testing component shall qualify the pharmacy technician to work only for the specific pharmacy and/or corporation for which the pharmacy technician was employed when the training was obtained. If the pharmacy technician becomes employed by another pharmacy and/or corporation, the pharmacy technician shall be required to complete the new employer's training program.

Certified pharmacy technicians who are employed at a pharmacist to certified pharmacy technician ratio greater than 1:2 must be under the supervision by a pharmacist with the following information outlined in the employment policy and procedure manual: confidentiality safeguards of patient information, documentation of in-service education, competencies, general duties and responsibilities of pharmacy technicians, all functions related to prescription processing including retrieval of prescription files and patient profiles and records, all functions and documentation related to legend drug and CDS ordering and inventory control, prescription refill and renewal authorization, procedures dealing with medication errors and classification, and pharmacy technician functions related to automated medication systems. Policies must also indicate functions that may not be performed by pharmacy technicians, and there must be a form signed by the pharmacy technician verifying that the manual has been reviewed and understood by the pharmacy technician.

There are many rules and regulations concerning pharmacy technicians, and it is very important for the PIC, pharmacists, and pharmacy technicians to understand the regulations, responsibilities, and functions of a pharmacy technician.

Guidance for Pharmacists Regarding Initial Prescriptions for Opioids

On March 1, 2017, the New Jersey Attorney General and the New Jersey State Board of Dentistry, State Board of Medical Examiners, Board of Nursing, and State Board of Optometrists adopted emergency rules with specific limitations for opioid drugs, which include prohibiting a prescriber from issuing an initial prescription for the treatment of acute pain for an opioid drug in a quantity exceeding a five-day supply and requiring the prescription to be for the lowest effective dose of an immediate-releasing opioid drug. Prescribers are also required to indicate on the prescription when it is an initial prescription for an opioid drug for the treatment of acute pain.

These amendments are effective immediately (as of March 1, 2017) and will remain in effect for 60 days. These emergency rules also are being concurrently proposed for readoption in order to permit members of the regulated community and the general public to submit comments concerning the rules and the intention of the Attorney General and the boards to make these amendments permanent. For a text of the rules and additional information, please visit the relevant board web pages at *http://www.njconsumeraffairs.gov/Pages/default.aspx*.

On February 15, 2017, P.L. 2017, c. 28, was signed into law, imposing certain restrictions on how opioids and other Schedule II CDS may be prescribed and establishing special requirements for the management of acute and chronic pain, including, in cases of acute pain, prohibiting a practitioner from issuing an initial prescription for an opioid drug in a quantity exceeding a five-day supply and requiring the prescription to be for the lowest effective dose of an immediate-releasing opioid drug. However, because P.L. 2017, c. 28, does not become effective until May 16, 2017, the Attorney General has determined that rulemaking is necessary, as the state of New Jersey is confronting a staggering public health crisis brought about by prescription opioid and heroin abuse.

Although the new law and rules will primarily impose additional responsibilities on prescribers, the information below may be useful for pharmacists:

- The law and rules do not impose any additional requirements for pharmacists to confirm that a prescription must be limited to a five-day supply of medication. However, note that pharmacists are required to perform their corresponding responsibility to ensure that all prescriptions for CDS are being written for a valid medical purpose.
- Beginning with the 2019 biennial renewal of pharmacist licenses, pharmacists must complete one credit of CE on programs or topics concerning prescription opioid drugs, including alternatives to opioids for managing and treating pain and the risks and signs of opioid abuse, addiction, and diversion. This is not an additional CE credit requirement and will be part of the existing 30-credit CE requirement for each renewal period.
- Insurance plans issued in New Jersey will charge copayments, coinsurance, or deductibles for an initial prescription of an opioid drug prescribed pursuant to the law that is either:
  - ◊ proportional between the cost sharing for a 30-day supply and the amount of drugs the patient was prescribed; or
  - ◊ equivalent to the cost sharing for a full 30-day supply of the opioid drug, provided that no additional cost sharing may be charged for any additional prescriptions for the remainder of the 30-day supply.

You may need to contact your insurance plans with any questions regarding how this component will be implemented.

A copy of the law is available at *www.njleg.state.nj.us/2016/Bills/AL17/28_.PDF*.

The *New Jersey State Board of Pharmacy News* is published by the New Jersey State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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