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News

New Hampshire Board of Pharmacy

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What's Happening at the Board

- Michael Bullek resigned from his seat as New Hampshire Board of Pharmacy commissioner on March 1, 2017, as he accepted the position of executive director and compliance chief for the Board under the direction of the Office of Professional Licensure and Certification (OPLC). Mike began to serve in this capacity on March 17. The Board is excited about this move, as Mike brings his experience both as a pharmacist and former commissioner as well as his legislative experience to this position. Under the new OPLC leadership of Peter Danles and Joe Shoemaker, the newly restaffed Board structure and staff place the Board in the strongest position it has been in for years. The Board is excited about the opportunity to serve the public and its license base in a prompt and efficient manner. The Board wishes Mike the best of luck in his new endeavor.
- After the lifting of the moratorium on rules instituted by Governor Chris Sununu on April 1, 2017, the Board will be moving forward on a number of rules that have been in various stages of the rulemaking process.

Current Board Rulemaking Initiatives

A summary of current rules in the works is as follows:

- **Pharmacy Rule (Ph) 600s – Limited retail drug distributor.** Public hearing completed and final draft will be submitted to the Office of Legislative Services (OLS) for scheduling before the Joint Legislative Committee on Administrative Rules (JLCAR).
- **Ph 2000s – Outsourcing facilities.** Rules have completed the public hearing process and will be submitted to OLS for final review and JLCAR hearing.
- **Ph 1800s – Advanced practice pharmacy technician.** Rules have been completed, and the initial proposal and fiscal impact statement will be requested and public hearing scheduled; stay tuned to the Board website for notification of the hearing date.
- **Ph 1500s – Prescription drug monitoring program (PDMP).** Update on the rules with numerous changes to implement recently passed legislation. These rules will be submitted for initial proposal and public hearing. Watch the Board website for scheduling of public hearing.
- **Ph 500s – Ethical standards.** Update has been made to the ethical standards by refreshing and including standards for pharmacists, technicians, and permit holders. Initial changes have been made to existing rules. The Board still needs to vote on the changes and then submit for fiscal impact statement, OLS review, and public hearing. Watch the Board website, as these will move forward over the next six months.

Noteworthy

The following is a legislative review of pending statutory changes currently working their way through the state House and Senate:

- **House Bill (HB) 469 –** Establishment of continuous quality improvement programs by stakeholders. Passed the House Executive Departments and Administration Committee as ought to pass and will move on to the Senate.
- **HB 291 –** Relative to veterinarians' removal from the PDMP. Passed the House with amendments. This would remove veterinarians from adopting prescribing rules and querying the PDMP.
- **HB 455 –** Relative to prohibiting pharmacy benefit managers from requiring special credentialing or accreditation. Passed the House and will move on to the Senate.
- **HB 264 –** Relative to pharmacists prescribing oral contraceptives. Passed with amendments; amendment would establish study commission to develop recommendations on pharmacists prescribing oral contraceptives. Moving to Senate.
- **Senate Bill (SB) 154 –** Relative to pharmacists prescribing oral contraceptives. Remains in committee.
- **SB 150 –** Relative to interns administering vaccines. Has not been scheduled for a hearing at the time of this *Newsletter.* Scheduling will occur toward the end of the Senate session.

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.

Registration of Pharmacy Technicians

Pharmacy technician registrations expired on March 31, 2017.

As a reminder, the pharmacist-in-charge (PIC) is responsible for ensuring that all personnel who work in the pharmacy are properly licensed or certified and that these licenses/certifications are current, per Ph 704.11(b)(11). It is important to note that Ph 803.01(d) states, "Training shall be documented by the [PIC] and be retrievable upon inspection." This includes certified and noncertified technicians.

Ph 704.11(a) states:

> Pharmacists looking to serve as a [PIC] shall:
>
> (1) Have worked as a pharmacist for a minimum of 2 years post-graduation;
>
> (2) Complete and pass with a minimum of 80% an exam designed by the board to assess the knowledge of the candidate in regard to their responsibilities as PIC; and
>
> (3) Work a minimum of 20 hours per week at the location where he/she serves as PIC except when absent due to scheduled vacation or other authorized leave.

Collaborative Practice Update

The committee working on updating and revising collaborative practice rules, Ph 1101, met on December 14, 2016, to finalize the draft rules and the application for collaborative practice. Two nurse practitioners who serve on the New Hampshire Board of Nursing attended the meeting, bringing the important provider viewpoint.

At the December Board of Pharmacy meeting, the Board reviewed the draft rules and approved them with a few modifications. A public comment period is tentatively scheduled for the April 19, 2017 Board meeting.

Key rules in the draft are as follows:

- Agreements may only be between a physician or nurse practitioner. RSA 318:1-XXVII defines "collaborative pharmacy practice agreement" as a written, signed agreement that is between a pharmacist and an attending practitioner. RSA 318:1-XXV defines "attending practitioner" to mean a physician or advanced practice registered nurse.
- Dedicated time means uninterrupted time, as defined in the agreement, that a pharmacist will use to exclusively perform duties specified in the agreement.
- Application should be no more than two pages, have demographic information and a summary of education and experience supporting the request to perform said duties, and include addresses of locations where the practice will occur.
- The draft rules include the process of submitting and approving an application.
- Each collaborative agreement must include a list of specific drugs to be managed; the process to implement, modify, or discontinue a drug; laboratory tests; quality metrics to monitor for safety and appropriateness; and the responsibilities of the pharmacist to the patient and provider.
- A pharmacist entering into a collaborative agreement shall hold an unrestricted license. In the event a restriction is placed on a license, it would require the pharmacist to discontinue the collaborative practice.
- Creation of an advisory council with six to 10 individuals representing various pharmacy practice settings and medical and nurse practitioners. The role of this council will be to review the collaborative agreements and make recommendations to the Board. Additionally, the council will be tasked to annually perform audits of at least 10% of collaborative agreements to verify compliance with current rules.

The draft rules and the application will be available on the Board website for review prior to the public meeting, tentatively scheduled for April 19. Individuals with questions, recommendations, or concerns should contact Commissioner Gary Merchant at rx.merchant@yahoo.com.

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