June 2017

Idaho State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Newsletter Goes Electronic

This is the last issue of the Idaho State Board of Pharmacy's **printed** *Newsletter.* Going forward, all future Board *Newsletters* will be provided as a downloadable pdf posted on the Board's contact page at *https://nabp.pharmacy/boards-of-pharmacy/idaho.* Licensees will receive an email alert whenever a new issue of the *Newsletter* becomes available. To ensure you receive these alerts, please keep your contact information up to date with the Board. The Board is undertaking this effort to deliver updates as timely as possible and make the information more easily accessible. The *Newsletter* will continue to be considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board and as such, it will be important to stay up to date on the new electronic format.

2017 Changes to Idaho Code

This *Newsletter* will highlight the pharmacy-related bills that were passed by the 2017 Idaho legislature and signed into law by Governor Butch Otter, with an effective date of July 1, 2017. Full details of the bills may be found on the state legislature's website at *https://www.legislature.idaho.gov/legislation/2017/minidata.htm.*

Pharmacist Prescriptive Authority for Tobacco Cessation Medications

The legislature unanimously passed House Bill (HB) 4, which adds tobacco cessation drugs to the list of drug products that pharmacists may autonomously prescribe under 54-1704, Idaho Code. There is often spontaneity to a patient's decision to quit smoking, and pharmacists can increase access and convenience to patients. Studies in other jurisdictions have demonstrated that pharmacists can achieve quit rates on par with, and in some instances higher than, other health professionals.

The bill is inclusive of **all** Food and Drug Administration (FDA)-approved tobacco cessation drugs. No collaborative practice agreement is necessary, and there is no statewide protocol that pharmacists must follow. Instead, pharmacists may autonomously prescribe tobacco cessation drugs using their professional judgment, provided the following conditions are met:

- Prescribing pharmacists must successfully complete an Accreditation Council for Pharmacy Education (ACPE)-accredited course on tobacco cessation therapy. There is no specific number of continuing education (CE) hours required, and many free options are available online.
- Pharmacists must screen patients for contraindications and refer patients as necessary. For example, patients with a history of seizures may not be good candidates for certain prescription tobacco cessation drugs, and pharmacists should have a mechanism in place to identify these patients and others.

When a pharmacist does prescribe a tobacco cessation drug, he or she must:

- Maintain documentation of the patient screening and the prescription record.
- Develop and implement a follow-up care plan that aligns with clinical guidelines.
- Notify the patient's primary care provider within five business days following the prescribing. In the event that the patient does not list a primary care provider, which has been the case in other jurisdictions, notification is not necessary.
- Recommend additional assistance for behavior change, particularly the Idaho QuitLine, an evidence-based tobacco cessation service that helps tobacco users quit through free counseling and nicotine replacement therapy. The Idaho QuitLine online or fax referral form is available at *projectfilter.org/hcp.*

Pharmacist-Administered TB Skin Testing

The legislature unanimously passed HB 3, which allows pharmacists to prescribe and administer a tuberculin purified protein derivative product approved by FDA. Pharmacy-based tuberculosis (TB) skin testing has increased access to care in other jurisdictions. In order for pharmacists to exercise this authority, they must:

- Complete a training program by the Centers for Disease Control and Prevention (CDC) or an ACPE-accredited program. The CDC training may be accessed at *https://www2c.cdc.gov/podcasts/player.asp?f=3739.*
- Follow the recommendations for Mantoux tuberculin skin testing from the CDC regarding test administration and interpretation of results. A helpful primer may be found from the CDC at *https://www.cdc.gov/tb/publications/posters/images/Mantoux_wallchart.pdf.*
- Document the test results and maintain them in the records of the pharmacy.

In the instance that a patient is found to have a positive test reading, the pharmacist must coordinate a timely referral to the patient's primary care provider (if the patient has one), or to a local clinic, in order to coordinate further diagnostics and follow-up care.

PMP Updates: Required Pharmacist Registration and Student Access

As of April 2017, 89% of Idaho pharmacists are registered with the prescription monitoring program (PMP). Registration is **free** and easy and may be completed at *https://idaho.pmpaware.net/identities/new.*

The legislature unanimously passed HB 5, which creates a requirement that all pharmacists register for access to the PMP prior to July 1, 2017. Thus, a pharmacist's license **will not be renewed** if he or she is not registered for access to the PMP.

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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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The bill also allows pharmacists to designate a student pharmacist to serve as a delegate on their behalf. A student pharmacist may access information to the extent that the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing any controlled substance (CS), or for the purposes of a pharmacist providing pharmaceutical care as defined in law.

To register a student pharmacist as a PMP delegate, the following must occur:

(1) A proposed delegate must submit a registration for access to the Board by visiting *https://idaho.pmpaware.net/identities/new* and verifying his or her email address using the link sent to him or her by the system.

(2) As part of the registration process, a proposed delegate must enter his or her supervising pharmacist's email address.

(3) The supervising pharmacist must log in to his or her PMP account and authorize the proposed delegate. Delegates associated with a pharmacist's account are displayed in a table found at User Profile → Delegate Management. From this location, a supervising pharmacist is able to approve or reject new delegates or deactivate existing delegates from his or her account. To approve, the user selects the delegate and clicks the approve button. To reject or deactivate, the user selects the delegate and clicks the reject button. This removes the delegate from the supervisor's list.

(4) Board staff confirms that all requirements have been met for the delegate's user account and approves the account. The delegate will receive an email stating that his or her account has been approved and is now active.

Please contact Teresa Anderson with any questions at teresa.anderson@bop.idaho.gov or call 208/334-2356.

Notice of Upcoming Rulemaking

The Board has scheduled its rulemaking meetings as follows:

- August 1-2, 2017 – negotiated rulemaking
- October 25-26, 2017 – proposed rulemaking

Both sessions are open to the public, and comments may be made in writing in advance of the meeting or verbally at the meeting.

Of note, the Board is seeking to divide its rulebook into separate chapters in order to better organize the rules. The proposed chapters are as follows:

(1) Rules Related to the Procedures of the Board – modest changes are envisioned.

(2) Rules Related to Licensing and Registration – the Board envisions streamlining CE requirements, removing the requirement that pharmacists must obtain a separate CS registration, among other changes. Fee changes are being considered to keep the Board budget neutral after the envisioned changes.

(3) Rules Related to Pharmacy Practice – the Board envisions streamlining these rules to focus on the **practice** of pharmacy, not the **business** of pharmacy, and allow opportunities for technology and practice enhancements to occur without first needing express permission.

(4) Rules Related to Pharmacist Prescriptive Authority – HB 191 enables the Board to adopt rules about which low-risk drugs, drug products, or devices pharmacists may prescribe. This chapter intends to implement the intent of this bill.

(5) Rules Related to Compounding – no changes are envisioned.

(6) Rules Related to Manufacturing and Distributing – no changes are envisioned.

All licensees and registrants are encouraged to engage actively with the Board as it begins the process of open, collaborative rulemaking.

Recent Board Discipline

For a more detailed report on cases, view the minutes of the relevant Board meetings at *http://bop.idaho.gov/board_meeting*.

T.B., PharmD: Fined $1,650, ordered to complete an 18-hour CE program on patient safety and medication error prevention, and received a seven-day suspension of license and registration for a medication error.

L.S., PharmD: Fined $1,000 for having outdated drug products in the pharmacy's stock.

Special Notice

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The *Idaho State Board of Pharmacy News* is published by the Idaho 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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