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North Dakota State Board of Pharmacy News

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Gabapentin as a Reportable Drug to the Prescription Drug Monitoring Program

The North Dakota State Board of Pharmacy requested the North Dakota Legislature to add gabapentin (Neurontin®) as a reportable drug to the prescription drug monitoring program (PDMP). The Legislature passed House Bill 1099, and Governor Doug Burgum signed the legislation. Effective August 1, the Board will require North Dakota dispensers to report gabapentin prescriptions to the PDMP. Your pharmacy will see communication shortly about this change to give ample time to make the appropriate software adjustments.

The Board has heard increasing reports on concerning activities around gabapentin. Although the rationale for gabapentin abuse is unknown, reports describe abuse due to gabapentin's effects of euphoria, improved sociability, a marijuana-like "high," relaxation, and sense of calm. Concerning activities described include obtaining high doses and utilizing multiple practitioners and pharmacies. Please be aware of this increasing trend and, when available, monitor patients through the PDMP when appropriate.

Pharmaceutical Compounding Standards Updates

Changes to compounding standards became effective April 1. The rules were adjusted to reference the current standards in United States Pharmacopeia Chapters <795> and <797> regarding nonsterile and sterile compounding. In order to require compliance with future revisions to Chapter <795> or <797>, the Board would need to go through the rulemaking process for adoption.

It is now clear that recent federal law changes set forward by the Drug Quality and Security Act do not allow for "office-use" compounding unless a facility is registered with Food and Drug Administration (FDA) as an outsourcing facility. Pharmacies can only compound pursuant to a practitioner's prescription for a patient.

There is an allowance to compound veterinary products to provide to veterinarians for administration in their office setting to meet patient needs.

As a reminder, compounding needs to only utilize FDA-approved substances and not substances that have been withdrawn from the market (deemed as unsafe or ineffective). A compounded medication cannot be essentially the same as a commercially available drug product.

Should you have any questions regarding this or other topics related to compounding, please contact the Board office.

Update on Registration With the PDMP

The number of pharmacy registrants and requests made by pharmacy registrants has increased quite substantially during the past year. Below you will see charts showing the increase. The Board is proud of the increase in utilization of the PDMP, which is continuing to prove to be the most powerful patient care tool to prevent and deter prescription drug abuse.

Registrants by Quarter		
Quarter	**Pharmacist**	**Pharmacy Technician**
2016 First	979	498
2016 Second	1,003	542
2016 Third	1,045	587
2016 Fourth	1,052	583
2017 First	1,081	601

Report Requests by Quarter	
Quarter	**Pharmacy Queries Requested**
2016 First	21,531
2016 Second	22,247
2016 Third	21,730
2016 Fourth	23,631
2017 First	21,983

The Board expects to see further increases in utilization for our profession to ensure compliance with the administrative rules for pharmacies to utilize the PDMP. If you have not created an account for direct access to the PDMP, if applicable, you should follow the steps below to receive online access and ensure that you utilize it in your practice.

To create your North Dakota PDMP account:

1. Visit *https://northdakota.pmpaware.net/identities/new.*
2. Enter your email address and password (must contain at least eight characters, upper and lower case letters, and punctuation or symbols) and then click register.
3. Select your role. For example, click the arrow next to Healthcare Professional and select the box next to Pharmacy Technician or Pharmacist, then click on the Update User Roles and Continue button.

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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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4. Fill in the online form. If you are a pharmacy technician, please scroll down to the "I am a delegate for…" box and enter the email address of your pharmacist-in-charge or any other pharmacist you work with who already has an account (from any location). Click the Finish button. Make sure to add your prefix with your license number (eg, RPH1111, TECH1111).
5. If your information matches the information on file for your license, you will receive instant access. If the information does not match, a notary form will be sent to you for completion to finalize the registration process.

If you have questions, please contact 701/328-9537 for assistance or call the 24-hour support line at 855/563-4767.

Pharmacies' Ability to Provide Epinephrine Administration Devices

The Board has recently received a few questions regarding the ability for a location to receive an epinephrine administration device from a pharmacy. Below are the applicable sections of the North Dakota Administrative Code:

33-37-01-01. Persons eligible to administer epinephrine. A person whose employment creates a reasonable expectation to care for the health and safety of others may administer epinephrine to persons suffering from an anaphylactic reaction. A person who is deemed to have a reasonable expectation to care for the health and safety of others includes a teacher, camp counselor, day care operator, and security person.

33-37-01-02. Training requirements. A person authorized to administer epinephrine under this chapter shall complete training by a physician licensed by the North Dakota state board of medical examiners or the physician's designee. The physician shall determine the training content, criteria for satisfactory completion, and frequency. The physician shall maintain a record of the training which identifies the individuals trained, the training content, and the date of the training. The physician shall make training records available to the state department of health upon request.

33-37-01-03. Administration devices. A person authorized to administer epinephrine shall utilize a single use disposable device that automatically injects a premeasured dose. The device may be obtained by a trained person from a pharmacy upon the request of a licensed physician. The device must be stored and maintained where trained staff are present.

Any branded or generic epinephrine administration device can be provided. A prescription for the device does not need to be obtained as long as the pharmacy has clear authorization from the practitioner. Additionally, if a practitioner wishes to have an epinephrine device for his or her office, the pharmacy can complete a wholesale transfer of the medication for the practitioner's discretion and use. Again, appropriate invoicing of the product should occur and be maintained in the pharmacy's records. Should you have any questions, feel free to reach out to the Board office.

Online Immunization/Injectable Certification

Pharmacists may now apply for or renew their immunization/injectable certification online at the Board's website, *www.nodakpharmacy.com.* The process involves scanning copies of your immunization course and current CPR card. The required continuing education credits can be submitted online as well. Once submitted and approved, a copy of the pharmacist's certification will be sent as a printable attachment on an email to the licensee.

Additional functionality has been added to allow the certification document to be reprinted from the Board's website at any time by entering the pharmacist's license number and Social Security number. The Board encourages you to utilize this free process, as your certifications expire every two years.

Address Changes

Please ensure that your address, email, and work information are promptly updated with the Board upon any change, as required by law. The Board has an easy process available on its website to make any changes necessary to your records. It will be important to maintain a regularly maintained email address, as this is increasingly becoming the way to communicate important changes and updates from the Board.

Reprinting and Verifying Licenses

Take note that you have the capability to verify any Board license or registration on the Board's website. License verification printouts to provide for various entities can be accomplished in this way.

The Board's website also allows you to reprint your license or registration at any time. This technology is useful in ensuring all licenses are properly posted at your facility.

The *North Dakota State Board of Pharmacy News* is published by the North Dakota 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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