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North Dakota State Board of Pharmacy News

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Tyler Lannoye, PharmD, Appointed to Board

Pharmacist Tyler Lannoye was appointed to serve on the North Dakota State Board of Pharmacy by Governor Doug Burgum on July 5, 2018. Tyler will fill the vacant seat caused by the expiring term of Gary Dewhirst, RPh, DPh.

Tyler resides in Churchs Ferry, ND, and serves as the chief pharmacist for the Quentin N. Burdick Memorial Health Care Facility. He is a Commissioned Corps commander with the United States Public Health Service. Tyler is a 2008 graduate of the University of Montana Skaggs School of Pharmacy.

The Board welcomes Tyler and thanks Gary for his 17 years of service to the profession of pharmacy by serving on the Board. Gary has been an outstanding leader for the Board and he continues to serve on the National Association of Boards of Pharmacy® Executive Committee.

North Dakota Tri-Regulator Position Statement on Opioid Prescribing/ Dispensing

The tri-regulatory boards of medicine, nursing, and pharmacy recognize that appropriately prescribed medications are an integral part of the medical care of patients who are dealing with acute or chronic pain. The boards are aware that prescription drug misuse continues to be a significant issue throughout the health care industry. To address this issue, the boards have adopted a joint statement on pain management. This statement is not a substitute or replacement of standards of care, but rather, it outlines proactive efforts that we expect from our licensees to help ensure safe and effective pain management.

In order to balance the risk of potential misuse with legitimate pain control, all health care professionals should, as their scope of practice allows, perform the following:

- Uphold their professional obligation to pursue educational opportunities to further their knowledge on standards of care and evidence-based approaches to pain management including, but not limited to, the Centers for Disease Control and Prevention Guidelines for Prescribing Opioids for Chronic Pain (2016).
- Document appropriate pain evaluation and management approach in the medical record of the patient.
- Consider non-medication and multi-modality therapeutic approaches to care as the firstline of treatment, when appropriate.
- Utilize the North Dakota Prescription Drug Monitoring Program (PDMP) as a tool to help make informed decisions. The PDMP can aid in monitoring a patient's past pharmacologic treatment and identifying other providers involved in the patient's care, which can foster collaboration.
- Consider a trial of a non-opioid medication at the lowest effective dose when medication therapy is deemed necessary prior to an opioid. If an opioid is necessary, start at the lowest effective dose. Avoid combining opioids with other central nervous system depressants (eg, benzodiazepines) when possible.
- Work with patients in setting realistic pain goals that are agreeable to both practitioner and patient.
- Educate the patient, their caregivers, and family about the risks and side effects associated with opioid therapy. Particular attention should be given to risk of addiction and side effects associated with central nervous system depression including respiratory depression and sedation.
- Discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle or any other mode of transportation. [National Transportation Safety Board Recommendation]

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation.* Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when

mixed with water and sequesters excess opioids and other drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further,,USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The Standard plan is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically.

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- Evaluate the patient's risk for opioid overdose and prescribe an opioid antagonist (naloxone) as necessary. If naloxone is prescribed, ensure the caregivers and family of the patient understand how to administer medication.
- Educate patient on appropriate storage and disposal of opioid medication to limit risk of diversion.
- Develop policies and protocols for staff that are specific to pain management in the patient care setting to ensure clinical vigilance in continuation of care.
- Refer patients to other providers, such as treatment specialists, when appropriate.

ONE Rx Launches This Fall to Help Ensure Safe Opioid Use

Pharmacists are often leaders in their communities and the pharmacy profession in North Dakota is known as a progressive national leader in the field. You will have an opportunity this fall to assist your patients through an innovative approach to safe medication use. ONE Rx (**O**pioid and **N**aloxone **E**ducation) is a program offered through the North Dakota State University School of Pharmacy that has the support of the Board, the North Dakota Pharmacists Association, and the North Dakota Department of Human Services. The mission of ONE Rx is to proactively help patients and communities by providing resources to pharmacists to educate about opioid misuse and accidental overdose.

Through ONE Rx, all pharmacists in North Dakota will be offered free, three-hour continuing education training to prepare themselves. This will be available in several cities, both in person and online, starting in October. Participating pharmacies will also receive a toolkit with resources to deliver the program, which involves screening patients receiving opioids for risk of misuse and accidental overdose.

You will be contacted by email, mail, and other methods with more information about this important program.

2019 Legislative Session

The 2019 legislative session is right around the corner. It certainly will be another busy session on a budgetary basis for the state and more tough decisions will need to be made. As always, there will most likely be multiple pieces of legislative items brought before the legislature that will involve pharmacy either directly or indirectly.

In the lead up to the legislative session, the Board encourages you to contact your legislators about issues and/or concerns that you may have in your practice. Of course, the legislative body may not be able to address each issue facing the practice of pharmacy. However, it is important that they be made aware of not only the challenges that pharmacy is facing but also the successes that our profession has created. The profession continues to be looked to for solutions to issues in health care delivery across the state. It is important that you, as their constituents, educate them on your professional perspective of the issues and your experiences.

FDA Biologics Interchangeability

The topic of interchangeability of a biologic drug to its biosimilar counterpart (generic) is becoming more relevant with the further approvals of biosimilars in the US. There are a couple of important issues that you need to be aware of with the expansion of these biosimilar products.

In determining the interchangeability of a biologic and biosimilar, reference the Food and Drug Administration (FDA) "Purple Book." Similar to the "Orange Book," this provides information on substitution, specifically in regard to these biological medications. A link to this online reference is available on the Board's website or can be accessed on FDA's website.

When a pharmacist determines to make a substitution of a biosimilar drug for a prescription written for the brand biologic, the pharmacist is required to notify the prescribing practitioner within 24 hours of the substitution (North Dakota Century Code 19-02.1-14.3). This communication can be done either verbally, in writing, or by electronic communication.

If you have any questions about this as biosimilars become more utilized, please contact the Board office.

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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