MARCH 2022

WYOMING STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

New Faces at the Board

Board Welcomes New Licensing Specialist Kaitlyn Tinman

The Wyoming State Board of Pharmacy welcomes the newest member of its team, **Kaitlyn Tinman.** Kate began working for the Board on December 1, 2021, as the office assistant, and has transitioned to the licensing specialist position. She is a native of New York and has spent her career expanding her knowledge in the medical field. She worked for several years as a credentialing specialist at a large health care company in Orange County, NY, before progressing to the admissions coordinator position at a skilled nursing facility in Dutchess County, NY. She has a lot of hands-on experience to bring to the Board office. Kate recently decided to make Wyoming her home and thoroughly enjoys the outdoor recreation and natural beauty it has to offer. She is looking forward to the exciting new opportunity to engage with the pharmacists and technicians around the state.

Board Welcomes New Inspector/Compliance Officer Shannon Ridge

The Board also welcomes **Shannon Ridge, PharmD, RPh,** to its team. Shannon began serving as one of the Board's inspectors/compliance officers in August 2021. She comes to the Board with knowledge and experiences gained from her background in independent retail pharmacy.

Shannon started her pharmacy career in Wyoming after she graduated from Campbell University in Buies Creek, NC. While she spent most of her life in North Carolina, Shannon has thoroughly enjoyed moving to Wyoming and feels it is a great place to raise her family and call home.

She looks forward to furthering her knowledge while working for the Board and hopes to build and foster relationships with pharmacists and Wyomingites alike.

Board Welcomes New Prescription Drug Monitoring Program Coordinator Liz Wood

The Board is also happy to welcome **Liz Wood, RPT.** Liz started with the Board on July 1, 2021, as the WORx coordinator. Liz has been a pharmacy technician since 2010 and has a background of retail, hospital, and pharmacy benefits management experience.

Liz started her pharmacy career with Walgreens as a technician-in-training. She became a certified pharmacy technician in 2011 and served patients in the retail setting until 2012. Liz then moved to hospital pharmacy and in 2017 became the sterile compounding supervisor for Cheyenne Regional Medical Center. She thoroughly enjoys the hospital setting and helping patients in a "behind the scenes" way.

In 2019, Liz moved into a new role to learn a different aspect of the pharmacy world. She began working at the Wyoming Medicaid help desk with Change Healthcare and at the hospital on an as-needed basis. Liz learned how to help pharmacies run successful claims and the prior authorization process for the state of Wyoming.

Liz has lived in Cheyenne, WY, since childhood and is an active member of the community. She is a mother to two children and one dog. Liz is an avid baseball fan and sits on the board of directors for the Cheyenne Mustangs Youth Baseball organization. Liz is very excited to share her knowledge and experience with the Board and Wyoming State, and the Board is fortunate to have her on the team.

Best Wishes to Robin Kus

The Board would like to thank Robin Kus for her hard work and service during the last four years. Robin joined the office staff as the senior office support specialist in 2018 and transitioned to the licensing specialist during her time as Board staff. The Board wishes her well in her future endeavors!

Oral COVID-19 Medications

In December 2021, Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for two oral coronavirus disease 2019 (COVID-19) medications, Pfizer's Paxlovid™ and Merck's molnupiravir. These medications are the first two COVID-19 treatment options that can be taken at home by patients who are infected or exposed to COVID-19 and at the greatest risk for illness and hospitalization. The EUA for these medications has been a step the drug industry and FDA has taken to attempt to lessen the burden on the overwhelmed hospital systems.

The first allocations of medications have been given by the Wyoming Department of Health to institutions that may get these medications to patients without the need for hospitalization. The Board has received questions from many licensees regarding the regulations that allow for the

distribution of these medications to patients appropriately. These medications are being supplied in unit-of-use packaging and should be treated and dispensed as such.

More information on the COVID-19 statistics and prevention and treatment strategies can be found on the Wyoming Department of Health website.

PDMP Platform Transition

The Board will be transitioning to the Bamboo Health (formerly known as Appriss Health) PMP AWARxE platform in the first half of 2022. Bamboo Health provides its prescription drug monitoring program (PDMP) platform to 44 of the 54 state and US territory PDMPs, as well as the Military Health System. The anticipated go-live date for the Board to transition to Bamboo Health is July 1, 2022. The Board will provide more information to PDMP users as it progresses through the migration process, such as dates when users may register with the new platform, training resources, and user guides. Please monitor your email and the Board's website to stay up to date.

Electronic Prescribing of Controlled Substances

In 2019, the Wyoming Legislature passed SF0047, requiring practitioners to submit electronic prescriptions for controlled substances (EPCS) in Wyoming. This requirement went into effect on January 1, 2021. The Board promulgated rules and provided exemptions to the electronic prescribing requirement. These may be found in the Wyoming Controlled Substances Act Rules Chapter 10 Section 5.

During the Board's December meeting, the Board had a discussion around the approach that Board staff will be taking to ensure compliance with the EPCS requirement. The Board will be issuing letters to the providers who appear to be unable to prescribe controlled substances electronically and working with them directly. Pharmacy licensees may receive letters or correspondence from Board staff requesting records or other information to help assist in these matters.

Clozapine REMS

By Laken Mitchell, PharmD Candidate

The clozapine risk evaluation and mitigation strategy (REMS) program was updated and opened for re-enrollment on August 16, 2021. This update changed the verification of safe use for pharmacists. It also introduced a new patient status form.

Clozapine is a second-generation (atypical) antipsychotic with labeled indications for treatment-resistant schizophrenia, suicidal behavior in schizophrenia, or schizoaffective disorder. Off label, it is also used for treatment-resistant bipolar disorder, treatment-resistant psychosis/agitation, and psychosis in Parkinson's disease. Clozapine is available as a tablet or oral suspension.

Clozapine REMS is required due to the risk of severe neutropenia. Severe neutropenia is defined as having an absolute neutrophil count (ANC) less than 500/µL. ANC is the total white blood

cell count multiplied by the total percentage of neutrophils. ANC is also often available from a complete blood count with differential. Severe neutropenia can increase the risk of serious infections and death. The risk of neutropenia has not been found to be dose related and is often higher during the first 18 weeks of treatment. Patients of African and Middle Eastern descent should be tested for benign ethnic neutropenia (BEN); this should be noted in the patient's REMS for correct monitoring. BEN does not increase a patient's risk of clozapine-induced neutropenia. Before patients begin treatment, baseline ANC should be drawn, and should be at least 1,500/μL for the general population and at least 1,000/μL for patients with BEN diagnosis. All patients should be monitored weekly during the first six months of treatment. During the second six months of treatment, monitoring can be reduced to every two weeks if the ANC remains within range. After the first year of treatment, monitoring can be completed monthly if the ANC continues to be normal. If a patient's clozapine is discontinued for more than 30 days, the monitoring should start over and be treated as new patient monitoring.

Both inpatient and outpatient pharmacies must be certified with clozapine REMS before they can purchase and dispense clozapine. Certification requires an authorized representative to certify the pharmacy online or by fax. This person can be a pharmacy manager, staff pharmacist, director of pharmacy services, or corporate executive overseeing pharmacy services. For certification, the authorized representative should review the guide for pharmacists, complete the knowledge assessment successfully, and complete the enrollment form. They should then train all staff on dispensing clozapine and put clozapine verification procedures in place. Newly added is the REMS dispense authorization (RDA) form for pharmacists to determine if a patient is authorized to receive clozapine. This can be done in one of two ways: by calling the contact center or using the website. A dispense rationale may also now be used if the patient status form has not been completed within the last 37 days and the authorized representative of the pharmacy has a current ANC from the patient within range. An RDA will be issued for each fill based on prescriber recommendations and labs. Quantity dispensed should be enough for treatment until the next labs are scheduled.

To be able to prescribe and manage a patient's clozapine, prescribers must be certified with the clozapine REMS program. Prescribers can become certified by reviewing the prescriber's guide, successfully completing the knowledge assessment, and completing the prescriber enrollment form. Prescribers must also register new patients in the clozapine REMS program. This can also be done on the website or by fax. In addition, patients must be counseled on the risk of severe neutropenia. Prescribers are required to monitor the patient's ANC according to the requirements previously mentioned. Newly added is that prescribers must submit each patient's ANCs to the clozapine REMS program monthly using the patient status form. This can be done by submitting all the month's labs at once or submitting each lab as it is obtained. Prescribers must provide authorization to continue treatment if the patient's ANC results meet the criteria for discontinuation or interruption of treatment.

FDA Is Temporarily Exercising Enforcement Discretion

The new clozapine REMS program was officially launched on November 15, 2021. Upon launch, there were some issues with the program. These issues included high call volumes with long wait times. FDA is now working closely with the program to ensure that patient care is continuous. Because of the problems that pharmacists and prescribers are experiencing, FDA has temporarily suspended some of the REMS program requirements. Pharmacists are currently allowed to dispense clozapine without an RDA. Wholesalers do not have to confirm enrollment in the REMS program before shipping clozapine to pharmacies and health care settings. Pharmacists and prescribers should continue to work with the clozapine REMS program to become certified. There is currently no end date for these suspended requirements; FDA is continuing to monitor the situation. Updates can be found on the FDA website.

Recent Disciplinary Actions

P.C., RPh, #4068; F.F., RPh, #3858; J.N., RPh, #3638; H.T., RPh, #4098; S.B., RPh, #2338; T.U., RPh, #2558; C.E., RPh, #2158; L.L., RPh, #2878; D.R., RPh, #2638; J.M., RPh, #4058; T.B., RPh, #2858; B.E., RPh, #4198; D.E., RPh, #3258; V.N., RPh, #2088: Failed 2021 continuing education (CE) audit. Required to pay administrative penalty of $500 and complete an additional 12 hours of CE for subsequent renewal, with three hours pertaining to pharmacy law.

M.D., RPT, #T2358: Failed 2021 CE audit. Required to pay administrative penalty of $150 and complete an additional six hours of CE for subsequent renewal, with three hours pertaining to pharmacy law.

T.M., RPT, #T2325: Failed 2020 CE audit. Required to pay administrative penalty of $150 and complete additional six hours of CE for subsequent renewal, with three hours pertaining to pharmacy law.

S.P., RPh, #2048; L.H., RPh, #1938; K.L., RPh, #2028; T.B., RPh, #2538: Failed to obtain required CE for 2021 license renewal. Surrendered license to practice pharmacy in the state of Wyoming.

Resident pharmacy license #52-03663: Medication error – filled the wrong strength of a medication that resulted in adverse effects experienced by patient. Required to pay administrative penalty of $2,000.

Resident pharmacy license #52-82718; nonresident pharmacy license #10-68469: Medication error by central fill and dispensing pharmacy that resulted in patient receiving wrong medication. Required each pharmacy involved to pay administrative penalty of $2,000.

M.R., RPh, #3047; M.G., RPh, #3667: As pharmacist-in-charge of respective pharmacies, allowed their pharmacy to mail medications into states where the pharmacy was not licensed. Issued a letter of admonition and was required to complete six hours of CE, specifically on pharmacy law, in addition to the annual CE requirement earned in 2021 for renewal of a pharmacist license for 2022.

J.S., RPh, #3747; Habitual use of alcohol and violating the code of ethics: Required to enter into and comply with a two-year monitoring agreement with the Wyoming Professional Assistance Program (WPAP). Upon successful completion of this monitoring agreement, required to complete an annual evaluation with WPAP for a period of three years and to comply with any WPAP recommendations made pursuant to each evaluation.

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