September 2020

Wyoming State Board of Pharmacy News

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Rule Revisions Signed by Governor Gordon

The changes to the Wyoming Pharmacy Act Rules and Regulations Chapters 10 and 16, and the new Chapter 9 of the Wyoming Controlled Substances Act Rules and Regulations were approved and signed by Governor Mark Gordon on July 1, 2020. The updated chapters are posted on the Wyoming State Board of Pharmacy's website, and can also be found on the Wyoming Administrative Rules website at *rules.wyo.gov.*

Board Meeting Location Change

The next Board meeting is September 9-10, 2020. It will be held in Public Meeting Room 5 at the Wyoming State Capitol, 200 W 24th St in Cheyenne, WY. Based on current health orders, the room is set up to maintain six feet of distance per chair and the room can only seat 13 people in the audience. Attendees are encouraged to wear face masks and to observe social distancing. Please contact the Board office in advance if you wish to attend in person as space will be limited. Virtual participation is encouraged. Participants may join through Google Hangouts. The Google Hangouts meeting information will be posted on the Board's website.

Influenza Vaccinations Are Important During the COVID-19 Pandemic

By Rebecca Darling, PharmD Candidate

During the current coronavirus disease 2019 (COVID-19) pandemic, it is important to decrease the strain on the health care system due to respiratory illnesses and protect vulnerable populations at risk for severe illness. Pharmacists are in a unique position to advance public health through immunization advocacy and assist with disease prevention by promoting vaccination among their communities. High-risk populations likely to have complications from influenza infections (eg, people with diabetes, asthma, heart disease, or who are pregnant or immunocompromised) can be identified by pharmacists and educated to reduce the spread of influenza.

In addition to vaccination, pharmacists can collaborate with providers to recommend treatment and prophylaxis to eligible individuals who develop or are exposed to influenza. In preparation for the upcoming influenza season, it is important to communicate the benefit of vaccination to patients, parents, and caregivers to help reduce the number of cases and potential hospitalizations due to complications.

The Centers for Disease Control and Prevention (CDC) recommends that anyone six months and older receive the annual influenza vaccine to decrease influenza-associated morbidity and mortality. Pharmacists who are licensed and hold an immunization registration from the Board may prescribe and administer influenza immunizations to healthy people age seven or older. It is advised that individuals receive the influenza vaccine in the months of September or October, but a vaccine should still be given later in the season if a person missed that window. Pharmacists should make use of every opportunity during the influenza vaccination season to administer influenza vaccines to all eligible people, including, but not limited to, essential workers, people at an increased risk for severe illness from COVID-19, and people at risk for influenza complications.

The CDC recommends that vaccinations should be deferred for suspected or confirmed COVID-19 patients until criteria for isolation has been met. The isolation protocols suggested by the CDC include both a time-based and test-based strategy.

- Test-based strategies require a negative result from a Food and Drug Administration emergency use authorized COVID-19 molecular assay for the detection of SARS-CoV-2 RNA from at least two consecutive respiratory specimens collected more than 24 hours apart.
- Time-based strategies for patients with COVID-19 and symptoms state at least three days have passed since resolution of fever without using fever-reducing medications, improvement in respiratory symptoms, and at least 10 days have passed since symptoms first appeared.
- For patients who have **not** had COVID-19 symptoms but tested positive suggests that at least 10 days have passed since the first positive COVID-19 test was taken and no symptoms have developed.

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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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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- Patients known to have been exposed to COVID-19 should isolate for at least 14 days of quarantine unless symptoms develop, then follow the symptomatic recommendations.

The upcoming influenza season will bring new opportunities for pharmacists to educate patients about the importance of immunization. Pharmacists can empower patients to take charge of their health. Through education and advocacy, pharmacists can help reduce influenza-related illness and hospitalization, potentially prevent influenza-related death, and help reduce any further strain on the health care system. For more information about CDC guidelines for influenza vaccinations during the COVID-19 pandemic, please visit the CDC website at *www.cdc.gov.*

Summary of Comments Received Regarding Rule Revisions

Wyoming Controlled Substances Act Rules and Regulations Chapters 6 and 10

Chapter 6. Issuing, Filing, and Filling of Prescriptions: The Board proposed to repeal Chapter 6 and create Chapter 10 of the Controlled Substances Act Rules and Regulations to simplify, modernize, and reorganize the rules. Chapter 10 is also being created to provide exemptions to Wyoming Statute §35-7-1030, which requires that all controlled substances (CS) be electronically prescribed. No written or verbal public comments were received regarding the repeal of Chapter 6.

Chapter 10. Issuing and Dispensing Prescriptions for CS: The Board received a total of four comments during the public comment period. The Board did not receive a request to hold a public hearing on the proposed changes. One comment from a Wyoming dentist opposed the statutory requirement that all CS be electronically prescribed. Two of the comments received were in support of the proposed changes and one was neutral. These three comments provided information that included:

- language from the federal Controlled Substances Act, specifically 21 United States Code 829, 21 Code of Federal Regulations (CFR) 1306.13, and CFR 1306.21;
- language from the SUPPORT for Patients and Communities Act; and
- language from the previous Chapter 6: Issuing, Filing, and Filling of Prescriptions.

The Board met and discussed the public comments that were received on August 5, 2020. The Board believes that there are two changes that should be made based on the public comments and that these changes are logical outgrowths from those comments. The proposed changes are:

Proposed Amendment #1 (Revisions Emphasized):

Section 9. Partial Filling of Controlled Substances.

a. A Schedule II controlled substance prescription may be partially filled if:
   (i) The patient or practitioner requests a partial fill; or
   (ii) The pharmacist is unable to supply the full quantity prescribed; and
   (iii) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
   (iv) The remaining portions of the partially filled Schedule II controlled substance prescription is dispensed no later than thirty (30) days, or sixty (60) days for terminally ill or long term care facility patients, after the date on which the prescription is issued.
   (v) If the pharmacist is unable to supply the full quantity prescribed, the remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Chapter 6 had language that addressed the 72-hour period wherein a Schedule II CS could be partially filled. The Board chose to leave that language out of Chapter 10 because it is believed that the new language would cover the situations when a Schedule II CS would need to be partially filled. Given the comments received, the Board believes it needed to be included. The Board also believes this change should be made to align with the federal Controlled Substances Act, and that this change provides for situations when a pharmacy needs to partially fill a CS prescription that was issued more than 30 days before the fill date.

Proposed Amendment #2 (Revisions Emphasized):

Section 7. Dispensing Controlled Substance Prescriptions.

a. The pharmacist or employee under supervision shall verify the identity of the person who presents a non-electronic controlled substance prescription or receives any controlled substance prescription.
   (i) Identification may be done by visual recognition.
   (ii) Identification may be verified by state ~~**and**~~ **or** federally issued identification.
   (iii) The pharmacist or employee shall record the individual's name, identification, and identification number, **or if visually identified, the individual's name.**

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(iv) The recorded information shall be readily retrievable.

The Board believes this change should be made to clarify the record keeping and identification requirements. The Board also noted in the discussion that in item (ii) the language should be "or," not "and." The Board did not intend to require individuals presenting non-electronic prescriptions to have to provide both a federal and state identification.

CE Requirement for 2021 Renewal

The 2019 Wyoming Legislature amended Wyoming Statute 33-24-121(d) to require one and one-half hours of continuing education (CE) related to the responsible prescribing of CS annually as part of the 12-hour CE requirement. This act went into effect July 1, 2019. Pharmacists who hold an immunization registration from the Board are also required to complete a minimum of one contact hour of CE related to immunizations annually. Failure to complete these CE requirements may be grounds for discipline.

50 Years as a Wyoming Pharmacist

The following pharmacists will be honored at the Wyoming Pharmacy Association November 2020 convention in Cheyenne for having a Wyoming license for over 50 years:

- Wade A. Buchanan #1764
- Carol Darlington #1769
- George Darlington #1770
- Lane Rolland #1773
- Ronald Wendling #1775
- John Woodbury #1776

The following pharmacists were honored at last year's Wyoming Pharmacy Association convention in Casper, WY, for having a Wyoming license for over 50 years:

- Felix Mercado #1740
- Steven Flora #1759

Congratulations!

Recent Disciplinary Actions

Pharmacy License #52-82718: Filled and dispensed prescriptions under the incorrect prescriber. The pharmacy was required to pay an administrative penalty of $8,000 and provide a plan outlining the steps that will be used to ensure that incorrect prescriber errors are prevented and corrected when discovered in the future and that all current and future pharmacists and pharmacy technicians have received training in incorrect prescriber error prevention and correction.

B.H., Pharmacist License #3857: As pharmacist-in-charge (PIC), allowed the pharmacy to mail medications into a state where the pharmacy was not licensed. Issued a letter of admonition and was required to complete six hours of CE, specifically 3.0 hours on pharmacy law and 3.0 hours on patient safety, in addition to the annual CE requirement earned in 2020 for renewal of a pharmacist license for 2021. (Total earned in 2020 must be 18 hours).

M.M., Pharmacist License #3166: As PIC, allowed a technician-in-training to work on an expired permit. Required to pay an administrative penalty of $1,000, to submit a plan for preventing unlicensed practice in the future, and to complete three hours of CE on the topic of pharmacy law, in addition to the annual requirement. (Total earned in 2020 must be 15 hours).

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