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News

State of Ohio Board of Pharmacy

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From the Director's Desk

Dear Ohio Pharmacist,

As part of a coordinated response to coronavirus disease 2019 (COVID-19), the state has launched *coronavirus.ohio.gov*. The Ohio Department of Health (ODH) has published materials, including COVID-19 checklists for businesses and employers, family and individuals, health care providers, and pharmacies. ODH is also committed to providing confirmed case numbers updated daily at 2 PM.

Additionally, ODH has also launched a call center to answer questions regarding COVID-19. The call center will be open seven days a week, from 9 AM – 8 PM, and can be reached at 1-833/4-ASK-ODH (1-833/427-5634).

The State of Ohio Board of Pharmacy is committed to protecting the health and safety of Ohioans during the COVID-19 outbreak. The Board posted a document on its website that provides COVID-19 guidance and response efforts, including the issuance of waivers to assist licensees in addressing operational needs. This document will be updated regularly and can be accessed by visiting *www.pharmacy.ohio.gov/COVID*.

If you have any questions, please do not hesitate to contact the Board via contact@pharmacy.ohio.gov or 614/466-4143.

Sincerely,

Steven W. Schierholt, Esq
Executive Director
State of Ohio Board of Pharmacy

Reminder: DEA Guidance on Oral Schedule II Prescriptions

Drug Enforcement Administration (DEA) is aware that during the COVID-19 pandemic there are obstacles to practitioners meeting with their existing patients and providing these patients with written prescriptions for Schedule II controlled substances (CS). As a result, practitioners and pharmacists have asked DEA to clarify the circumstances under which oral Schedule II prescriptions are permitted. DEA has issued guidance on this topic and has also announced temporary exceptions. This guidance has been posted to the Board's website and can be accessed here.

Please be advised that the Board, pursuant to a resolution adopted on March 2, 2020, hereby authorizes the exceptions in DEA guidance for the duration of the public health emergency or unless modified or withdrawn by DEA.

Compounding of Certain Alcohol-Based Hand Sanitizer Products

Food and Drug Administration has issued additional guidance permitting the use of alcohol (ie, ethanol or ethyl alcohol) produced by alcohol production firms to be used as the active pharmaceutical ingredient in alcohol-based hand sanitizers for consumer and health care personnel use for the duration of the COVID-19 public health emergency, which was declared by the secretary of the United States Department of Health and Human Services on January 31, 2020. The Board's updated guidance on compounding alcohol-based hand sanitizer products can be accessed here.

Annual CS Inventory Requirements Updated March 31, 2020

In order to provide pharmacies added flexibility during the COVID-19 outbreak, the Board has adopted the following guidance for compliance with annual CS inventory requirements pursuant to Rule 4729:5-3-07 of the Ohio Administrative Code (OAC). This guidance

Continued on page 4

National Pharmacy Compliance News

May 2020

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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

Continued from page 1

is being issued in accordance with a Board resolution adopted on March 2, 2020. For any annual CS inventory that is required between March 2, 2020, and June 30, 2020, the Board is extending the date to obtain the annual inventory to August 1, 2020. The inventory must incorporate the additional months included as part of the extension period.

Emergency Rule for Dispensing Chloroquine and Hydroxychloroquine – Effective March 22, 2020

On March 22, 2020, Governor Mike DeWine authorized the Board to file emergency Rule 4729-5-30.2 of the OAC, which reads:

4729-5-30.2 – Prescription requirements for chloroquine or hydroxychloroquine

(A) Unless otherwise approved by the board's executive director, no prescription for chloroquine or hydroxychloroquine may be dispensed by a pharmacist or sold at retail by a licensed terminal distributor of dangerous drugs unless all the following apply:

(1) The prescription bears a written diagnosis code from the prescriber;

(2) If written for a COVID-19 diagnosis, the diagnosis has been confirmed by a positive test result, which is documented on the prescription and both of the following apply:

(a) The prescription is limited to no more than a fourteen-day supply; and

(b) No refills may be permitted unless a new prescription is furnished.

(B) Prescriptions for either presumptive positive patients or prophylactic use of chloroquine or hydroxychloroquine related to COVID-19 is strictly prohibited unless otherwise approved by the board's executive director in consultation with the board president, at which time a resolution shall issue.

This rule is now effective and enforceable. To assist licensees in complying with this rule, the Board has developed the following frequently asked questions document available at *www.pharmacy.ohio.gov/COVIDrx.*

Registered Pharmacy Technician Renewal Deadline Extended to July 29, 2020

On March 16, 2020, the Board authorized the extension of the registered pharmacy technician renewal deadline to July 29, 2020. Registered pharmacy technicians who have not yet renewed have until July 29, 2020, to renew as well as complete the continuing education requirements. Any registration renewed after the expiration date of July 29, 2020, will be assessed a late fee.

A helpful step-by-step guide with information on how to renew is available at *www.pharmacy.ohio.gov/techrenewalguide.*

Important: If a registered pharmacy technician has obtained a national certification (eg, Exam for the Certification of Pharmacy Technicians or Pharmacy Technician Certification Board exam), he or she can apply as a certified pharmacy technician. A registered pharmacy technician who obtains registration as a certified pharmacy technician prior to the expiration of his or her current registration will not be required to renew. A technician must submit a new application and fee in order to obtain a certified pharmacy technician registration. Submission of a certification will not update the registration to certified pharmacy technician.

Mandatory Statewide Inventory of Ventilators and Other Breathing Devices

Governor DeWine announced on March 31 that Ohio is taking action to gather a statewide inventory of ventilators and other machines and devices that provide breathing assistance.

ODH Director Amy Acton issued an order requiring weekly online reporting of these devices by any entity in the supply chain, from creation through end use. Example entities include manufacturers, producers, wholesalers, transporters, distributors, retailers, physicians, clinics, hospitals, and medical facilities.

Along with mechanical ventilators, other devices to be reported are CPAP and BiPAP machines commonly used to treat sleep apnea, as well as anesthetic machines, and various treatment masks and tubing.

Exemptions include:

- ventilators in the possession of individuals for personal use; and

Continued on page 5

Continued from page 4

- ventilators that are in transit across Ohio but are being delivered from and to other states.

Inventory is to be reported online at *http://coronavirus.ohio.gov/VentInventory* each Wednesday by 5 PM.

Hospitals must also continue to report daily ventilator data through the Ohio Hospital Association reporting tool.

OARRS Update — ICD-10 Codes

Per Rule 4729:8-3-02 of the OAC, the Ohio Automated Rx Reporting System (OARRS) continues to monitor and audit pharmacies for the inclusion of ICD-10 codes when reporting a prescription to OARRS. This information should be reported to OARRS in field DSP25 of your version ASAP 4.2A upload. Please address this with your software vendors to be sure that they are using ASAP 4.2A and including the information in the correct field. Entering the ICD-10 code in a different field (such as "Rx Notes" or "PA") may not get reported to OARRS, making the pharmacy noncompliant to this reporting element. In some software systems, it may not be clear in which field the ICD-10 code needs to be entered as the field may be named something like "Med Con" or "DX." Electronically received prescriptions may have the ICD-10 code translating to a field not on your home screen.

It is the responsibility of the pharmacist to contact his or her software vendors to learn where the ICD-10 needs to be so that it translates to ASAP 4.2 field DSP25 to get transmitted to OARRS. Also, audits are revealing pharmacists are not recording ICD-10 codes on verbally received CS prescriptions. The rule requires all CS to be recorded, regardless of schedule or the CS being prescribed.

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