



State of Ohio Board of Pharmacy

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77 S High St, 17th Floor • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

From the Director's Desk

Dear Ohio Pharmacist,

In August 2020, the United States Department of Health and Human Services (HHS) issued a third amendment to the Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to increase access to lifesaving childhood vaccines and decrease the risk of vaccine-preventable disease outbreaks as children across the US return to day care, preschool, and school.

The federal amendment authorizes state-licensed pharmacists – and pharmacy interns acting under their supervision to administer vaccines, if the pharmacy intern is licensed or registered by his or her state board of pharmacy – to order and administer vaccines to individuals ages three through 18 years, subject to several requirements.

Additionally, HHS also released guidance authorizing the administration of coronavirus disease 2019 (COVID-19) vaccines and immunity under the PREP Act. This guidance authorizes state-licensed pharmacists to order and administer – and state-licensed or registered pharmacy interns acting under the supervision of the qualified pharmacist to administer – COVID-19 vaccinations to persons ages three or older, subject to certain requirements.

These federal authorizations differ from Ohio requirements. Therefore, to assist licensees in complying with federal and/or state requirements, the State of Ohio Board of Pharmacy published several guidance documents:

- ◆ Administration of Childhood Vaccines during the COVID-19 Pandemic: www.pharmacy.ohio.gov/CV2020
- ◆ Administration of COVID-19 Vaccines during the COVID-19 Pandemic: www.pharmacy.ohio.gov/COVIDvaccine

As a reminder, there is an option on the Board's website to subscribe to updates. Licensees can choose to sign up

for automatic email alerts regarding laws and rules, license renewal, and Board publications. Subscribe to updates at www.pharmacy.ohio.gov/RSS/Subscription.aspx.

At this time, Board staff continue to work remotely. If you have any questions, please do not hesitate to contact the Board by email at contact@pharmacy.ohio.gov or phone at 614/466-4143.

Sincerely,

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

Board of Pharmacy Warns of Increasing Extortion Scam Calls During COVID-19

The Board continues to receive reports of scams threatening legal action if an exorbitant fine is not paid immediately over the phone. The callers identify themselves as either Board or Drug Enforcement Administration (DEA) personnel and instruct their victims to pay a "fine" via wire transfer to avoid arrest, prosecution, imprisonment, and/or license revocation.

The reported scam tactics are continually changing, but share many of the following characteristics:

- ◆ Callers use fake names and badge numbers or names of well-known senior officials.
- ◆ The tone of calls is urgent and aggressive; callers refuse to speak or leave a message with anyone other than the person for whom they are calling.
- ◆ Callers threaten arrest, prosecution, imprisonment, and license revocation.
- ◆ Callers demand thousands of dollars via wire transfer or in the form of untraceable gift cards.
- ◆ Callers falsify the number on caller IDs to appear as a legitimate phone number.

National Pharmacy Compliance News

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NABPF

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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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

“Even during this global pandemic, we have continued to prioritize addressing the opioid crisis,” said FDA Commissioner Stephen M. Hahn, MD, in a press release. “Today’s action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family.”

The complete list of changes is available through an July 2020 [Drug Safety Communication](#).

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would

still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the [announcement](#) published in the *Federal Register*, this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients



This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have

you experienced a medication error or close call? Report such incidents in confidence to ISMP’s National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fentaNYL patches for elderly patients. In most cases, the pharmacists reviewing the patients’ orders determined that the fentaNYL patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fentaNYL patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fentaNYL patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fentaNYL patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fentaNYL patch. The ED physician reported that the resident had received "three small IV push doses" of fentaNYL in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fentaNYL patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fentaNYL patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fentaNYL patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fentaNYL patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

FentaNYL patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fentaNYL patches for opioid-naïve patients and/or patients with acute pain in our [Targeted Medication Safety Best Practices for Hospitals](#). In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might

help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fentaNYL patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fentaNYL patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the [HHS Fact Sheet](#).

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

Continued from page 1

- ◆ Callers often ask for personal information, such as Social Security number or date of birth.
- ◆ When calling a medical practitioner, callers often reference National Provider Identifier numbers and/or state license numbers and threaten revocation of the license.

The Board would like to remind you to stay vigilant to avoid scammers. Board and DEA employees do not contact health care providers or members of the public by telephone to demand money or any other form of payment.

Anyone receiving a telephone call from a person purporting to be a Board or DEA employee seeking money should refuse the demand and report the threat using the Board's online complaint form and DEA's online form. Reporting scam calls will greatly assist the Board and DEA in investigating and stopping this criminal activity.

Board Encourages All Licensees to Review DEA and NABP Guidance on Pharmacy Robberies and Burglaries

The Board would like to remind all pharmacists and pharmacy staff that pharmacy robberies and burglaries can and do occur. In an effort to safeguard licensees, the Board recommends that all pharmacy personnel familiarize themselves with joint guidance issued by DEA and the National Association of Boards of Pharmacy® (NABP®). This guidance can be accessed at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf.

Reminder: Enforcement of USP Chapters <797> and <795> Compounding Standards

In June 2019, the US Pharmacopeial Convention (USP) released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of General Chapters <797> and <795>. Because of pending appeals, the effective date of the revised chapters is postponed until further notice.

To ensure compliance, compounding pharmacies are reminded that the Board is conducting compliance inspections using the current version of USP Chapter <797> (last revised in 2008) and USP Chapter <795> (last revised in 2014) – not the revised version released in June 2019, which is currently on hold pending further review.

Please be advised that any change in compounding enforcement standards will be communicated to licensees well in advance of implementation. For more information about the USP revision process, visit the following links:

- ◆ USP Chapter <797>: www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-797-rbnotice-20200424.pdf
- ◆ USP Chapter <795>: www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-795-rbnotice-20200424.pdf

Reminder: Temporary Extension of Basic Life-Support Requirements

To address limited access to basic life-support training recertification, the Board has adopted the following guidance regarding certifications maintained by Ohio pharmacists and pharmacy interns.

Pharmacists and pharmacy interns whose basic life-support training certification is set to expire on or after March 1, 2020, will be permitted to continue to administer immunizations and dangerous drugs in accordance with Ohio Revised Code Section 4729.41 under the following conditions:

- ◆ The pharmacist or intern maintains documentation demonstrating that his or her basic life-support training certification expired on or after March 1, 2020.
- ◆ The pharmacist or intern obtains recertification no later than December 1, 2020 (formerly July 29, 2020).

Important: Unless circumstances warrant, the Board does not expect to extend this requirement past the new December 1, 2020 deadline. Licensees should plan to have their basic life-support training recertification current by December 1, 2020.

A copy of this updated waiver can be accessed at www.pharmacy.ohio.gov/BLS2020.

Reminder: New Outpatient Pharmacy Rules Effective December 1, 2020

Effective December 1, 2020, new rules for outpatient pharmacies (Chapter 4729:5-5 of the Ohio Administrative Code) go into effect. To assist licensees in complying with the new rule chapter, the Board recently published an outpatient pharmacy inspection guide that can be accessed [here](#).

The inspection guide aligns with internal guidance used by Board inspectors and allows licensees to conduct self-inspections to ensure compliance. The guide also includes links to the new rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board.

Continued on page 5

Continued from page 4

Reminder: Outpatient Inspection Guide Continuing Education Opportunity

To assist with the implementation of the new outpatient pharmacy rules, the Board has developed a one-hour jurisprudence quiz. This quiz is intended to test a participant's knowledge of the new outpatient pharmacy rules and provides one contact hour (0.1 CEU) of Board-approved jurisprudence for pharmacists and registered pharmacy technicians.

For more information on the quiz, visit www.pharmacy.ohio.gov/OPquiz.

OARRS Account Update and Delegate Reverification Workflow

A new process requiring biannual verification of account details and delegates will ensure accuracy and security of Ohio Automated Rx Reporting System (OARRS) data.

Since September 30, 2020, OARRS users are prompted to update or confirm their PMP AWARD_xE profile information on a biannual basis. The purpose of this verification requirement is to ensure that all OARRS profile information is up to date and accurate.

Additionally, OARRS will also be requiring semi-annual confirmation of all linked delegates to protect the security of the patient data in the system.

Emails to account holders indicating they have 45 days to complete this verification process were sent as of September 30, 2020.

OARRS account holders are strongly encouraged to log in to their accounts to verify the required information. Failure to confirm account details and delegates may disrupt user access, including delegate access.

Important: This provision will not impact integrated systems where OARRS information is directly accessed via an electronic medical record or pharmacy dispensing system.

For more information on these processes, the Board has developed the following guidance documents:

- ◆ **Delegate Reverification Workflow:** www.pharmacy.ohio.gov/workflow
- ◆ **OARRS Account Update:** www.pharmacy.ohio.gov/accountupdate

Account holders should review these documents for any questions. For additional inquiries, account holders should contact the OARRS Department by email at support@pharmacy.ohio.gov.

Page 5 – November 2020

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Steven W. Schierholt, Esq - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor &
Executive Editor
Amy Sanchez - Communications Manager
