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News

Alabama State Board of Pharmacy

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Regulatory Requirements You Should Know

The Alabama State Board of Pharmacy has been made aware that practitioners may not have knowledge of or may be confused about some Drug Enforcement Administration (DEA) and other regulatory agency requirements. These requirements and/or communications are set out below per Title 21 Code of Federal Regulations (CFR); Part 1301: Registration of manufacturers, distributors, and dispensers of controlled substances.

Responsibility to Report

§1301.91 Employee responsibility to report drug diversion

> Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has **an obligation to report** such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy. (emphasis added).

Employment Restrictions

§1301.76 Other security controls for practitioners

> (a) The **registrant shall not employ,** as an agent or employee who has access to controlled substances [CS], any person who has been convicted of a felony offense relating to [CS] or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term 'for cause' means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of [CS]. (emphasis added)

A waiver may be applied for with DEA. If granted, the waiver should be kept on file and made available for inspection if requested.

OSHA Bloodborne Pathogen Training

Bloodborne pathogen training is a requirement by the Occupational Health and Safety Administration (OSHA) for employers with facilities incurring possible exposure to blood, blood products, or other potentially infectious materials. The OSHA training requirement is part of the OSHA Bloodborne Pathogens Standard (Title 29 CFR 1910.1030). The requirements state what employers must do to protect employees.

The requirements in their entirety may be found by visiting *www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030.*

While the Board does not currently have specific requirements for immunization training and education, the Board does require pharmacists/pharmacies to comply with all state and federal regulations.

DEA Theft or Loss Notification Requirements

An email address has been established for registrants within the state of Alabama to report thefts and significant losses of CS. Below is communication regarding this notification process from DEA:

Effective immediately, the New Orleans Field Division has created an email address (BDO.theftorloss@usdoj.gov) to facilitate registrants located within the state of Alabama in notifying the field office of significant theft or losses of CS as required by federal regulation. This email address was created to enable registrants to meet the initial notification requirement of the regulation.

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National Pharmacy Compliance News

November 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.

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

ISMP Institute for Safe Medication Practices An ECRI Affiliate

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 fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** 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 fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** 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 fenta**NYL** 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 fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** 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 fenta**NYL** 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 fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** 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 fenta**NYL** 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 fenta**NYL** 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 fenta**NYL** 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."

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The regulation governing the reporting of thefts and losses of CS is outlined in Title 21 CFR §1301.76(b), which is provided below for your convenience.

Title 21 CFR §1301.76(b) states in part, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft."

The regulation has a two-part requirement consisting of the **initial notification via email** and the completion of **online DEA Form 106.**

Please click or copy and paste the URL: *www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html* into your browser for the completion of DEA Form 106. Please do not print and email a copy of DEA Form 106 to the email address provided above.

Change of Supervising Pharmacist

Incoming or departing supervising pharmacists are required to notify the Board within 10 days of their position changes. This also applies to temporary changes in position (eg, medical leave).

Online forms for change of supervising pharmacist and temporary change of supervising pharmacist are available. These forms may be accessed on the Board's website.

1. Visit *https://www.albop.com*
2. Choose Applications and Forms on the right side of the web page
3. Scroll to Pharmacists, In-State Pharmacies, or Non-Resident Pharmacies and choose "Change of Supervising Pharmacist"
4. Choose temporary or permanent position change when prompted

Additionally, a link has been added under each category of license/permit for requesting a duplicate copy if needed.

Alabama Administrative Code Rule Changes

680-X-3-.03 Time and Method of Payment; Renewal and Non-Disciplinary Penalty for Late Renewal of Controlled Substances Permit

The rule change allows for a non-disciplinary penalty for a one-time only late renewal (by January 31) occurrence in compliance with all other applicable rules.

680-X-2-.04 Prescription Department Technical Equipment

This rule change was implemented to remove antiquated equipment requirements.

680-X-2-.14 The Role of Technicians in Pharmacies in Alabama

This rule change was to ensure accurate communication of requirements for each renewal cycle and implement background checks for technician reinstatements.

680-X-2-.23 Drug Manufacturers, Wholesale Distributors, Private Label Distributors, Repackagers, Third-Party Logistics, 503B Outsource

These rules were updated to add language consistent with federal requirements and provide clarity for new categories of facilities.

680-X-2-.37 Continuing Education for Pharmacy Technicians

This rule change updates the continuing education requirements timeline to coincide with renewal cycles.

680-X-2-.45 Noncontrolled Prescription Requirements

These rules provide clarity of requirements for non-controlled prescription documentation.

The new rules are effective as of October 15, 2020, and may be viewed on the Board's website under Statutes/Rules.

Board Reminders

Effective January 1, 2020, all newly registered technicians are required to complete a Board-approved training program within six months of registration. Because of the coronavirus disease 2019 pandemic, the deadline for all newly registered technicians has been extended to December 31, 2020, or six months from initial registration, whichever is later.

Pharmacist licenses and pharmacy permits are required to be renewed prior to December 31, 2020. Please ensure that all licenses/permits are renewed timely. It is highly recommended that pharmacists/entities do not wait until December to renew as that may cause a delay in processing/receiving the updated license. Failure of the license/permit renewal process to be completed by December 31 is the responsibility of the licensee/permitee, so please send in renewals timely and early. Any pharmacist or entity practicing pharmacy with an expired license or permit is subject to disciplinary action.

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