August 2019

News

Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

111 Village St • Birmingham, AL 35242 • Tel: 205/981-2280 • Fax: 205/981-2330

Alabama Pharmacists Beware

Investigators with the Alabama State Board of Pharmacy have seen an increasing number of fraud cases in pharmacies. There are a couple common scenarios that pharmacists should be aware of and avoid.

One scenario involves non-pharmacist owners and/or companies buying independent pharmacies and asking the independent owner to stay on to "aid in the transition" or continue his or her employment with the new owner. In almost every case, the pharmacist owner states that the offer accepted was "too good to pass up." In these situations, the new owner gradually infuses the business with faxed or electronic prescriptions from a location outside of the state. These prescriptions are being generated from call centers that are unethically obtaining patient information and manipulating patients into accepting prescriptions that are not needed, and all co-pays are waived. These prescriptions are refilled every month, regardless of whether the patient requests them or not. In many cases, the patients have asked for the prescriptions to be stopped, but the call center continues to transmit the prescriptions to the pharmacy.

In other cases, the prescriptions are processed and reimbursement is received, but the prescription is never physically filled or delivered. Some prescriptions are filled and mailed to the patient, at which time the patient will ship the prescription back due to the patient's lack of need for the prescription. However, the prescription is never reversed from the insurance, and the non-pharmacist owner and/or company retains the insurance reimbursement. To be valid, prescriptions must be the outcome of a patient-physician relationship. In this scenario, that relationship is questionable.

This is not to say that every non-pharmacist drugstore owner is unethical or committing fraud. However, as the old saying goes, if it is too good to be true, it probably is. Pharmacists should be inquisitive of any new processes or changes that do not seem right, or if the new owner cannot answer questions to the pharmacist's satisfaction.

A second scenario that is becoming increasingly common is the use of "menu" prescriptions, which allow pharmacists to choose which medications to dispense. These prescriptions are sourced through a sales force employed by the pharmacy owner, which works with a physician's office to identify patients. The prescriptions are faxed or electronically submitted from the physician's office with a statement similar to the following one.

> I authorize the pharmacist-in-charge to substitute the prescribed product that I prescribed with an alternate formula or product if the patient does not have insurance, has a high deductible or co-pay, or has an insurance policy that does not cover the particular product or compound I have prescribed.

Prescriptions bearing this type of statement are invalid, as this blanket statement is not compliant with the Alabama Practice of Pharmacy Act.

In addition, the prescription will have a "menu" of product options from which to choose. The interesting part is that every option has an extremely high reimbursement rate. In some cases, the items on the "menu" are injectable antibiotics with instructions for topical use. These particular items provide very lucrative reimbursement with **no** value to the patient. In most cases, using the injectable medication as a topical medication could have detrimental effects and/or lead to resistance to the antibiotic, rendering it useless when needed. In a few cases, the pharmacist questioned the owners as to the validity of the therapy. The owner produced articles as to the veracity of the therapy. However, if proper examination of the articles was done, the pharmacist would quickly realize that the therapy was not proper, and that dispensing the product would not only be unprofessional, but would be unethical at best and fraudulent at worst.

Continued on page 4

National Pharmacy Compliance News

August 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

Continued from page 1

Options on the "menu" may also contain ointments that are to be added to water for a "soak." Ointments do not dissolve and therefore would be useless in a soak. Pharmacists must use their professional judgment in ascertaining whether a prescription product is effective in the manner prescribed by the physician.

Pharmacists often speak of "corresponding responsibility" regarding the dispensing of controlled substances. It is important to note that **all** filled prescriptions require the pharmacist to ensure that the prescriptions are compliant with all federal and state laws and are for the health care benefit of the patient. Pharmacists have an ethical responsibility to be the advocate for the patient. Issues for the Board arise when the pharmacist loses sight of why he or she chose pharmacy as a profession or is manipulated by outside influences. Unfortunately, in those situations, not only is the offending pharmacist reprimanded and harmed professionally, the reputation of the profession as a whole is harmed as well.

If, at any time, a pharmacist is concerned that actions at his or her place of employment may be questionable, he or she should contact the Board. Investigators will aid in determining whether there is an issue and will work with the informing pharmacist to identify the next steps. As our illustrious attorney, James S. "Jim" Ward, Esq, always says, "When it comes to practicing pharmacy in Alabama, it is always better to ask permission than forgiveness."

2019 Legislative Session

The 2019 legislative session was extremely productive for the practice of pharmacy in Alabama.

The most monumental bill passed in 2019 addressed collaborative practice. Alabama had been one of only two states that did not have collaborative practice legislation.

House Bill (HB) 35, known as the collaborative practice bill, received unanimous support in both the Alabama State House of Representatives (96-0) and the Alabama Senate (27-0). Governor Kay Ivey signed the bill on June 4, 2019. Now known as Alabama Act 2019-368, this legislation requires the Alabama State Board of Pharmacy and the Alabama Board of Medical Examiners to complete the rule writing procedure before Alabama Act 2019-368's effective date of October 1, 2019.

This important legislation would not have been possible without the tireless efforts of the Alabama Pharmacy Association, Alabama Society of Health-System Pharmacists, Auburn University Harrison School of Pharmacy, Samford University McWhorter School of Pharmacy, and the Alabama pharmacists who advocated for the bill to gain support in both the House of Representatives and the Senate.

The bill's final passage was due to Representative Ron Johnson's skillful handling of the bill through the Alabama House of Representatives Insurance Committee and the House of Representatives floor to receive a unanimous vote there. Senator Tom Butler relentlessly pursued the bill and, with untiring efforts, achieved its unanimous passage by the Alabama Senate through a special order calendar. Health care in Alabama owes these legislators a debt of gratitude.

HB 7, known as the Venue Bill, was also passed and became Alabama Act 2019-357. This legislation allows for appeals from orders of the Board to be filed in the circuit court of the county where the aggrieved party resides or where the Board maintains its headquarters.

HB 34, which addresses pharmacy technician reinstatement, passed and became Alabama Act 2019-128. This legislation removes the five-year limit for reinstating the registration of a pharmacy technician without examination by the Board and limits the total penalties and lapsed fees.

HB 69, which addresses signature line requirements, also passed and became Alabama Act 2019-441. This legislation removes the requirement for an electronic, verbal, or e-fax prescription to contain two signature lines. This legislation also allows for a therapeutically equivalent product to be dispensed unless otherwise communicated by the prescribing physician.

The *Alabama State Board of Pharmacy News* is published by the Alabama 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.

Donna Yeatman, RPh, Executive Secretary - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager