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News

Massachusetts Board of Registration in Pharmacy

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Identification Requirements for CS Prescriptions

A pharmacy that dispenses federally designated controlled substances (CS) and Schedule VI prescription monitoring program (PMP) drugs (eg, gabapentin) is required to check that the photo identification (ID) matches the customer taking possession of the prescription, and that the ID is valid and not out of date.

A customer identifier is defined as the identification number on a valid government-issued ID, including state-issued ID, military ID cards, permanent resident cards, passports, driver's licenses, Massachusetts Commission for the Blind ID cards, or other ID as specified by the Massachusetts Department of Public Health.

The pharmacy may dispense medication to the patient or the patient's representative. For example, a parent may pick up a prescription for a child or a relative may pick up a prescription for a housebound family member. The pharmacy must check the ID of the person picking up the prescription.

However, there are situations when a pharmacy may dispense these medications without a customer's identification.

If the pharmacist has reason to believe that the failure to dispense the medication would result in a serious hardship for the patient, he or she may dispense it without identification if:

a. the reason is documented;
b. the patient or agent of the patient prints his or her name and address on the reverse side of the prescription and signs his or her name; or in the case of an electronic prescription, provides an electronic signature; and
c. the pharmacist enters "cust signed rx" in the PMP customer ID field (AIR05) rather than leaving the field blank.

Instructions, including a full list of acceptable customer identifiers, are detailed in the PMP Data Submission Guide.

MassPAT Integration Can Improve Pharmacy Workflow

Last June, the Massachusetts PMP presented to the Massachusetts Board of Registration in Pharmacy an update on efforts to integrate the Massachusetts Prescription Awareness Tool (MassPAT) directly into pharmacy software systems. Since then, the Massachusetts PMP has brought Walmart pharmacies, Boston Medical Center pharmacies, Cure-Aid pharmacies, and the Holyoke Health Center pharmacy live with the integration. The Massachusetts PMP is now looking to onboard additional facilities and will cover integration costs.

The integration fits seamlessly into the pharmacists' workflow, allowing them to view a patient's MassPAT prescription history directly within their pharmacy software system. This eliminates the need to log in to a separate web portal and enter the patient's information. Instead, the pharmacy is able to send an automatic query to MassPAT, which will return the patient's prescription information, viewable in the same system the pharmacist uses to fill a prescription.

Integration saves time and effort, and therefore it is not surprising that the Massachusetts PMP reports that patient searches have increased significantly at integrated pharmacies. This can only contribute to patient safety and better outcomes.

If your pharmacy is interested in integrating with MassPAT, please visit the MassPAT Electronic Health Record (EHR) Integration website and follow the steps there to review the MassPAT EHR Integration Welcome Packet, fill out the Integration Request Form, and then review and sign the terms and conditions.

The Massachusetts PMP is eager to work with you to improve pharmacist access to critical prescription history

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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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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information and to combat the opioid crisis in Massachusetts.

Reporting the Loss of CS – Update

On December 6, 2018, the policy detailing the requirements for reporting a theft or loss of CS to the Board was updated, and a new electronic fillable loss reporting form was instituted.

The updated policy requires pharmacies to email the Board within seven business days of the discovery of a **possible significant loss.**

Within the next **21 days,** or upon **completion of investigation, whichever comes first,** the pharmacy must then report to the Board the findings of its investigation. **Regardless of the outcome of the investigation, the pharmacy must submit the outcome of its investigation in accordance with the requirements defined in Board Policy 2018-05.**

If it is determined that **a significant loss did not occur,** the pharmacy must report back to the Board with a detailed description of the investigatory process that concluded no reportable loss occurred.

If the investigation **confirms a significant loss,** the report must be submitted within seven business days of confirming a significant loss.

The policy includes updated descriptions for types of losses, including those that are considered "not reportable." Non-reportable losses include insignificant losses and losses resulting from confirmed dispensing errors.

Common errors in reporting include untimely and incomplete submissions (eg, an incomplete reporting form or missing documentation requirements from Appendix I).

The reporting form must be completed electronically, and then emailed to dhpl-opp.admin@massmail.state.ma.us.

Getting to Know the Board Staff

This quarter, we are highlighting Board staff member **Ed Taglieri, MSM, NHA, RPh.** Ed is the current pharmacy substance use disorder (PSUD) program supervisor.

Ed graduated from Massachusetts College of Pharmacy and Health Sciences with a bachelor of science degree in pharmacy in 1982. Shortly after graduation, he discovered that he had a very strong interest in health care management. This encouraged him to start his own business, a home health care agency called Health Force, to which he dedicated the next twenty years of his career.

In 2013, Ed was chosen to be a Board member and he filled the long-term care pharmacist seat on the Board. He served as president during his fourth year on the Board and remained a Board member until early August 2017.

During his fifth and final year on the Board, the newly instituted position of PSUD program supervisor became available, which caught Ed's attention. "It was a combination of my entire career, as I encountered cases of employees diverting medications due to substance use disorders in my previous jobs," Ed explained. He began working full-time as the PSUD program supervisor in late August 2017.

Ed enjoys the diversity of this job, in that he is able to be involved with many other initiatives within the Board. He has said that he simply enjoys "helping people once they decide they are ready to be helped." When asked about why he wanted to be involved in PSUD, Ed responded, "I am entering the last phase of my career, and I would like to give back before finishing my career as a pharmacist. Students come out of pharmacy school and their first goal, as was mine, is to help people, but sometimes that goal is lost along the way. I want to exit my career with the same mindset I came into it: to help people and make a difference."

Did You Know?

- Board meetings are open to the public and held at 239 Causeway Street, 4th Floor, Room 417, beginning at 8:30 AM on the first Thursday of the month. The schedule for the 2019 Board meetings can be found here.
- Massachusetts lawmakers recently passed legislation mandating electronic prescribing for all Schedule II-VI drugs, effective January 1, 2020. Stay tuned for more information!

Board Staff

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