



Iowa Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Sales of CS Between Registrants

A pharmacy is authorized to transfer (sell) a controlled substance (CS) to another registrant, such as another pharmacy or a practitioner, but only in accordance with state and federal rules and regulations. A pharmacy wishing to sell or transfer a CS to another registrant must ensure that the individual or pharmacy is legally authorized to handle that CS. To ensure that the correct legal authority is in place, the pharmacy should verify the current Controlled Substances Act registration and professional licensure of the pharmacy or practitioner seeking the substance. Once verified, the pharmacy must create a distribution record of the substance being transferred or sold, in compliance with Iowa Pharmacy Board Rule 657.10.16(1). This record is not unlike an invoice provided by a wholesale distributor. One copy needs to be provided to the purchaser and one copy is to be retained in the pharmacy's records. The pharmacy must not process the transfer of CS through its pharmacy software system as a prescription record, as these are not prescriptions. Drug Enforcement Administration (DEA) has noted recently that it is still seeing pharmacy prescription monitoring program (PMP) reports with such distributions listed. Sales and transfers must be handled as a distribution, including a record that is maintained with other receipt and distribution records.

Can a pharmacy request a Schedule II prescription from a prescriber? Yes. A pharmacy can relay to a prescriber a patient's request for a Schedule II prescription. The pharmacy may **not**, however, provide a pre-populated prescription for the prescriber to simply sign. DEA reserves the task of preparing a prescription for the prescriber's signature to an agent of the prescriber, which a pharmacist or pharmacy is not. The pharmacy may provide the prescriber with information relating to the prescription being requested by the patient, but it cannot be in such a form that is essentially preparing the prescription for the prescriber's signature.

TPV Programs Update

In the December 2018 *Newsletter*, information was provided following the amendment to Iowa Administrative Code (IAC) during the 2018 legislative session relating to techni-

cian product verification (TPV) programs. The IAC changes followed a multi-year demonstration pilot study conducted by the Iowa Pharmacy Association and Drake University College of Pharmacy and Health Sciences to study the safety and impact of TPV programs in the community setting to increase pharmacist availability for the provision of clinical pharmaceutical services. The study's results showed that patient safety was not impacted; therefore, the Iowa Legislature authorized the practice of TPV through an amendment in the IAC. As authorized, the Board developed a proposed revision to IAC Chapter 40, Tech-Check-Tech Programs, and sent the proposed revised chapter to all pharmacists and technicians in Iowa to solicit feedback before officially submitting a Notice of Intended Action. The Board received approximately 30 comments to the proposed revision. From those comments, several changes were made to the proposed revision of Chapter 40. The updated, revised chapter was approved by the Board for submission as a Notice of Intended Action to formally start the rulemaking process. The rulemaking is available for public comment until March 5, 2019. The Board welcomes all interested parties to comment on the proposed rulemaking. You may submit your comments online at <https://rules.iowa.gov>.

Statewide Protocols Update

In the December *Newsletter*, information was provided on the Iowa Code provision authorizing the Board to develop statewide protocols, in collaboration with the Iowa Department of Public Health, for pharmacists to order and administer medications relating to naloxone, nicotine replacement tobacco cessation therapy, and immunizations. The Board has adopted rulemaking to establish the minimum standards for pharmacists who wish to participate in any or all of the statewide protocols upon their release. The rulemaking will become effective on March 6, 2019, and includes such parameters as pharmacist training and education, as well as required notification to the patient's primary care provider following the provision of a medication or immunization. The rules are available on the Board's [website](#). The Board is actively working on developing and finalizing the statewide protocols for these three practice areas. Check the Board's website for updates.

National Pharmacy Compliance News

March 2019



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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 Con-

trolled 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 repackaging 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.

Chapter 37: Iowa PMP Update

Information was also provided in the December *Newsletter* on the myriad elements of House File 2377, known as the Opioid Bill, and the possible changes to rules that are expected. The bill passed during the 2018 legislative session. The Board approved a proposed revised IAC 657 – Chapter 37 to be submitted for Notice of Intended Action to start the rulemaking process. The public comment period was open until January 22, after which the rules committee and the Board considers comments and makes changes to the rulemaking as deemed appropriate. The Board will likely consider the proposed rules for final adoption at its March meeting. As always, all published rulemaking documents can be found at <https://rules.iowa.gov>.

Electronic Prescribing Mandate – January 1, 2020

In 2018, the Iowa Legislature passed legislation that will require all prescriptions, including CS, to be electronically prescribed by prescribers and electronically received by pharmacies beginning January 1, 2020.

According to Surescripts data from October 2018, Iowa prescribers' e-prescribing activity is still well below national averages. Of Iowa prescribers, 66.5% (versus 73.6% nationally) are submitting electronic prescriptions to pharmacies. A total of 63% of Iowa's prescribers have certified, audit-approved software that is capable of transmitting electronic prescriptions for controlled substances (EPCS). Yet, only 15.3% of Iowa's prescribers have enabled this feature within their e-prescribing software (versus 30.4% nationally).

Conversely, Iowa's pharmacies are on par with the national average for the ability to receive electronic prescriptions (98.1% versus 98.4%, respectively) while the rate of EPCS-enabled pharmacies in Iowa hedges out the national averages by nearly 2% (96.7% versus 94.8%, respectively).

The legislation requiring e-prescribing permitted several exceptions to the e-prescribing mandate. Exclusions from the mandate include prescriptions that:

1. Are for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
2. Are authorized by a licensed veterinarian.
3. Are dispensed by a United States Department of Veterans Affairs pharmacy.
4. Require information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.
5. Are for a compounded preparation containing two or more components.
6. Are issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.

7. Are issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.
8. Are issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location, provided that a prescription issued pursuant to this exception shall indicate on the prescription that the practitioner or pharmacy is experiencing a temporary technical or electronic failure.
9. Are issued in an emergency situation pursuant to federal law and regulation rules of the Board.

Additionally, a practitioner, medical group, or pharmacy that is unable to timely comply with the electronic prescribing requirements may petition the Board for an exemption based on economic hardship; technical limitations that the practitioner, medical group, or pharmacy cannot control; or other exceptional circumstances. The Board may grant exception requests for a period of time that may not exceed one year, which may be renewable with Board approval. The Board is in the process of creating the necessary forms and rules to establish the exception-petition framework.

After the mandate becomes effective on January 1, 2020, a pharmacist who receives a written, oral, or faxed prescription that is otherwise legitimate will not be required to verify that the prescription is subject to an exception listed above and may dispense the prescription. However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations of the e-prescribing mandate to either the Board or the appropriate professional licensing board of the practitioner.

A prescriber who violates this mandate is subject to an administrative penalty of \$250 per violation, up to a maximum of \$5,000 per calendar year. The administrative penalty assessed by the prescriber's primary licensing board will not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of the administrative penalty, which will initiate a contested case proceeding. The administrative penalties collected will be deposited into the drug information program fund to further support and enhance the state's PMP.

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