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Utah Board of Pharmacy News

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Amendments to the Utah Pharmacy Practice Act

The amendments to the Utah Pharmacy Practice Act Rule became effective on December 27, 2018. The following is a summary of the amendments.

Senate Bill (SB) 184, passed during the 2018 Utah Legislative General Session, amended the Pharmacy Practice Act to permit a pharmacist to dispense a self-administered hormonal contraceptive under a standing prescription order. As required by SB 184, which was passed in 2018, this rule filing provides necessary definitions and establishes and clarifies the requirements for such dispensing. The Utah Board of Pharmacy proposes the remaining amendments to establish and clarify certain internship requirements and continuing education (CE) requirements, and to provide easier practice re-entry into the pharmacy professions by adding a license reinstatement option for certain previously licensed pharmacists and pharmacy technicians.

Section R156-17b-102: The following definitions are added:

1. The term "self-administered hormonal contraceptive" is defined by referring to Section 26-62-102(9).
2. The new "Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire" is defined as the self-screening risk assessment questionnaire that is approved by the Division of Occupational and Professional Licensing pursuant to Section 26-62-106.
3. The "professional entry degree" required for licensure under Subsection 58-17b-303(1)(f) is defined as the professional entry degree that was offered by the applicant's Accreditation Council for Pharmacy Education (ACPE)-accredited school or college of pharmacy in the applicant's year of graduation, either a baccalaureate in pharmacy (BSPharm) or a doctorate in pharmacy (PharmD).
4. References to United States Pharmacopeia (USP)-National Formulary (NF) are updated to USP 41-NF 36 and are incorporated into rule by reference.

Section R156-17b-303b: These proposed amendments delete duplicative provisions and update and clarify pharmacy internship standards required for licensure as a pharmacist, in accordance with *ACPE Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* (Standards 2016).

Section R156-17b-303c: This proposed amendment increases from two to three the number of North American Pharmacist Licensure Examination® or Multistate Pharmacy Jurisprudence Examination® failures an applicant is allowed before he or she must meet with the Board to request an additional authorization to test.

Section R156-17b-304: These proposed amendments make non-substantive formatting changes for clarity and provide consistency for temporary licenses with licensure examination requirements.

Section R156-17b-308: These proposed amendments clarify and update renewal and reinstatement procedures. In particular, as allowed by Subsection 58-1-308(5)(a)(ii)(B) and Section 58-17b-506, the proposed amendments will allow former Utah licensees whose licenses expired while active and in good standing, easier re-entry into pharmacy practice by extending their permissible reinstatement period from two years to eight years. This means that if these former licensees meet CE and certain other requirements, they may apply for reinstatement instead of being required to submit a new application for licensure complete with all the supporting documents required of individuals initially applying for a license and demonstrating they meet all current qualifications for licensure.

Section R156-17b-309: These proposed amendments make the following clarifications and updates to CE requirements by:

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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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1. making non-substantive formatting changes throughout for clarity;
2. for pharmacists, updating CE standards and topics by deleting the old topics of "drug therapy or patient management," and substituting the current topics of "disease state management/drug therapy," "AIDS/HIV therapy," or "patient safety";
3. for pharmacy technicians, reducing the eight-hour "live or technology-enabled participation" requirement to six hours;
4. for pharmacists, clarifying the existing CE requirements regarding individual licensee practices (such as requiring two CE hours in topics related to long-acting injectables if the licensee will be providing administration of long-acting injectable drug therapy, and requiring two hours in topics related to hormonal contraceptive therapy if the licensee will be prescribing and dispensing a self-administered hormonal contraceptive);
5. adding additional options for fulfilling CE requirements, including allowing one "live" CE hour for attending one Board meeting, for a maximum of two CE hours during each two-year period, and allowing two CE hours for each hour of lecturing or instructing a CE course or teaching in the licensee's profession, for a maximum of ten CE hours during each two-year period; and
6. requiring licensees to prove compliance with their CE requirements through registration with the CPE Monitor® service, accessible through the National Association of Boards of Pharmacy® website. Either of the two CPE Monitor plans, the standard or the plus, meet this requirement. Licensees using the free CPE Monitor standard plan are also required to maintain a certificate of completion or other adequate documentation for CE that cannot be tracked through this plan.

Section R156-17b-402: These proposed amendments add to the fine and citation schedule for, "failing to act in accordance with Title 26, Chapter 62, Family Planning Access Act, when dispensing a self-administered hormonal contraceptive under a standing order, in violation of 58-17b-502(14)."

Section R156-17b-610: These proposed amendments provide guidelines for patient counseling by a pharmacist or pharmacy intern who dispenses a self-administered hormonal contraceptive. The guidelines require the pharmacist or pharmacy intern to obtain a completed Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire, and provide the written information and counseling described in Section 26-62-106.

Section R156-17b-621b: This proposed rule establishes the operating standards for pharmacists and pharmacy interns dispensing a self-administered hormonal contraceptive. These standards require special initial training, CE, and the use of the new Utah Hormonal Contraceptive Self-Screening Risk Assessment Questionnaire, which was adopted by the Division of Occupational and Professional Licensing in collaboration with the Board.

Pharmacy Technician Training Programs

"On-the-job" pharmacy technician training pharmacies will no longer meet the education requirement for pharmacy technician trainee applications submitted after December 31, 2018. Pharmacy technician trainees must attend a program that is American Society of Health-System Pharmacists (ASHP)-accredited; in ASHP candidate status; or conducted by the National Pharmacy Technician Association, Pharmacy Technicians University, or a branch of the United States Armed Forces. Please refer to the following excerpt of the rule for further clarification.

R156-17b-303a. Qualifications for Licensure – Education Requirements.

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician shall complete a training program that is:

(a) accredited by ASHP; or

(b) conducted by:

(i) the National Pharmacy Technician Association;

(ii) Pharmacy Technicians University; or

(iii) a branch of the Armed Forces of the United States, and

(c) meets the following standards:

(i) completion of at least 180 hours of directly supervised practical training in a licensed pharmacy as determined appropriate by a licensed pharmacist in good standing; and

(ii) written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technician trainees that address:

(A) the specific manner in which supervision will be completed; and

(B) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician trainee.

(4) An individual shall complete a pharmacy technician training program and successfully pass the required examination as listed in Subsection

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R156-17b-303c(4) within two years after obtaining a pharmacy technician trainee license, unless otherwise approved by the Division in collaboration with the Board for good cause showing exceptional circumstances.

(a) Unless otherwise approved under Subsection (4), an individual who fails to apply for and obtain a pharmacy technician license within the two-year time frame shall repeat a pharmacy technician training program in its entirety if the individual pursues licensure as a pharmacy technician.

(5)(a) Pharmacy technician training programs that received Division approval on or before April 30, 2014 are exempt from satisfying standards established in Subsection R156-17b-303a(3) for students enrolled on or before December 31, 2018.

(b) A student in a program described in Subsection (5)(a) shall comply with the program completion deadline and testing requirements in Subsection (4), except that the license application shall be submitted to the Division no later than December 31, 2021.

(c) A program in ASHP candidate status shall notify a student prior to enrollment that if the program is denied accreditation status while the student is enrolled in the program, the student will be required to complete education in another program with no assurance of how many credits will transfer to the new program.

(d) A program in ASHP candidate status that is denied accreditation shall immediately notify the Division, enrolled students and student practice sites, of the denial. The notice shall instruct each student and practice site that:

(i) the program no longer satisfies the pharmacy technician license education requirement in Utah; and

(ii) enrollment in a different program meeting requirements established in Subsection R156-17b-303a(3) is necessary for the student to complete training and to satisfy the pharmacy technician license education requirement in Utah.

(6) An applicant from another jurisdiction seeking licensure as a pharmacy technician in Utah is deemed to have met the qualifications for licensure in Subsection 58-17b-305(1)(f) and 58-17b-305(1)(g) if the applicant:

(a) has engaged in the practice of a pharmacy technician for a minimum of 1,000 hours in that jurisdiction within the past two years or has equivalent experience as approved by the Division in collaboration with the Board; and

(b) has passed and maintained current PTCB or ExCPT certification.

The *Utah Board of Pharmacy News* is published by the Utah 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, the State of Utah, or the Board unless expressly so stated.

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