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USP Chapter <797> Update

By Kerri J. Kilgore, RPh, and Matt Martineau, RPh

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Term: 2013-2019

The Wyoming State Board of Pharmacy recently amended the Wyoming Pharmacy Act and the Wyoming Controlled Substances Act Rules and Regulations. These changes were approved by then Governor Matt Mead on December 19, 2018. Among these changes were an update to the version of United States Pharmacopeia (USP) Chapter <797> as it existed on July 27, 2018, including amendments adopted by USP as of that date. Copies of this standard can be obtained from the Board upon request.

Previously, compounded sterile preparations (CSPs) were assigned a beyond use date (BUD) according to their risk level. These risk levels were: high, medium, low, low risk with a 12-hour BUD, and immediate use. These risk levels were based on the complexity of the CSP, the environment in which it was made, and the types of ingredients that were used in its preparation.

Under the updated USP Chapter <797>, CSPs are now divided into either Category 1 or Category 2, and a BUD is assigned according to the environment in which the CSP was made. Category 1 CSPs may be prepared in an unclassified, segregated compounding area. Their BUD may be 12 hours or less at room temperature (20°-25°C) or 24 hours or less at refrigerated temperature (2°-8°C). Meanwhile, Category 2 CSPs may have a greater BUD (see Table 1), but they must be prepared in a cleanroom suite.

Previously, sterile compounding rooms were allowed to be designed according to either an air displacement or differential air pressure model. An air displacement design is one where the buffer room and cleanroom were not physically separated. A differential air pressure model is where the cleanroom and buffer rooms are physically separated.

Under the updated USP Chapter <797>, a cleanroom suite is defined as, "A classified area that consists of both an anteroom and buffer room." In Appendix 2 of USP Chapter <797> it is clarified that the cleanroom suite is modeled after the previous differential air pressure room design, where the cleanroom and anterooms were separate and distinct rooms (see Figure 1, on Page 4 of this *Newsletter*). This means that a facility with an air displacement room design would be reclassified as a segregated compounding area and could only assign Category 1 BUDs to their CSPs.

The Board has received information that approximately 58% of sterile compounders in Wyoming will be affected by these changes. Some sterile compounders may still be able to function by decreasing their BUD. Other sterile compounders will have to remodel to make use of the greater Category 2 BUDs. To facilitate this, the Board has decided to have its inspectors provide information during the 2019 inspection period regarding the updates to USP Chapter <797>. There are other changes in the updated version of USP Chapter <797>, so it is highly recommended that sterile compounders obtain a copy of the July 27, 2018 version of USP Chapter <797> from the Board and familiarize themselves with the new standard. In the past, the Board has provided a grace period to allow pharmacies to develop and implement the necessary action to be compliant. The Board will expect sterile compounders to be compliant with the updated USP Chapter <797> on or after July 1, 2020.

Table 1. Category 2 BUDs

Preparation Characteristics		Storage Conditions		
Sterilization Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20° to 25°C)	Refrigerator (2° to 8°C)	Frozen (-25° to -10°C)
Aseptically Prepared CSPs	No	≥1 nonsterile starting component(s): 1 day	≥1 nonsterile starting component(s): 4 days	≥1 nonsterile starting components(s): 45 days
		Sterile components only: 4 days	Sterile components only: 9 days	Sterile components only: 45 days
	Yes	30 days	45 days	60 days
Terminally Sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

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National Pharmacy Compliance News

March 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.

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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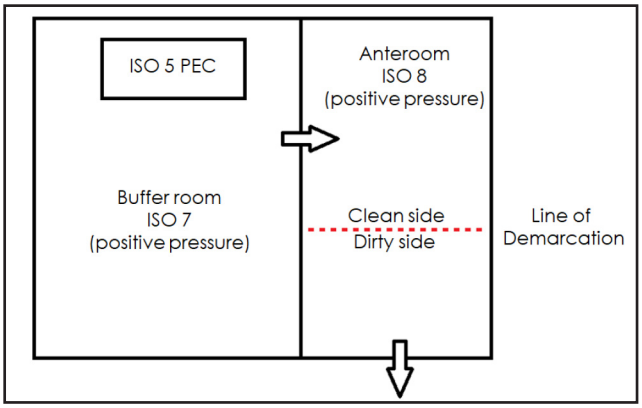
Figure 1. Cleanroom Suite Example



Wyoming Healthy U Self-Management Programs

By Dominick Jean Duhamel, Wyoming Center on Aging, University of Wyoming

Healthy U offers a suite of evidence-based programs that help people with chronic health conditions play a more active and productive role in their health management, and it is now available to patients across Wyoming. Healthy U is Wyoming's statewide implementation of the widely disseminated chronic disease self-management education programs developed at Stanford University, which includes the Chronic Disease Self-Management Program (CDSMP), the Chronic Pain Self-Management Program (CPSMP), and the Diabetes Self-Management Program (DSMP).

Trained facilitators offer the three Wyoming programs. Participants meet once a week for two-and-a-half hours for the duration of the six-week course. Participants learn and practice a variety of skills intended to help themselves manage their chronic health condition, including techniques to deal with frustration, fatigue, pain, and isolation; appropriate exercise for maintaining and improving strength, flexibility, and endurance; appropriate use of medications; how to communicate effectively with family, friends, and health professionals; nutrition; decision making; action planning; problem solving; and how to evaluate new treatments.

Healthy U is highly participative and uses mutual support and success to build participants' confidence in their ability to manage their health and maintain active, fulfilling lives. The programs are designed to enhance regular treatment and disease-specific education; they do not conflict with existing programs or treatments.

Originally developed at Stanford Patient Education Research Center in 1996 and now administered internationally by the Self-Management Resource Center, these programs have been extensively studied, widely published, and peer-reviewed. Over 1,000 participants with chronic diseases enrolled in the initial three-year, randomized, controlled study evaluation of CDSMP. Those who participated demonstrated a significant improvement in exercise, cognitive symptom management, communication with physicians, self-reported general health, health distress, fatigue, disability, and social/role activities limitations. They also spent fewer days in the hospital and tended toward fewer outpatient visits and hospitalizations. On average, this reduction saved the health care system $364 per year per participant, a cost-to-savings ratio of approximately 1:4. These programs are offered in every state and numerous countries around the world.

In Wyoming, Healthy U is administered and coordinated statewide by the Wyoming Center on Aging (WyCOA) in partnership with the Wyoming Department of Health, Aging Division and Public Health Division. There are 48 Healthy U facilitators statewide who offer CDSMP in 17 of Wyoming's 23 counties. CPSMP is currently available in Sheridan and Natrona counties. Over the next three years, CDSMP will be expanded to all 23 counties, and both CPSMP and DSMP will be made available in 12 counties. Healthy U is offered in a variety of community settings, including public health organizations, senior centers, medical centers, libraries, subsidized housing facilities, and wellness centers. All Healthy U programs are offered free of charge and are open to any person over the age of eighteen.

For more information about Healthy U, the programs available in your area, or how you can refer your patients to local programs, contact Dominick Duhamel, the WyCOA program coordinator, at dduhamel@uwyo.edu or 307/766-2765.

WORx Features

By Lisa V. Hunt, RPh, MBA-HM, and David Wills, MBA

Delegate Access

Beginning in April 2019, practitioners and pharmacists will be able to appoint up to two delegates on their behalf to access the Wyoming Online Prescription Drug Monitoring Program Database (WORx). WORx will allow delegates to prepare patient utilization reports for practitioners to review. Pharmacists will be able to appoint licensed pharmacy interns or technicians as their delegates and practitioners can appoint their agents. The WORx delegate accounts were authorized by Wyoming Statutes Annoated §35-7-1060(c)(i).

A delegate will register by visiting the WORx website home page, clicking on the Register now button, and completing the initial registration questions. When completed, the primary account holder (a WORx-registered practitioner or pharmacist) is notified by email that a delegate is requesting access into WORx on the primary account holder's behalf and is waiting for the delegate's appointment access approval. The primary account holder then logs in to WORx using his or her verified account and approves the delegate's request.

Delegates do not gain access to WORx reports or data until the primary account holder approves their delegate status. A delegate may have several appointments if he or she happens to work for more than one pharmacist or practitioner. Delegates must identify the authorizing primary account holder

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they are accessing patient data for every time they request a patient utilization report. For security reasons, there is a limit to the number of searches that may be performed each day by a delegate, and delegate login information must be updated every 180 days.

Protect Access to WORx

For patient privacy and security, every time a registered, verified account holder accesses WORx, it is documented, recorded, and auditable. Each WORx registrant must have a unique email address that is private and accessible only to the registrant.

Employees of clinics and pharmacies should never share usernames, passwords, or emails due to the potential for violating patient privacy. All persons who access WORx are required to abide by all applicable state and federal laws governing protected health information.

Registrant-Defined Clinical Alerts

WORx will also be configured to allow practitioners and pharmacists to receive email notifications on issues they have concerns about regarding their patients. Email alerts will not contain any patient identifiable information. The alerts will let primary account holders know that specific information they previously requested is waiting for them in WORx.

The alerts are defined by the primary account holder. The basic function of the clinical alerts feature will be to provide practitioners with informational notifications from WORx upon request. For example, registrants may set up alerts for every time a patient of theirs refills a prescribed controlled substance (CS) at least four days early. They may only want alerts for a certain subset of patients or for patients who refill at least seven days early. The practitioner will define the alerts.

Interstate Data Sharing

WORx will allow verified, approved registrants to search for prescription information on their patients who receive CS in other states. If they have patients who travel to other states and are concerned that a patient may be receiving CS prescriptions in those states, the practitioner or pharmacist will soon be able to search other states' prescription drug monitoring programs (PDMPs) through WORx. This access to information on prescriptions filled by patients in other states is called interstate data sharing of PDMP information and is facilitated through NABP PMP InterConnect®, a service developed by the National Association of Boards of Pharmacy®.

For questions about WORx, call the Board at 307/634-9636 or visit the Board's website at *www.worxpdmp.com.*

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