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Multiple Schedule II Prescriptions Up to a 90-Day Supply

By Travis Beck, PharmD Candidate, University of Wyoming School of Pharmacy

The Wyoming Controlled Substances Act, Rules and Regulations, Chapter 6, states:

> An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met: (i) Each separate prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice; (ii) Each individual prescription is dated with the date it was prescribed and contains all other information required by this chapter; (iii) The practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription; (iv) The practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.

These rules and regulations mirror the Title 21 Code of Federal Regulations §1306.12.

Another rule that applies in Chapter 6 states that prescriptions shall be dated as of and **signed on the day when issued,** and shall bear the full name, address, telephone number, and Drug Enforcement Administration (DEA) registration number of the issuing practitioner. **No postdating of controlled substance (CS) prescriptions is allowed.**

Some Schedule II prescriptions are being brought in where the prescribers are writing and documenting on one date, and then dating it again a few days ahead, indicating that this is when they want the first prescription of a series to be filled. This prescription would be classified as postdated and invalid to fill. As stated in the Rules and Regulations, the prescriber needs to date the prescription when it was actually written, and provide written instructions on the prescription when it is to be filled if he or she does not want it filled immediately.

Here are some questions to think about with the rule of allowing up to a 90-day supply from multiple Schedule II prescriptions. If a patient comes in with two prescriptions dated on the same date one month ago, is it legal to dispense the two-month supply on the same visit? Yes, this is within the legal boundaries, but it should also be questioned by the pharmacist as to why this is occurring. Is the patient not taking his or her medications correctly, resulting in subtherapeutic effects, or does he or she have other prescriptions filled that are duplicating therapies resulting in delay of fills? As always, contact the prescriber and document what you discuss.

This rule allows prescribers the flexibility to prescribe a longer duration of a controlled maintenance medication for a specific condition, like attention deficit hyperactivity disorder, without having the patient come in every month. It is also a tool for the pharmacist to be able to see the course of therapy, as opposed to getting one prescription for a 90-day supply that is more than likely going to warrant a follow-up call to the prescriber for verification.

If a pharmacist has any concerns about the filling of multiple controlled prescriptions, the rules state that every new prescription shall have the offer to counsel (Wyoming Pharmacy Act, Rules, Chapter 9). Even if three prescriptions are issued in this manner, they can be considered new, and this gives the pharmacist a chance to talk to the patient about them. By creating this dialogue, a pharmacist has a chance to discuss proper medication use and also get a sense of the patient-prescriber relationship. If there are still concerns about a patient's well-being, every pharmacist has the option to use his or her professional judgment as to whether he or she fills a prescription or not.

HCPs Move to Schedule II; Wyoming Statute Leaves Out Optometrists

According to Wyoming Statute §33-23-102, optometrists will no longer be able to prescribe hydrocodone-containing products:

> An optometrist shall be allowed to administer and prescribe pharmaceutical agents related to the practice of optometry, excluding the following categories of oral medications: immunosuppressives, steroids, anti-fungals, sedative-hypnotics, and schedule I and II narcotics. No medication shall be given by injection. Oral anti-glaucoma medications may be administered for a period not to exceed forty-eight (48) hours. An optometrist who administers or prescribes pharmaceutical agents for examination or for treatment shall provide the same standard of care to patients as that provided by a physician utilizing the same pharmaceutical agents for examination or treatment.

Pharmacists are reminded that an inventory was to be made on October 6, 2014, when hydrocodone combination products (HCPs) changed to Schedule II CS, and a copy of that inventory needs to be faxed to the Wyoming State Board of Pharmacy office. Perpetual inventory logs will be reviewed by the inspectors. The new DEA rule allows prescriptions written for HCPs before October 6, 2014, to be refilled until April 8, 2015, if refills were prescribed. Transfers of HCP prescriptions are no longer allowed, and all doses must be recorded in the perpetual inventory log, even if the prescription was refilled as a Schedule III CS.

Compliance Corner

By Richard Burton, RPh, Inspector/Compliance Officer

Schedule II Perpetual Inventory

The Board inspectors are finding multiple issues and are being asked multiple questions as to how the pharmacy should maintain the perpetual inventory. The Wyoming Controlled Substances Act, Rules and Regulations,

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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Chapter 4, Section 1 (c)(iv) states, in part: "All retail and institutional pharmacies shall maintain a perpetual inventory for all schedule II controlled substances. This inventory shall be reconciled no less than once a quarter." The rule does not state how the inventory is to be maintained, which leaves much discretion on the part of each individual pharmacy. This has led to numerous ways that the perpetual inventory is maintained within each pharmacy. Some pharmacies keep the inventory electronically and some keep information by hard copy. Either way is permissible by the Board. Some pharmacies reconcile quarterly, some reconcile monthly, and some reconcile with each dispensing of a Schedule II drug. An important note to remember is that the reconciliation (at least quarterly) should be documented in whatever format the pharmacy is using (hard copy or electronically). If a particular Schedule II drug has no activity during the previous three months, it should be counted and the reconciliation documented (the rule states "all" Schedule II CS). Discrepancies discovered during reconciliation should be documented in the inventory with the entry "inventory adjusted" and the correct quantity entered. Those discrepancies in the actual inventory count differing by more than five percent from the recorded inventory shall be reported to the Board within 10 calendar days by using the DEA Form 106. Documentation in the perpetual inventory should reflect this action with the entry of "inventory adjustment" and the correct count entered.

Incomplete Directions on Prescription Labels

The inspectors have noticed during reviews of prescriptions and their labels that sometimes the directions are not complete. This is a patient safety issue as well as part of the definition of "unprofessional conduct" as stated in the Wyoming Pharmacy Act (W.S. 33-24-101): "(iv) 'Unprofessional conduct' means: (A) Dispensing a drug or brand of drug in filling a prescription which differs from that specified by the prescription, without authority of the issuer of the prescription, regarding the patient's name, drug, strength, quantity, directions or number of authorized refills."

If the label directions state "take one or two tablets every four hours" without adding the prescribed "as needed for pain," the patient may think this means around the clock, and a possible dangerous overdose could result. If the prescriber adds notes such as "must last 30 days" or "maximum of 8 tablets in 24 hours" and those statements are left off the label, then the communication between the prescriber, patient, and pharmacist is not complete. The Board has held pharmacists and pharmacy technicians accountable for such medication safety lapses. Even if good counseling occurs, the patient or caregiver needs the label to be correct.

Sterile Compounding

The inspectors have found a lot of progress made in compliance with Chapter 17 of the Wyoming Pharmacy Act Rules and Regulations, which is based on United States Pharmacopeia Chapter <797>. The Board members want to thank pharmacists and pharmacy technicians for their hard work in making the changes to the equipment, environment, garbing, monitoring, and policy/procedures. Your efforts on behalf of the patients in Wyoming are recognized and appreciated!

Renewals of Pharmacist and Pharmacy Technician Licenses for 2015

Notices were mailed in early November, and the renewal period ends on December 31, 2014, when late fees will go into effect at midnight. The Board has a new licensing system, so check the information carefully and correct any errors. You must create a new username and password, and then use them to log in to complete the renewal at the Board's website: *http://pharmacyboard.state.wy.us*. You may use Visa, MasterCard, or Discover, but the state system does not accept American Express. Note that you are to print your own certificates, including an additional separate one for preceptors and/or immunization registration. These renewal certificates have a new look and must be posted at your work site with your wall certificate. If you cannot process online, you can use the paper form that was mailed and include a check or money order. If the employer information is incorrect, simply click "next," or the system may prevent the completion of the renewal. **Be sure you have the correct number of continuing education credits earned during 2014 before processing your renewal (six hours for registered pharmacy technicians and 12 hours for pharmacists).**

Board Policy Regarding Immunizations

On November 7, 2014, the Board members approved the addition of pneumococcal conjugate vaccine to the list of vaccines that can be prescribed and administered to healthy adults by pharmacists who are registered immunizers, and administered by pharmacy interns who are registered to administer vaccines in Wyoming.

Special Notice About This Newsletter

The *Wyoming State Board of Pharmacy Newsletter* has been designated as the official method of notification to pharmacists and pharmacy technicians licensed by the Wyoming State Board of Pharmacy. Please read these *Newsletters* and keep them for future reference. These *Newsletters* will be used in hearings as proof of notification. *Newsletters* are available for review on the Board web page at *http://pharmacyboard.state.wy.us* or at *www.nabp.net/publications/state-newsletters* under Wyoming.

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