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Guidance for New Hydrocodone Implementation

By now, everyone who is involved with the prescription business knows that **all** hydrocodone products, whether they are hydrocodone only or a hydrocodone combination, have been reclassified as Schedule II controlled drugs. Because this case of rescheduling has been different than most other cases, there have been numerous questions about what can and cannot be done. Although many of your questions may have been answered by now, the Alabama State Board of Pharmacy felt it important to review the more frequently asked questions.

The new rescheduling went into effect October 6, 2014. As of that date, any prescription for hydrocodone products issued on or after October 6, 2014, will be a Schedule II prescription, and all regulations regarding Schedule II controlled drugs will apply. Of course, that means no refills on the prescription; no prescriptions phoned in, unless in the case of an emergency; the prescription may not be signed by a physician's assistant, a certified nurse practitioner, or a nurse midwife; and there are limits on the specific items recorded on the prescription that may be altered by the pharmacist.

"Upon the effective date of this final rule, any person who handles [hydrocodone combination products (HCPs)] will be subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, engaging in research, conducting instructional activities, and conducting chemical analysis, of schedule II controlled substances." Source: *www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm*.

Prescriptions for hydrocodone products filled before October 6, 2014, and having refills may be refilled for no more than five total refills; refills may not occur more than six months after the original filling of the prescription; and no refill may occur after April 8, 2015. For the life of this prescription, it is being treated as a Schedule III controlled drug.

The computer system in the pharmacy must have the ability to record and document the handling of the prescription and refill it as a Schedule III refill. If the computer system can only document the prescription as Schedule II, then refills or prescription transfers are not allowed. In that case, all prescriptions must be treated as new Schedule II prescriptions.

Transfer of Schedule III prescriptions from before October 6, 2014, with refills remaining. This is one of the most confusing parts of the new regulation. If the receiving pharmacy has a computer system that can record refills at a Schedule III level, and if the prescription is treated as a transfer throughout the process, a prescription may be transferred to another pharmacy and the refills remaining may be dispensed from the second pharmacy. However, if the receiving pharmacy created a "new" prescription rather than handling the prescription as a transfer, then the new prescription would be Schedule II and there would be no refills.

The Drug Enforcement Administration (DEA) website, *www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0822.htm,* makes the following statement. Note that it states refills may be dispensed in accordance with 21 CFR 1306.25, which is the policy on transferring Schedule III drugs.

> *Prescriptions.* All prescriptions for HCPs must comply with 21 U.S.C. 829(a) and must be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of October 6, 2014. No prescription for HCPs issued on or after October 6, 2014 shall authorize any refills. Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed in accordance with 21 CFR 1306.22-1306.23, 1306.25, and 1306.27, if such dispensing occurs before April 8, 2015.

Manufacturer labeling, quotas, and repackaging. DEA has stated that "All labels, labeling, and packaging for commercial containers of HCPs must comply with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of October 6, 2014, except with respect to exchanges for purposes of relabeling/repackaging as provided below under 'Quotas.'" There will not be a similar requirement for having only products labeled as Schedule II controlled drugs in retail pharmacies. However, a pharmacy may send hydrocodone products back to the manufacturer for relabeling from Schedule III to Schedule II. This relabeling will be allowed

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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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if it occurs before December 8, 2014. A DEA Form 222 or invoice would be used to record the transfer and reflect that the transfer occurred pursuant to the authority contained in this final rule.

No manufacturer may produce hydrocodone products after October 6, 2014, without obtaining an individual manufacturing quota. Products being returned for relabeling shall not be considered part of that quota.

Concern for safe storage of Schedule II drugs. Retail pharmacies are not required by the Controlled Substances Act (CSA) or DEA regulations to place Schedule II controlled substances (CS) in a vault or safe. In accordance with 21 CFR 1301.75(b), pharmacies may disperse Schedule II CS throughout their stock of non-CS in such a manner as to obstruct the theft or diversion of the CS.

Inventory. Although the time has passed, the law required that all registrants take an inventory of their hydrocodone products before business hours on October 6, 2014. They will also need to keep a copy of this inventory in an easily retrievable file.

Reminder About Continuing Education Hours

The Board has begun the process of renewing licenses for both pharmacists and for pharmacies and pharmacy businesses. That will continue through December 31, 2014. You may renew after that date, but there is a penalty attached. If you visit the Board's website, you will find instructions regarding use of the renewal software.

One of the questions asked in the renewal process is whether or not you will have acquired all necessary continuing education (CE) hours by December 31, 2014. With the new National Association of Boards of Pharmacy® (NABP®) service CPE Monitor® to document CE hours, it will be much easier for the Board office to view the number of CE hours actually acquired over the last two-year period. It is easy to reason that you will pay the fine or acquire extra CE hours if you are short. While that may be true, most pharmacists forget that not having sufficient CE hours is a charge that the Board must report to the National Practitioner Data Bank (NPDB). The Board's contract with NABP requires that the Board report a variety of charges to the NPDB, and those charges range from addiction, to unprofessional conduct, to missed child support, to not participating in sufficient CE.

In an effort to be accommodating for technicians during last year's registration, the Board altered the way it calculates CE hours. Pharmacists must still acquire a total of 30 hours of CE, with 15 hours per year, and of those 30 hours, three hours in each year must be live CE. When tallying hours for technicians, the Board found some people who had all their hours, but the hours were not evenly divided into two years. The Board determined that it would not bring charges against people who had the correct total number of hours, even though the hours may not be evenly distributed over two years. The Board agreed that it would apply the same standard to pharmacist hours for this year's renewal cycle, which is helpful in case you did not complete all required hours for 2013.

If you need to know the number of hours you have acquired to date, you can visit *www.MyCPEmonitor.net* and log into your e-Profile. There is still time to complete your CE hours, and there are some very interesting programs in the state. Of course, you also have the options of online programs and pharmacy journals.

Reminder

Please notify the Board in writing of any change of address or employment within 10 days.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help line at 205/981-2273 or 251/866-5585. The Board Wellness Program e-mail address is bopwellness@gmail.com. All communications are confidential.

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