



## Arizona State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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### **Attorney General Announces New Drug Take-Back Effort to Help Tackle Rising Threat of Prescription Drug Addiction and Opioid Abuse**

Calling prescription drug addiction an “urgent and growing threat” to our nation’s public health, on September 8, 2014, Attorney General Eric Holder announced a new Drug Enforcement Administration (DEA) regulation that would allow pharmacies, hospitals, clinics, and other authorized collectors to serve as authorized drop-off sites for unused prescription drugs. Under the new policy, long-term care facilities will also be able to collect controlled substances (CS) turned in by residents of those facilities, and prescription drug users everywhere will have permission to directly mail in their unused medications to authorized collectors.

Attorney General Holder said the new changes will help save lives and protect American families from the increased dangers of prescriptions drug misuse. In 2011 alone, more than half of the 41,300 unintentional drug overdose deaths in the United States involved prescription drugs, and hazardous opioid pain relievers led to about 17,000 of those deaths. Young people are especially susceptible to these dangers. The Attorney General noted that nearly four in 10 teens who have misused or abused a prescription drug have obtained it from their parents’ medicine cabinet.

“These shocking statistics illustrate that prescription drug addiction and abuse represent nothing less than a public health crisis,” the Attorney General said in a video message posted on the US Department of Justice’s website. “Every day, this crisis touches – and devastates – the lives of Americans from every state, in every region, and from every background and walk of life.”

The new policy builds on existing take-back programs launched by DEA. A recent prescription drug take-back event coordinated by DEA last April resulted in the safe return of 390 tons of prescription drugs at nearly 6,100 sites. Over the last four years alone, DEA and other partnering organizations have taken in over 4.1 million pounds – or more than 2,100 tons – of prescription pills. DEA’s last prescription drug take-back event was on September 27, 2014.

Attorney General Holder’s video message also states:

[As] we’ve learned from scientific studies, treatment providers, victims, and investigations, prescription drug abuse can easily lead to the abuse of heroin – an addiction that has become increasingly lethal. In fact, in the decade from 2002 to 2011, the annual number of drug poisoning deaths involving heroin doubled, making prescription opioids and heroin some of the most lethal substances in common use. [ . . ]

The Department of Justice has taken aggressive steps to fight back – by targeting the illegal supply chain; by disrupting so-called “pill mills”; and by expanding public health, education, and law enforcement efforts. But we also recognize that much of this work must start at home. [ . . ]

That’s why, today, I am announcing that we are expanding drug take-back efforts – by introducing new ways for people to safely dispose of old or unused prescription drugs. Through new DEA regulations, patients will be allowed to more easily join the fight against prescription drug abuse by dropping off their leftover medications at pharmacies, hospitals, clinics, and other “authorized collectors.” Beyond authorizing new drop-off sites, the new DEA rule will allow long-term care facilities to assist in the disposal of prescription controlled substances belonging to current or former residents. And most importantly, patients or their family members can mail their prescription controlled substances to an authorized collector using pre-paid mail-back packages that can be obtained right from their pharmacy, or from other locations like libraries and community centers. [ . . ]

Once collected, these medications are then responsibly destroyed to ensure that they don’t damage our environment by ending up in landfills or in the water supply. With these new regulations, and with continued take-back events – like the one scheduled in the coming weeks for September 27th – we hope to increase those numbers, and prevent more potentially harmful medications from being misused or abused by young people and others.

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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](http://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!<sup>®</sup> Community/Ambulatory Care Edition by visiting [www.ismp.org](http://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](http://www.ismp.org). E-mail: [ismpinfo@ismp.org](mailto: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](http://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](http://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](http://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](http://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](http://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](http://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](http://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).

As a lifelong member of America's law enforcement community – as a former judge and U.S. Attorney – I have seen the devastating consequences of prescription drug abuse firsthand. And as Attorney General – and as a parent – I am committed to ending the national epidemic that has already stolen too many lives and torn apart too many families. I thank you for your help and your partnership in ensuring that we can continue to save lives and protect the futures of our young people.

For more information, please visit DEA's website at [www.dea.gov](http://www.dea.gov).

### **DEA Has Rescheduled HCPs from Schedule III to Schedule II**

DEA has announced its final rule moving hydrocodone combination products (HCPs) from Schedule III to Schedule II, effective October 6, 2014. The controversial scheduling change was recommended by the Assistant Secretary for Health of the US Department of Health & Human Services and supported by DEA's own evaluation of relevant data, according to an August 21, 2014 DEA news release.

The final rule states that Schedule II requirements will apply to "all pharmaceuticals containing hydrocodone currently on the market in the United States." These requirements include, but are not limited to, requirements related to security protocols, labeling and packaging, inventory, and record keeping and reporting.

Only prescriptions issued before October 6, 2014, and authorized for refills may be dispensed as refills, as long as such dispensing occurs before April 8, 2015. DEA does state that a practitioner may issue multiple Schedule II prescriptions to provide up to a 90-day supply of medication. DEA cautioned, however, that practitioners must make their own decisions "based on sound medical judgment and in accordance with established medical standards" regarding whether multiple prescriptions are appropriate for a patient.

Technically, a Schedule II medication may not be refilled in Arizona, but since this rescheduling was initiated by DEA, the Arizona State Board of Pharmacy will follow DEA's lead in the rescheduling with respect to refills. **Please note that if you transfer an HCP prescription (whenever written), it becomes a Schedule II CS immediately and may not be refilled.**

### **Tramadol Products Have Been Placed in Schedule IV**

On July 11, 2014, DEA [announced](#) that tramadol has been placed into Schedule IV of the Controlled Substances Act (CSA), effective August 18, 2014. The new scheduling applies to all tramadol salts, isomers, and salts of isomers. This action imposes the regulatory controls applicable to Schedule IV CS on persons who handle or propose to handle tramadol.

The CSA is the federal US drug policy under which the manufacture, importation, possession, use, and distribution of certain narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and other chemicals is regulated. Under the CSA, every CS is classified in one of five schedules based

upon its potential for abuse, currently accepted medical use, and the degree of dependence the drug or other substance may cause. Abuse of the drug may lead to limited physical dependence or psychological dependence relative to the drugs in Schedule III.

Only prescriptions issued before August 18, 2014, and authorized for refills may be dispensed as refills, as long as such dispensing occurs prior to August 18, 2015. Once again, this Board will follow DEA's lead in the rescheduling with respect to refills.

### **Disciplinary Actions and Updates Pharmacists**

**Alnoah, Fahad (S015734)** – Probation terminated. Effective September 22, 2014.

**Hines, Jacinta (S014158)** – Probation terminated. Effective June 26, 2014.

**Huston, John (S018419)** – Suspension terminated. Four-year probation imposed. Effective June 26, 2014.

**Karim, Soral (S017429)** – Suspension terminated. Five-year probation imposed. Effective June 26, 2014.

**McKee, Mark (S012049)** – Probation terminated. Lifetime monitoring (Pharmacists Assisting Pharmacists of Arizona) terminated. Effective June 26, 2014.

**Mowers, Gregory (S007608)** – Five-year probation imposed. Effective August 28, 2014.

**Omodara, Olufemi (S011406)** – Probation terminated. Effective June 25, 2014.

**Stump, Andrea (S018207)** – Probation terminated. Effective September 28, 2014.

### **Technician**

**Downing, Kelly (T007378)** – One-year probation imposed. Effective August 28, 2014.

### **Other**

**Lange, Dorian (No # Issued)** – Hearing on denial of licensure application. Application denied upon appeal. Effective June 25, 2014.

### **Disciplinary Actions and Updates – Other Health Boards**

#### **Arizona Medical Board (MDs)**

**Riemke Brakema, MD #18508** – *Order for Letter of Reprimand and Probation and Consent to the Same.* Respondent is issued a letter of reprimand and placed on probation for five years. While on probation, respondent is prohibited from practicing emergency medicine and from working more than 40 hours per week. In addition, respondent shall comply with all of the terms and conditions of the order. Effective August 8, 2014.

**Paul R. Butzine, MD #8694** – *Order for License Reactivation, Probation, and Consent to the Same.* Respondent's license is reactivated upon payment of the renewal fee. Respondent is placed on probation for five years subject to specified terms and conditions. Effective August 25, 2014.

**Colin N. Cavenaile, MD #31936** – *Request for License Inactivation with Cause and Order Inactivating License with*

*Cause.* License inactivated with cause. Before respondent can request that his license be reactivated, he shall successfully complete a long-term care residential or inpatient hospital treatment program or both, and meet the applicable requirements. Effective August 8, 2014.

**Gabrielle Goodrick, MD #22811** – *Second Amended Order for Probation with Practice Restriction.* Practice restriction in Paragraph IV, Subparagraph 16 of previous order is terminated. All other terms and conditions of the order remain in effect until at least December 21, 2015. Effective July 17, 2014.

**Paul A. Guzman, MD #33313** – *Order of Suspension.* Respondent did not renew his license while the subject of a pending Board investigation. Respondent's Arizona medical license is suspended by operation of law. He is prohibited from engaging in the practice of medicine in the state of Arizona. His license shall remain suspended until investigation MD-14-0071A is resolved and the Board has taken final action with respect to the investigation. Suspension effective May 29, 2014.

**Rodney S. Iancovici, MD #28530** – *Interim Order for Practice Restriction and Consent to the Same.* Respondent is prohibited from prescribing, administering, or dispensing CS until he has taken and completed an evaluation conducted by The Center for Personalized Education for Physicians and has received the Board's affirmative approval to do so. Effective May 6, 2014.

**Jeanne M. Kapenga, MD #35939** – *Order for Surrender of License and Consent to the Same.* Respondent ordered to surrender her license immediately. Effective June 12, 2014.

**Brian F. McCabe, MD #23045** – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives permission to do so. Respondent may not request release from or modification of this interim consent agreement until he has completed a Physician Health Program assessment and any recommendations that arise as a result of the assessment including evaluation and treatment. Effective July 25, 2014.

**Robert C. Osborne, MD #9796** – *Order for Revocation.* License revoked. Motion for rehearing/review denied. Effective August 6, 2014.

**Joseph Francis Piazza, MD #35035** – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License.* Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing any form of medicine in the state of Arizona. Effective August 6, 2014.

**Jack L. Potts, MD #12185** – *Interim Order for Practice Restriction and Consent to the Same.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives permission to do so. Respondent may not apply for reinstatement until he has completed an assessment and the Board is in receipt of the assessment report and recommendations. If the report indicates respondent is safe to practice medicine, the executive director may lift the restriction. Effective May 21, 2014.

**Phillip Thomas Rajadas, MD #43411** – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License.* Respondent's license to practice medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in state of Arizona and is prohibited from prescribing any form of treatment including prescription medications or injections of any kind. Effective May 13, 2014.

**Robert J. Rauscher, MD #13109** – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the Board and receives permission to do so. Respondent may not apply for termination of the restriction until he has completed a Physician Health Program assessment and any recommendations that arise as a result of the assessment including evaluation and treatment. Effective July 23, 2014.

**Edward Jack Sayegh, MD #40787** – *Interim Findings of Fact, Conclusions of Law and Order for Summary Suspension of License.* Respondent's license to practice allopathic medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications or injections of any kind. Effective June 27, 2014.

**Donald F. Stonefeld, MD #14712** – *Order for Surrender of License and Consent to the Same.* Respondent ordered to surrender his license immediately. Effective August 8, 2014.

## **Arizona Regulatory Board of Physician Assistants (PAs)**

**Steven Carbonniere, PA #3258** – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine with physician supervision in the state of Arizona. Respondent shall not return to the practice of medicine under physician supervision until he applies to the Board and demonstrates his ability to safely carry out approved health care tasks and receives the Board's permission to do so. Effective June 23, 2014.

**David Cardosi, PA #4212** – *Interim Consent Agreement for Practice Restriction.* Respondent is prohibited from engaging in the practice of medicine with physician supervision in the state of Arizona. Respondent shall not return to the practice of medicine under physician supervision until he applies to the Board and demonstrates his ability to safely carry out approved health care tasks and receives the Board's permission to do so. Effective July 22, 2014.