



New Jersey State Board of Pharmacy

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NJPMP Update

As of September 1, 2014, the New Jersey Prescription Monitoring Program (NJPMP) has entered its third year of operation. Thanks to the hard work of the New Jersey Division of Consumer Affairs and the NJPMP staff, the program can now boast of a system utilized by over 14,000 health care professionals, including over 4,500 pharmacists in New Jersey. The program receives 116,000 user requests a month, and the NJPMP database contains over 36 million records. For 2014, the NJPMP continues to partner with adjacent states to allow sharing of data. With Connecticut and Delaware connecting through the NABP PMP InterConnect[®] hub in the first half of 2014, the program is actively working to add New York State by early 2015. For additional information, please visit the NJPMP website at www.njconsumeraffairs.gov/pmp.

Pain Management Council

The New Jersey Division of Consumer Affairs will convene a Pain Management Council on October 21, 2014. The council has been tasked with reviewing current professional standards and regulations for all prescribers and dispensers with the intended purpose of establishing best practices for managing pain while maintaining effective controls against diversion and abuse of prescription medications. Members and representatives of the following groups and organizations are among those invited to participate in the Pain Management Council:

- ◆ New Jersey Department of Health
- ◆ New Jersey Department of Human Services, Division of Mental Health and Addiction Services
- ◆ New Jersey Department of Children and Families
- ◆ Medical Society of New Jersey
- ◆ New Jersey Academy of Family Physicians
- ◆ American College of Emergency Physicians, New Jersey Chapter
- ◆ New Jersey Association of Osteopathic Physicians and Surgeons
- ◆ New Jersey Society of Interventional Pain Physicians
- ◆ New Jersey Podiatric Medical Society
- ◆ New Jersey State Nurses Association, Institute for Nursing
- ◆ New Jersey Pharmacists Association
- ◆ Independent Pharmacy Alliance
- ◆ New Jersey Retail Merchants Association
- ◆ New Jersey Dental Association

- ◆ Rutgers, The State University of New Jersey
- ◆ Saint Barnabas Medical Center
- ◆ Kessler Institute for Rehabilitation
- ◆ New Jersey State Board of Medical Examiners
- ◆ New Jersey State Board of Pharmacy
- ◆ New Jersey State Board of Optometrists
- ◆ New Jersey Board of Nursing
- ◆ State Board of Veterinary Medical Examiners

Information for Pharmacists Regarding Optometrist TPA Certification

The New Jersey Division of Consumer Affairs, in conjunction with the New Jersey State Board of Pharmacy, is providing the following information concerning doctors of optometry, optometrists, and the medication prescriptive authority granted to optometrists with a Therapeutic Pharmaceutical Agents (TPA) Certification in order to assist pharmacists and pharmacy personnel in filling prescriptions issued by optometrists.

- ◆ **If an optometrist has a TPA Certification number that begins with the prefix "27TO,"** the optometrist is certified to prescribe **topical pharmaceutical agents only.**
- ◆ **If an optometrist has a TPA Certification number that begins with the prefix "27OM,"** the optometrist is certified to prescribe **oral medications and topical pharmaceutical agents.**

In addition, if an optometrist has a Drug Enforcement Administration (DEA) registration number, the optometrist is authorized to prescribe Schedule III, IV, and V controlled dangerous substances (CDS).

This information shall not supersede a pharmacist's professional responsibility to verify a prescription with the prescriber if, in the pharmacist's professional judgment, such verification is warranted.

Tramadol Is Now a Schedule IV CDS Medication

On August 18, 2014, tramadol became a Schedule IV CDS in the state of New Jersey based upon the recent federal DEA final rule.

As a Schedule IV CDS, tramadol is now subject to the prescription requirements in N.J.A.C. 13:45H-7.13 and 7.14, which preclude a pharmacy from filling or refilling a prescription more than six months after the date on which the prescription was

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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).

issued. In addition, the prescription cannot be refilled more than five times.

In accordance with the New Jersey CDS Rule N.J.A.C. 13:45H-5.8 and federal requirements, on August 18, 2014, every CDS registrant was required to take an inventory of all stock of tramadol on hand. Also, going forward, CDS registrants must keep records of tramadol on hand and include tramadol in the biennial inventory made pursuant to N.J.A.C. 13:45H-5.7.

Pharmacies must begin reporting the dispensing of tramadol to the NJPMP pursuant to N.J.S.A. 45:1-45 et seq.

For additional information, please visit:

- ◆ The Drug Control Unit website: www.njconsumeraffairs.gov/drug
- ◆ The Board website: www.njconsumeraffairs.gov/pharm
- ◆ The NJPMP website: www.njconsumeraffairs.gov/pmp

Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

As noted in the *National Pharmacy Compliance News* on page two of this *Newsletter*, DEA has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register*, which becomes effective on October 6, 2014. The Board will publish guidance for pharmacists to follow regarding this change on the Board's website.

Compounding Sterile and Nonsterile Preparations in Retail and Institutional Pharmacies

The substantially modified N.J.A.C. 13:39-11 (Compounding Sterile and Non-Sterile Preparations in Retail and Institutional Pharmacies) is now in effect, and can be accessed in the updated "Pharmacy Regulations" hyperlink at www.njconsumeraffairs.gov/pharm/phar_rules.htm, which was last revised on June 3, 2013. The new regulation divides the subchapter into sterile compounding (N.J.A.C. 13:39-11.1-24) and nonsterile compounding (N.J.A.C. 13:39-11A.1-15), and brings New Jersey regulations into agreement with the practice standards established by the United States Pharmacopeia General Chapter 797 (Pharmaceutical Compounding of Sterile Preparations) and General Chapter 795 (Pharmaceutical Compounding of Nonsterile Preparations). The Board urges all licensees to become familiar with the new regulation.

This is the sixth article in a series of issues summarizing critical changes in the new regulation and will cover N.J.A.C. 13:39-11.18-20 of the sterile compounding regulations, describing compounded sterile preparations for prescriber practice use; stability criteria and beyond-use dating; documentation; and audit trail.

- ◆ **N.J.A.C. 13:39-11.18 is a new rule** permitting a pharmacy to prepare compounded sterile preparations for a licensed prescriber for use in the prescriber's practice without a prescription, consistent with state and federal laws pertinent to the prescriber's health care practice. Pharmacies in New Jersey that intend to compound medications for office use should also review the Drug Quality and Security Act (21 USC §353a and §353b) to determine whether they should register with Food and Drug Administration as a wholesaler, manufacturer, or outsourcing facility.
- ◆ **N.J.A.C. 13:39-11.19 sets forth new rules** relating to stability criteria and beyond-use dating for compounded sterile preparations.
 - ◇ **N.J.A.C. 13:39-11.19(a)** defines stability for the purposes of the section.

- ◇ **N.J.A.C. 13:39-11.19(b)** sets forth the dates and times for storage and for the initiation of administration of compounded sterile preparations in the absence of supporting valid scientific sterility testing and stability information that is directly applicable to specific preparations.
- ◇ **N.J.A.C. 13:39-11.19(c)** prohibits extension of the dates and times set forth in proposed N.J.A.C. 13:39-11.19(b) without verifiable supporting valid scientific sterility and stability information that is directly applicable to the specific preparation or compound.
- ◇ **N.J.A.C. 13:39-11.19(d)** requires a pharmacist to determine the beyond-use date for a compounded sterile preparation consistent with proposed N.J.A.C. 13:39-11.19(b), and to assign the preparation an appropriate discard-after date. The discard-after date must appear on the label consistent with proposed N.J.A.C. 13:39-11.21.
- ◇ **N.J.A.C. 13:39-11.19(e)** sets forth a time limit on the use of opened or needle-punctured single-dose sterile products used in the compounding of sterile preparations for immediate use if opened in worse than ISO Class 5 air quality.
- ◇ **N.J.A.C. 13:39-11.19(f)** sets forth a time limit on the use of single-dose vials used in the compounding of sterile preparations exposed to ISO Class 5 or cleaner air quality.
- ◇ **N.J.A.C. 13:39-11.19(g)** prohibits opened single-dose ampules used in the compounding of sterile preparations from being stored for any period of time.
- ◇ **N.J.A.C. 13:39-11.19(h)** sets forth a time limit on the use of opened or needle-punctured multiple-dose vials used in the compounding of sterile preparations.
- ◆ **N.J.A.C. 13:39-11.9 is being amended and recodified as N.J.A.C. 13:39-11.20.** This section relates to the documentation that a pharmacist must complete and the audit trail that he or she must maintain for all compounded sterile preparations.
 - ◇ **N.J.A.C. 13:39-11.20(a)** is being amended to **delete a reference to N.J.A.C. 13:39-11.5**, and to add provisions requiring that pharmacists ensure that compounded sterile preparations have been properly prepared consistent with the assigned risk level of the preparation and that filled prescriptions are accurate and appropriate. **Existing subsections (b) through (e), relating to documentation of the dispensing process and the maintenance of an audit trail, are proposed to be deleted in their entirety.**
 - ◇ **The Board proposes to add a new subsection N.J.A.C. 13:39-11.20(b)**, requiring that a pharmacy maintain an audit trail for all compounded sterile preparations consistent with N.J.A.C. 13:39-7.6.
 - ◇ **The Board also proposes to add a new subsection N.J.A.C. 13:39-11.20(c)**, setting forth the information that a pharmacy must maintain as part of the compounding record for each compounded sterile preparation that it prepares.