



New Jersey State Board of Pharmacy

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NJPMP Update

Mobile App

The New Jersey Prescription Monitoring Program (NJPMP) recently completed the development of a new mobile application (app) for Apple devices. The app is located at <https://appsto.re/us/oUv23.i> and is free of charge to users. Android and Windows Mobile versions of the app will be available this summer. The app will allow users to receive push notifications about suspicious activity, pharmacy practice updates, or other important notifications.

Frequency Change

On March 1, 2015, the NJPMP updated the Data Collection Manual to reflect a change in uploading frequency from weekly to daily reporting. As previously indicated, the NJPMP has delayed enforcement of the new requirements until September 1, 2015, in order to allow pharmacies ample time to comply with the new requirements. Pharmacies are reminded that after September 1, 2015, pharmacies not uploading data as outlined in the Data Collection Manual may be subject to fines from the NJPMP as well as action by the New Jersey State Board of Pharmacy. The Data Collection Manual is available via <https://www.njrxreport.com/documentation/manual/njdatacollectionmanualfinal.pdf>.

Counterfeit Prescriptions

The NJPMP has become aware of an increase in counterfeit prescription blanks in the central New Jersey area. Pharmacists are reminded that the new prescription blanks implemented in 2014 contain features that are designed to allow for easier identification of counterfeit prescriptions. The counterfeit prescriptions identified were not able to replicate either the microprint or the thermochromic ink features. In one instance, the color pattern was incorrect.

For your reference, the new prescriptions blanks include the following features:

- ◆ **Thermochromic ink**, which changes color in response to body heat. The heat-activated ink will appear in a small Rx logo on the front of the prescription blank. It will fade when touched, and return to its original color when it cools.
- ◆ **Microprint** of 0.5-point type or smaller. The front of each prescription blank will include a line of microprint

that is readable when viewed at 500% magnification, but becomes illegible when scanned or photocopied.

- ◆ **A hollow “VOID”** hidden word feature that is invisible on a genuine prescription blank, but should appear in illegally scanned or copied versions.
- ◆ **A unique 15-digit identification number** for each prescription blank. The alphanumeric code will identify the vendor that created the blank, the vendor’s order number, and a six-digit serial number for each separate prescription blank.
- ◆ **A barcode** matching the prescription blank’s unique 15-digit identification number. The barcode will enable pharmacists to scan prescription data into the NJPMP. The NJPMP, maintained by the New Jersey Division of Consumer Affairs, records all prescription sales in New Jersey of controlled dangerous substances (CDS) and human growth hormone (more information is available at www.njconsumeraffairs.gov/pmp).
- ◆ **A complete list of all security features** will be printed on the back of the prescription blank.
- ◆ **The new prescription blanks** will be green on the front and blue on the back. This will enable them to be more easily distinguished from the old blanks, which are blue on the front and green on the back.

Pharmacists who believe a prescription may be counterfeit should verify the prescription with the prescriber. Pharmacists should attempt to verify that the phone number is correct, as counterfeit prescriptions may contain altered phone numbers.

If a counterfeit prescription is verified, pharmacists should contact their local police department as well as follow-up with the NJPMP.

Licensee Requirements Regarding Adequate Storage

Current regulations require pharmacists and pharmacies to maintain all prescription drugs and chemicals under adequate storage conditions, including proper lighting, ventilation, and temperature control, as recommended by the drug manufacturer. That specific requirement can be found at N.J.A.C. 13:39-5.7. Licensees often do not fully comprehend their responsibilities and obligations associated with this requirement.

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox[®] was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at www.fda.gov/Drugs/DrugSafety/ucm443217.htm.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy[®] (NABP[®]) Verified-Accredited Wholesale Distributors[®] (VAWD[®]) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

 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. Email: ismpinfo@ismp.org.

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit www.ismp.org/communityRx/tools/ambulatoryhighalert.asp. ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat



muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- ◆ In “NDC Directory,” pharmacists demonstrate how to use this quick, easy, online resource.
- ◆ In “FAERS,” pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications’ drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- ◆ MUCINEX FAST-MAX Night-Time Cold & Flu;
- ◆ MUCINEX FAST-MAX Cold & Sinus;
- ◆ MUCINEX FAST-MAX Severe Congestion & Cough; and
- ◆ MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for

safe disposal, is available on the FDA website at www.fda.gov/Safety/Recalls/ucm444028.htm.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACCP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACCP website, www.aacp.org.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2,4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The “Orange Notice” warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at www.interpol.int/News-and-media/News/2015/N2015-050.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, “Pathways to Safer Opioid Use,” also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at <http://health.gov/hcq/training.asp#pathways>.

If the drug manufacturer has not specified the appropriate temperature, the prescription drug or chemical should be maintained at “controlled room temperature.” The definition of “controlled room temperature” can be found in United States Pharmacopeia Chapter <36>. “Controlled room temperature” indicates a temperature maintained thermostatically that encompasses the usual and customary working environment of 20°C to 25°C (68°F to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15°C and 30°C (59°F and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Provided the mean kinetic temperature remains in the allowed range, transient spikes up to 40°C are permitted as long as they do not exceed 24 hours. Spikes above 40°C may be permitted if the manufacturer so instructs. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations. An article for which storage at **controlled room temperature** is directed may, alternatively, be stored and distributed in a **cool place**, unless otherwise specified in the individual monograph or on the label. For more information, visit the United States Pharmacopeia – National Formulary website at www.usp.org.

Heating and air conditioning equipment failures that expose drug inventory to temperatures beyond the manufacturer’s storage recommendations compromise product integrity, and extended or repeated excursions in temperature may necessitate quarantining and destroying drug inventory. Proper operation of heating and air conditioning equipment therefore is not just a convenience for customers and pharmacy staff, but a necessity to operate a pharmacy within regulatory compliance.

Recently the Board reviewed and approved newly proposed draft regulations that further delineate storage condition and temperature monitoring requirements. These new regulations, once adopted, will further advance and protect public health. There are a number of administrative steps in the rule adoption process that must be completed prior to the new regulation taking effect. Next steps for the proposed regulations include administrative law review, then publication of the proposed regulations for public comment.

CDS Biennial Inventory Requirements

The Board has received inspection reports from the New Jersey Division of Consumer Affairs’ Enforcement Bureau that identify a number of pharmacies that are not following the requirements for Title 21 Code of Federal Regulations Part 1304.11 and N.J.A.C. 13:45H-5.4.

As a registrant, you are required to complete a biennial inventory at least every two years. The biennial inventory may be taken on any date that is within two years of the previous biennial inventory date.

The biennial inventory should be readily retrievable for the Board inspector to review. This includes access for staff pharmacists who should be aware of the location where the biennial inventory is being stored.

The following information is required to be on the biennial inventory:

1. The date of the inventory.
2. Whether the inventory was taken at the beginning or close of business.

3. The name of each controlled substance inventoried.
4. The finished form of each of the substances (eg, 10 milligram tablet).
5. The number of dosage units of each finished form in the commercial container (eg, 100 tablet bottle).
6. A count of the substance; if the substance is listed in Schedule II, an exact count or measure of the contents, or if the substance is listed in Schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case, an exact count of the contents is required.
7. The Schedule II inventory shall be maintained separately from the Schedule III, IV, and V inventory.

Information for Pharmacists Regarding Schedule II CDS Dispensing Limits for Liquids

In March 2015, the New Jersey Division of Consumer Affairs, in conjunction with the Board, provided the following information to pharmacists concerning the dispensing limits of Schedule II CDS for liquid medications.

Pursuant to the New Jersey CDS rule, N.J.A.C. 13:45H-7.8(f), prescriptions for Schedule II CDS medications are not to exceed 120 dosage units or a 30-day supply, whichever is less, with limited exceptions. When dispensing Schedule II CDS liquid medications, pharmacists should follow the concentration volume as determined by the manufacturer’s packaging insert.

Pharmacists are reminded that they should **always** use their professional judgment before dispensing any prescription to a patient (see N.J.A.C. 13:39-7.13).

Example #1

A manufacturer that indicates a product’s concentration as 125 mg/5 mL would have the concentration volume of **5 mL per dosage unit**. This would result in a maximum dispensable quantity of 600 mL or a 30-day supply, whichever is less. (5 mL per dosage unit x 120 dosage units = 600 mL.)

Example #2

A manufacturer using a product concentration of 50 mg/1 mL would have the concentration volume of **1 mL per dosage unit**. This would result in a maximum dispensable quantity as 120 mL or a 30-day supply, whichever is less. (1 mL per dosage unit x 120 dosage units = 120 mL.)

If a product has multiple product concentrations (eg, morphine sulfate), a pharmacist should consult the manufacturer’s packaging insert to determine the appropriate manufacturer’s **dosage unit** to use when dispensing a patient prescription. For a copy of the guidance document, please visit the Board website at www.njconsumeraffairs.gov/phar.

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