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Guidance for Pharmacists Dispensing Naloxone

On May 2, 2013, Governor Chris Christie signed into law the Overdose Prevention Act (P.L. 2013, c. 46, N.J.S.A. 254:6J-1 et seq.). One of the purposes of the law is to reduce the number of opioid overdose deaths by making naloxone, an opioid antidote, more widely available and accessible. The statute allows health care professionals to prescribe or dispense naloxone, or similarly-acting drugs, not only to patients who may be in danger of overdosing, but also to first responders, family members, caregivers, or peers who are not at risk for an opioid overdose but who, "in the judgment of a physician, may be in a position to assist another individual during an overdose."

The New Jersey State Board of Pharmacy will draft regulations to implement this new law. Until those regulations are published, the Board is issuing this guidance for licensees who are presented with a prescription for naloxone or another similar-acting drug.

When presented with a prescription for naloxone, pharmacists should:

1. Ask if the prescription is for use by the person whose name is on the prescription.
2. Document on the prescription that the question was asked, along with the answer.
3. If the prescription is for the end user, fill as any usual prescription, including the offer of counseling.
4. If the prescription is for a person who "may be in a position to assist another individual during an overdose," then set up a separate profile, similar to a veterinary prescription, for "caregiver" or "first responder" so that it is readily retrievable. You can place notes in the profile if you wish, but the prescription should not be included in any drug utilization review. These prescriptions should not be processed through insurance.

Counseling need not be provided, as the statute provides that the patient will receive information from the physician or other sources.

The Board recognizes that in accordance with the new law, pharmacists filling a prescription for naloxone or other opioid antidote may rely upon the judgment of the physician and be assured that the requisite information was provided.

Guidance on Administering Influenza Vaccinations to Patients Seven Years of Age and Older

The Board recognizes the importance of pharmacists being able to provide influenza vaccinations to patients seven years of age and older. The Board has determined that the law (P.L. 2013, c.254) is self-executing, and the New Jersey State Board of Medical Examiners (BME) has agreed with that determination. The Board, in consultation with the BME, is proposing regulations to implement the law.

Pharmacists authorized to administer vaccines may immediately begin immunizing children seven years of age and older against influenza.

Until regulations are finalized, follow these guidelines when administering influenza vaccines to children:

(a) A licensed pharmacist must be authorized to administer vaccines and related emergency medications pursuant to and in compliance with the requirements of N.J.A.C. 13:39-4.21.

(b) For a patient who is under 18 years of age, a pharmacist must obtain the written consent of the patient's parent or legal guardian.

(c) For a patient who is under 12 years of age (and at least seven years of age), a pharmacist may administer the influenza vaccine only pursuant to a prescription by a licensed physician.

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

Guidance for Pharmacists on Making Changes to Schedule II Prescriptions

The Board has received many inquiries from pharmacists asking what types of changes, if any, can be made to hard copy prescriptions written for Schedule II medications. The Board has compiled the below list of changes, with appropriate protocols to be followed, in order to provide direction for pharmacists when confronted with the following scenarios.

It should be noted that this document has been reviewed and approved, to be released as guidance, by the New Jersey State Board of Pharmacy, the New Jersey Drug Control Unit, and the Director's Office of the New Jersey Division of Consumer Affairs. Drug Enforcement Administration (DEA) has had an opportunity to review this Guidance Document; however, the Board has not received any formal comment from that agency.

1. **The following items may be changed upon consultation with the prescriber:**
   - ♦ Patient's address
   - ♦ Drug strength
   - ♦ Drug quantity (both numeric and alpha representations)
   - ♦ Drug dosage form
   - ♦ Directions for use
   - ♦ Date issued
   - ♦ DEA number (if omitted)
2. **The following items may be added without consultation with the prescriber:**
   - ♦ Patient's address
   - ♦ Date of birth
   - ♦ A notation to correct a misspelled name
3. **The following items are never permitted to be changed:**
   - ♦ Patient's name (other than as noted above)
   - ♦ Controlled substance prescribed (except to substitute a generic)
   - ♦ Prescriber's signature

General Information:

- ♦ If the hard copy prescription is scanned into the pharmacy management system, any changes and annotations made to the hard copy should be captured on the scanned image.
- ♦ For electronic prescriptions, any changes made to the electronic prescription by the pharmacist should be annotated on the electronic record.

Visit *www.nabp.net/news/assets/DEA-missing-info-schedule-2.pdf* to view a letter from DEA to Carmen Catizone, executive director of the National Association of Boards of Pharmacy®. Mr Catizone reached out to DEA for clarification regarding DEA policy on what information a pharmacist may add to a prescription written for a Schedule II medication.

The Board encourages pharmacists to review this letter for additional details of DEA's expectations of pharmacists relating to dispensing Schedule II controlled dangerous substances and compliance with the Controlled Substances Act.

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 available 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 fifth article in a series of issues summarizing critical changes in the new regulation and will cover N.J.A.C. 13:39-11.16-17 of the sterile compounding regulations, which describes training and evaluation requirements and batch preparation.

- ♦ **N.J.A.C. 13:39-11.7 is being amended and recodified as N.J.A.C. 13:39-11.16.**
  - ◊ **N.J.A.C. 13:39-11.16(d)** is a new rule setting forth the requirements for pharmacists, pharmacy technicians, interns, and externs relating to gloved fingertip/thumb samplings.
  - ◊ **N.J.A.C. 13:39-11.16(e)** is a new rule prohibiting individuals who have failed the written test or the test of aseptic technique from compounding sterile preparations until both tests have been passed.
  - ◊ **N.J.A.C. 13:39-11.16(f)** is a new rule prescribing the length of time that permit holders must retain test results.

N.J.A.C. 13:39-11.16 Training and Evaluation Requirements

(d) All pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs engaging in the compounding of sterile preparations shall successfully complete an initial gloved fingertip/thumb sampling

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procedure prior to compounding sterile preparations. Gloved fingertip/thumb sampling shall be conducted annually for all personnel engaged in compounding low- and medium-risk level preparations and semi-annually for all personnel engaged in compounding high-risk level preparations.

(e) Individuals who fail the written test and/or the test of aseptic technique shall be prohibited from compounding sterile preparations until passing both tests.

(f) All test results shall be maintained by the permit holder for five years and shall be made available to the Board for inspection upon request.

♦ **N.J.A.C. 13:39-11.8 is being amended and recodified as N.J.A.C. 13:39-11.17 and relates to batch preparation.**

◊ **N.J.A.C. 13:39-11.17(a)** is being amended to **delete references to nonsterile preparations.** The rule is also being amended to set forth in linear fashion the conditions that must be met in order to compound sterile preparations prior to receipt of a valid written prescription or medication order.

◊ **N.J.A.C. 13:39-11.17(b)** is a new rule that sets forth the conditions under which pharmacists, pharmacy technicians, interns, and externs may compound sterile preparations without a prescription for use by a licensed prescriber for use in his or her practice.

13:39-11.17 Batch Preparation

(a) Pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs, consistent with N.J.A.C. 13:39-11.13, may compound sterile preparations in a quantity that is supported by prior valid prescriptions or medication orders before receiving a valid written prescription or medication order, provided the pharmacist:

1. Documents a history of valid prescriptions or medication orders subsequently received, within the beyond-use dating time of each product, which have been generated solely within an established professional prescriber-patient-pharmacist relationship;
2. Maintains the prescription or medication order on file for all such products dispensed at the pharmacy;
3. Documents the batch preparation process, including selection of the drugs, containers, and diluents, lot numbers and expiration dates of the drugs, containers and diluents, if any, and verification that the compounded sterile preparation has been visually inspected to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling. Each batch shall be given a unique batch number to identify the specific batch; and
4. Ensures that the labeling requirements set forth at N.J.A.C. 13:39-11.21(a)1, 5, 7, 9, and 10 are satisfied.

(b) Pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs, consistent with N.J.A.C. 13:39-11.13, may batch prepare compounded sterile preparations for use by a licensed prescriber in his or her practice without a prescription, pursuant to N.J.A.C. 13:39-11.18, provided the pharmacist:

1. Complies with all requirements of N.J.A.C. 13:39-11.18; and
2. Documents the batch preparation process in accordance with N.J.A.C. 13:39-11.20(c).

The *New Jersey State Board of Pharmacy News* is published by the New Jersey State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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