



# New Jersey State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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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. 24:6J-1 et seq.). This act was amended on February 5, 2015. 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 are deemed capable of administering the antidote to an overdose victim in an emergency.

The New Jersey State Board of Pharmacy has not yet determined if it will draft regulations to implement this new law. If and 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, or who wish to dispense such medication under a standing order issued by a physician.

### Dispensing Naloxone via a Patient-Specific Prescription

When presented with a prescription for naloxone, the pharmacist should:

- ◆ Ask if the prescription is for use by the person whose name is on the prescription.
- ◆ Document on the prescription that the question was asked along with the answer.
- ◆ If the prescription is for the end user, then fill as any usual prescription, including the offer of counseling.
- ◆ If the prescription is for a person who is deemed capable of administering the antidote to an overdose victim in an emergency, then set up a separate profile, similar to a veterinary prescription, for “**caregiver**” 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.

### Dispensing Naloxone via a Physician’s ‘Standing Order’

A pharmacist directly or through a standing order may dispense an opioid antidote to any recipient who is deemed by the pharmacist to be capable of administering the opioid antidote to

an overdose victim in an emergency. As per P.L. 2013, c. 46, a pharmacist may dispense naloxone (pursuant to a specific valid standing order) to “emergency medical responders” and other “professionals” (eg, emergency medical technicians, those employed by the criminal justice system, addiction professionals, “professional entities”) who are acting in their regular course of business. Please review the [complete text of the law](#) for details outlining the requirements of standing orders and those authorized to receive opioid antidotes through a standing order.

### Dissemination of Overdose Prevention Information

The pharmacist must document that overdose prevention information was provided to the antidote recipient regardless of the method used to obtain the medication (ie, patient-specific prescription versus standing order).

The requisite overdose prevention information shall include, but is not limited to: information on opioid overdose prevention and recognition; instructions on how to perform rescue breathing and resuscitation; information on opioid antidote dosage and instructions on opioid antidote administration; information describing the importance of calling 911 emergency telephone service for assistance with an opioid overdose; and instructions for appropriate care of an overdose victim after administration of the opioid antidote.

N.J.S.A. 24:6J-5(a)(1) states:

A prescriber or other health care practitioner who prescribes or **dispenses** an opioid antidote in accordance with subsection a. of section 4 of P.L.2013, c.46 (C.24:6J-4), shall ensure that overdose prevention information is provided to the antidote recipient. (emphasis added)

N.J.S.A. 24:6J-5(b)(2) states:

The dissemination of overdose prevention information in accordance with this section, and the contact information for the persons receiving such information, to the extent known, shall be documented by the prescribing or **dispensing** health care practitioner, professional, or professional entity, as appropriate, in: (a) the patient’s medical record, if applicable; or (b) **another appropriate record or log**, if the patient’s medical record is unavailable or inaccessible, or if the antidote recipient is a professional or professional entity acting in their professional capacity . . . (emphasis added)



## **FDA Calls for Review of Opioids Policy, Announces Action Plan**

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm).

## **More Selected Medication Safety Risks to Manage in 2016**



*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*

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## **Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags**

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as  $154 \text{ mEq}/0.9\% = x/3\%$  and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ( $77 \text{ mEq}/0.9\% = x/3\%$ ).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

## **Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications**

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,<sup>1-5</sup> and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.<sup>6</sup> The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

most of these errors happened within the first 14 days after discharge.<sup>5</sup> The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).<sup>4</sup>

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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## USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at [www.usp.org](http://www.usp.org) in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

## FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. 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. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

## FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at [www.fda.gov/Drugs/DrugSafety/ucm489676.htm](http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm).

## FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm).

## **Drug Diversion Prevention, Reporting, and Handling a DEA Audit**

### **Background**

Drug diversion prevention and recognition is a component of pharmacy practice. Unfortunately, statistics demonstrate that:

- ◆ An estimated 18% to 21% of pharmacists have misused prescription drugs. In most of those cases, addiction developed after taking medications that had been prescribed for physical ailments, notably pain.<sup>1</sup>
- ◆ An estimated 10% of nurses are dependent on some type of drug. The American Nurses Association used the analogy that if one works with 10 nurses, one of the 10 is probably struggling with some type of addiction. With almost 3 million nurses working in their field, that could mean that approximately 300,000 may be substance abusers.<sup>2</sup>
- ◆ Approximately 10% to 12% of physicians will develop a substance use disorder during their careers, a rate similar to or exceeding that of the general population.<sup>3</sup>

### **Recognizing a Drug-Impaired Coworker**

The following signs of a drug-impaired coworker were taken from the Drug Enforcement Administration (DEA) Office of Diversion Control's Resources web page.<sup>4</sup>

Drug abusers often exhibit similar aberrant behavior. Certain signs and symptoms may indicate a drug addiction problem in a health care professional. Have you observed some of the following signs?

- ◆ Work absenteeism: absences without notification and an excessive number of sick days used;
- ◆ Frequent disappearances from the work site, having long unexplained absences, making improbable excuses, and taking frequent or long trips to the bathroom or to the stockroom where drugs are kept;
- ◆ Excessive amounts of time spent near a drug supply. They volunteer for overtime and are at work when not scheduled to be there;
- ◆ Unreliability in keeping appointments and meeting deadlines;
- ◆ Work performance that alternates between periods of high and low productivity and may suffer from mistakes made due to inattention, poor judgment, and bad decisions;
- ◆ Confusion, memory loss, and difficulty concentrating or recalling details and instructions. Ordinary tasks require greater effort and consume more time;
- ◆ Interpersonal relations with colleagues, staff, and patients suffer. Rarely admits errors or accepts blame for errors or oversights;
- ◆ Heavy "wastage" of drugs;
- ◆ Sloppy record keeping, suspect ledger entries, and drug shortages;
- ◆ Inappropriate prescriptions for large narcotic doses;
- ◆ Insistence on personal administration of injected narcotics to patients;
- ◆ Progressive deterioration in personal appearance and hygiene;
- ◆ Uncharacteristic deterioration of handwriting and charting;
- ◆ Wearing long sleeves when inappropriate;
- ◆ Personality change: mood swings, anxiety, depression, lack of impulse control, or suicidal thoughts or gestures;
- ◆ Patient and staff complaints about health care provider's changing attitude/behavior; and/or
- ◆ Increasing personal and professional isolation.

## **CDS Diversion Prevention**

A common theme among the literature is that health care professionals develop an addiction most notably post-injury or post-surgery. While there is no foolproof method to prevent drug diversion, there are some methods that can be used to prevent controlled dangerous substances (CDS) diversion. Below are some practical methods of diversion prevention.<sup>5</sup>

- ◆ Maintain a perpetual inventory for Schedule II and III medications and other items identified to have high street value.
- ◆ Conduct a random manual reconciliation once each month to include at least five drugs that are in the top 10% risk for diversion and three that are at lower risk for diversion. The same pharmacist should not conduct the monthly reconciliation count any two consecutive months.
- ◆ Inventory and manual reconciliation results should be maintained for two years.
- ◆ Inventory for all CDS (Schedule II-V) should be done once a year on the same day and month that your biennial inventory would usually be completed.
- ◆ The same person should not have responsibility for ordering and receiving CDS.
- ◆ All pharmacists should register with New Jersey Division of Consumer Affairs' Prescription Monitoring Program (PMP) and should regularly access the PMP when filling prescriptions to monitor for instances of doctor shopping or abuse.
- ◆ Pharmacies should consider utilizing video surveillance technology, including quality security cameras placed to capture activity anywhere CDS are stored, counted, held, dispensed, or returned to stock.
- ◆ If utilizing automated dispensing technology, monitor the type and quantity of transactions and confirm the discrepancy reasons entered by the users are accurate and comprehensible.

### **Reporting Requirements**

Despite the best practices in place, if you have a recognized CDS diversion, theft, or loss issue, the following must be performed:<sup>6</sup>

- ◆ DEA must be contacted within 24 hours after discovery of significant CDS diversion, theft, or loss, regardless if the investigation or complete details have been completed. You may amend the original submission within 30 days. To report the loss:
  - ◇ Notify the Newark Field Division Office by calling 973/776-1100;
  - ◇ Fax the Newark Field Division Office a memo regarding the diversion to 973/776-1166; and
  - ◇ Complete a DEA Form 106, which must be filed electronically at <https://www.deadiversion.usdoj.gov/webforms/dtLogin.jsp>. The DEA Form 106 must be kept for two years and must be amended within 30 days of the original submission. To do so, use the amendment key provided in the upper right-hand corner of the DEA Form 106 after original submission.
- ◆ Use the following criteria from DEA to determine a "significant" theft or loss.<sup>6</sup>
  - ◇ The actual quantity of CDS lost in relation to the type of business;
  - ◇ The specific CDS lost;
  - ◇ Whether the loss of the CDS can be associated with access to those CDS by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the CDS;

*Continued on page 5*

- ◇ A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
- ◇ Whether the specific CDS are likely candidates for diversion; and/or
- ◇ Local trends and other indicators of the diversion potential of the missing CDS.
- ◆ The New Jersey Drug Control Unit must be contacted upon discovery of diversion, theft, or loss, presumably within 24 hours, by:
  - ◇ Notifying the New Jersey Drug Control Unit by calling 973/504-6351; and
  - ◇ Completing and faxing form DDC-52 (download from [www.njpublicsafety.com/ca/drug/CDSLoss.pdf](http://www.njpublicsafety.com/ca/drug/CDSLoss.pdf)) to 973/504-6326, attention: Drug Control Unit.
- ◆ If the CDS diversion is attributable to a crime, contact the local police department.
- ◆ If the police department is contacted regarding the CDS diversion, theft, or loss, the New Jersey Department of Health must be contacted within 24 hours via the web-based Hippocrates program, found at <https://hippocrates.nj.gov/common/processLoginAuthentication.action>. If the Hippocrates report cannot be submitted electronically, call 800/792-9770.
- ◆ If the CDS diversion, theft, or loss involves a health care practitioner, the practitioner's board must be contacted and a Health Care Professional Responsibility and Reporting Enhancement Act Reporting Form must be filled out (download from [www.njconsumeraffairs.gov/Pages/hcreporting.aspx](http://www.njconsumeraffairs.gov/Pages/hcreporting.aspx)) within seven days of the event and sent to:  
Francine Widrich  
New Jersey Division of Consumer Affairs  
PO Box 46024  
Newark, NJ 07102  
You may also call 973/504-6310 to request a fax number and fax the report.

### DEA Audit

DEA will require the following information during the on-site unannounced audit:

- ◆ A copy of the previous or specified biennial CDS inventory. The biennial CDS inventory must contain:
  - ◇ Separate reports of Schedule II CDS and Schedule III-V CDS;
  - ◇ All CDS in active, secured inventory;
  - ◇ All CDS (expired, damaged, unusable) pending for destruction and/or in "return bins" for internal removal/wasting or for acquisition and removal by a reverse distributor; and
  - ◇ All CDS secured in remote automated dispensing machines (eg, hospitals, long-term acute care).
- ◆ Copies of purchases of selected CDS within a specified time period;
- ◆ Copies of selected CDS destroyed/wasted within a specified time period;
- ◆ Copies of documentation of selected CDS dispensed within a specified time period;
- ◆ Documentation of estimated or calculated CDS lost to diversion, theft, or loss;
- ◆ Documentation of all suspected diverter's or diverters' transactions and activities with selected CDS;
- ◆ A physical inventory of selected CDS in active inventory, pending for destruction, and CDS inventory in remote automated dispensing machines, if applicable

(physical inventory will be performed on site and with DEA agents present);

- ◆ Documentation of all professional staff and/or corporate owners/management affiliated with business, to include but not limited to job position, contact information, professional license numbers, and driver's license numbers;
- ◆ A summary of the origin and nature of the business, institution, and/or organization; and
- ◆ A copy of all CDS policies and procedures.

DEA investigators will utilize a computation sheet that matches all CDS received/purchased with CDS dispensed/wasted and look for an accounting balance of zero, meaning purchased CDS inventory should equal dispensed/wasted CDS inventory.

### Summary

There is no guarantee that CDS drug diversion will not occur and statistically, all organizations with health care providers who procure, handle, dispense, and administer CDS are inherently at risk. The key for a successful audit is to not only ensure practices and processes are in place for the prevention of CDS diversion, but also to ensure processes are in place for the quick detection of diversion and accountability of CDS inventory. Reporting diversion is a key regulatory component to expedite the discovery, security, and protection of public safety with respect to CDS diversion and loss. Numerous checks and balances need to be in place as well as constant vigilance by all employees of an organization or business. DEA, as well as all other regulatory agencies, want to ensure that the processes, policies, and culture of an organization or business minimize risk of diversion, enhance discovery of discrepancies, provide optimal control and reconciliation of inventory, and provide protection of public safety associated with all CDS utilization and issues.

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