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Delaware State Board of Pharmacy News

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Pharmacy Issues

Nasal Naloxone for Opiate Overdose

The purpose of this notice is to remind pharmacists about nasal naloxone for opioid overdose. Naloxone is indicated for the reversal of respiratory depression or unresponsiveness caused by an opioid overdose. Naloxone is not a controlled substance (CS) and can be prescribed by anyone with a medical license or prescriptive authority. It may be delivered intranasally with the use of a nasal adaptor/mucosal atomization device (MAD). Naloxone for nasal administration can be dispensed by a pharmacist with a prescription for patients at risk of an opioid overdose. The State of Delaware Division of Professional Regulation (DPR) and the Delaware Department of Health and Social Services support a comprehensive approach to increase access to naloxone by persons at high risk of opioid overdose and friends or family of persons at high risk of opioid overdose. Historically, naloxone has been administered by emergency medical personnel or in a hospital environment. However, rates of overdose and death from prescription opiates and heroin are increasing nationwide. Pharmacists providing opioid overdose education and naloxone to patients at risk can help save lives and reduce opioid overdose mortality.

Some indications for naloxone might be:

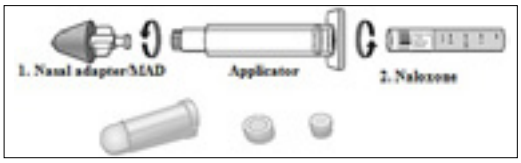
1. Previous opioid intoxication or overdose
2. History of non-medical opioid use
3. Initiation or cessation of methadone or buprenorphine for opioid use disorder treatment
4. Higher-dose (>50 mg morphine equivalent/day) opioid prescription
5. Receiving any opioid prescription for pain, plus:
   a. Rotated from one opioid to another because of possible incomplete cross-tolerance
   b. Smoking, chronic obstructive pulmonary disease, emphysema, asthma, sleep apnea, respiratory infection, other respiratory illness
   c. Renal dysfunction, hepatic disease, cardiac illness, HIV/AIDS
   d. Known or suspected concurrent alcohol use
   e. Concurrent benzodiazepine or other sedative prescription
   f. Concurrent antidepressant prescription
6. Patients who may have difficulty accessing emergency medical services (eg, distance, remoteness)
7. Voluntary request from patient or caregiver

Side Effects

Naloxone can **neither** be abused **nor** cause overdose. Hypersensitivity (eg, rash, worsening difficulty breathing, anxiety) is very rare. Too much naloxone can cause withdrawal symptoms such as anxiety, runny nose and eyes, chills, muscle discomfort, disorientation, combativeness, nausea/vomiting, and diarrhea.

Instructions to Dispense Nasal Naloxone

Naloxone for nasal administration may be prescribed via a naloxone prefilled needleless syringe and a nasal adapter.



1. Nasal Adaptor/MAD (Catalog Number: MAD 300)
   The nasal atomizer can be ordered from the manufacturer LMA (1-800/788-7999), but it is not usually covered by insurance. It may take 24 hours to set up an account with LMA, and the minimum order size is 25.
2. Naloxone HCl 1 mg/mL
   2 mL as prefilled Luer-Lok needleless syringe
   (National Drug Code 76329-3369-1)

If you need further information, please email customerservice.dpr@state.de.us or call 302/744-4500.

Year 2016 CE Renewal Reminder

As a reminder from the Delaware State Board of Pharmacy, the requirements for renewals and continuing education (CE) are found in 24 Del. C. §2512, Issuance and Renewal of License, and Pharmacy Regulations 1.4. Please remember that as per this statute and regulation, at least two hours of CE per biennial licensure period must be in the area of medication safety/errors. The Board is currently determining CS-related CE credits, but they have not been finalized with regulation at this time.

The amount of CE required depends on when your Delaware license was issued. You must complete the required CE credit hours before your license expires.

A program given by a Board-approved Delaware provider or approved by the Accreditation Council for Pharmacy Education (ACPE) automatically qualifies for CE credit. If a program is not already ACPE-approved, you should **promptly** file a Request for Individual Program Approval form to request the Board's approval of the program. (The form is available at *http://dpr.delaware.gov/*

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Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

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boards/pharmacy/forms.shtml.) **Do not hinge renewal of your license on approval of a last-minute application!** Note that the Board may not approve the program or may approve it for less credit than you request.

Following the renewal, a percentage of pharmacists will be selected for audit of their CE. However, please do not submit CE documentation until you receive the audit notice.

Only pharmacists who are registered as immunizers and who maintain their continuing competency are allowed to administer injectable medications, biologicals, and adult immunizations (Regulation 14.1.3). You will be asked a question about your registration as an immunizing pharmacist on the renewal application. If you are registered as an immunizer, it is your responsibility to take at least two hours of CE, out of the 30 hours required each licensure period, in the area of immunization. It is the responsibility of each registered pharmacist to maintain his or her current status.

If you fail to renew your Delaware pharmacist license by September 30, your license will lapse. It is illegal to continue practicing without an active license. There is no grace period.

PIC Self-Inspection Report

The Pharmacist-in-Charge (PIC) Self-Inspection Report is now available on the Board's website at *http://dpr.delaware.gov/boards/pharmacy/forms.shtml.* Please be aware that Pharmacy Regulations 3.1.2.7 and 3.1.2.7.1A require PICs to complete an annual self-inspection report by February 1 of each year. New PICs must complete a self-inspection report within 30 days of becoming a new PIC. All pharmacists and pharmacy staff must be informed of where the self-inspection form is filed and located. The staff **must** be able to locate this form at the time of any Board inspection. Delaware law holds the PIC responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy, including the above regulation. Failure to complete the self-inspection report or staff's inability to be able to locate this form during the Board inspection may result in fines and/or actions against the pharmacy and/or pharmacist license. The self-inspection report may be downloaded from the Board website above.

Delaware Professionals' Health Monitoring Program

The Delaware Professionals' Health Monitoring Program (DPHMP) supports the DPR in meeting three key goals:

- Supporting both public and workplace safety.
- Helping licensees with substance use and mental health issues to recover and continue working safely.
- Helping keep experienced, trained professionals employed.

Further information regarding the DPHMP is available on the DPR website at *www.dpr.delaware.gov.*

Newly Licensed Pharmacists

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A1-0004843 – Sara Elizabeth Knoll; A1-0004844 – Joseph Michael Mulroy; A1-0004845 – Ghislain Ketcha Tchemy; A1-0004846 – Christopher J. Duffy; A1-0004847 – Tameko Janelle Roberson; A1-0004848 – Kirbie D. Hanlon; A1-0004849 – Jade V. English; A1-0004850 – Lauren Emilee Ruf; A1-0004851 – Brittany Lynn Coleman; A1-0004852 – Betsy George Daniel; A1-0004853 – Amanda Benak; A1-0004854 – Robert Y. Scharr; A1-0004855 – Melissa G. Covert; A1-0004856 – Quynh Nhu Thi Dao; A1-0004857 – Palmer T. Wetzel III; A1-0004858 – Patrick Daniel Baker; A1-0004859 – Matthew J. Lord; A1-0004860 – Michael C. Dejos; A1-0004861 – Jeffrey Allen Perrone, A1-0004862 – Lena Ceranski; A1-0004863 – Joseph Rowlands; A1-0004864 – Temeka Magett; A1-0004865 – Michael Edwin Rada; A1-0004866 – Alya Zayed; A1-0004867 – Jane Elizabeth Schmidt; A1-0004868 – Ralph Michael Bonofiglio; A1-0004869 – Christina Marie Becker; A1-0004870 – Thomas Joseph McCool; A1-0004871 – Nikunj N. Shah; A1-0004872 – David D. Bot; A1-0004873 – Sarah Youngeun Kim; A1-0004874 – Dorota J. Jozwiak; A1-0004875 – Jingbo Sun; A1-0004876 – Karen Elizabeth Slagle; A1-0004877 – Cheree T. Caesar; A1-0004878 – Stacy M. Yoo; A1-0004879 – Mayur S. Tripathi; A1-0004880 – Ryan P. Courtney; A1-0004881 – Kawthar Elbishlawi; A1-0004882 – Patrick Fuh; A1-0004883 – Reshma Rao; A1-0004884 – Michael C. Bartels; A1-0004885 – Wendy Lisa Shore; A1-0004886 – Russell B. Mantooth; A1-0004887 – Christopher C. Williams; A1-0004888 – Julius Asofar; A1-0004889 – Carl J. Isenberg; A1-0004890 – Kristin K. Ball; A1-0004891 – Fabrice Afanyu-Lorater; A1-0004892 – Elizabeth Ann Darbee; A1-0004893 – Allison B. Henry

Distributor Permits

32 Issued From October 1, 2015, to December 31, 2015

A4-0000510 – The Harvard Drug Group, LLC, dba Major Pharmaceuticals; A4-0000787 – PharMedium Services, LLC; A4-0002241 – Synergy Rx Express, LLC; A4-0002242 – Unique Pharmaceuticals, LTD; A4-0002243 – Cardinal Health, dba Specialty Pharmaceutical Services; A4-0002244 – PureTek Corporation; A4-0002245 – Exel, Inc; A4-0002246 – Sigma Aldrich, Inc; A4-0002248 – QuVa Pharma, Inc; A4-0002249 – Cardinal Health, dba Metro Medical Supply; A4-0002250 – Cardinal Health, dba Metro Medical Supply; A4-0002251 – Trigen Laboratories, LLC; A4-0002252 – BDI Pharma, Inc; A4-0002253 – Amneal Pharmaceuticals, LLC; A4-0002254 – YS Marketing, Inc, dba NUMED; A4-0002256 – Hospira Worldwide, Inc; A4-0002257 – Hospira Worldwide, Inc; A4-0002258 – Woodfield Distribution, LLC; A4-0002259 – Hospira Worldwide, Inc; A4-0002260 – UPS Supply Chain Solutions, Inc; A4-0002261 – St Mary's Medical Park Pharmacy, Inc; A4-0002262 – Advanced Pharma, Inc; A4-0002263 – BioComp Pharma; A4-0002264 – Boehringer Ingelheim Pharmaceuticals, Inc; A4-0002265 – Boehringer Ingelheim Pharmaceuticals, Inc; A4-0002266 – Hospira Worldwide, Inc; A4-0002267 – Hospira Worldwide, Inc; A4-0002268 – Independent Pharmacy Distributor, LLC; A4-0002269 – PharMEDium Services, LLC; A4-0002270 – Sigma Pharmaceuticals, LLC; A4-0002271 – PharMEDium Services, LLC; A4-0002272 – PharMEDium Services, LLC

In-State Pharmacy Permits

Six Issued From October 1, 2015, to December 31, 2015

A3-0000991 – Nanticoke Pharmacy, LLC; A3-0000992 – Acme Markets, Inc, dba Acme Pharmacy #2679; A3-0000993 – Acme Markets, Inc, dba Acme Pharmacy #2682; A3-0000994 – Acme Markets, Inc, dba Acme Pharmacy #2680; A3-0000995 – Delaware CVS Pharmacy, LLC; A3-0000996 – Delaware CVS Pharmacy, LLC

The *Delaware State Board of Pharmacy News* is published by the Delaware 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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