

South Dakota State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Registered Pharmacists

The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Michelle Faber, Daniel Asarch, Gail Boehne, Jeremy Gieseke, Michael Dosch, Nicholas Novotny, Mitchell Schultz, Chintal Patel, Hong Yen Thi Vi, Craig Spangler, Jennifer O’Callaghan, Anthony Changelo, Taryn Cunningham, Glenn Hanson, Jada Le, Eric Mathiowetz, Jennifer Wagner, Chad Forinash, Alex Middendorf, Jean Silverman, Philip Song, Vindha Prasad, and Tamara Squier.

Rules for Narcotic Dependant Maintenance or Detoxification

There can be some misinterpretations on the prescribing and dispensing rules for narcotic dependent patients for the purpose of maintenance or detoxification. Drug Enforcement Administration (DEA) cites in **21 CFR §1306.07 – Administering or dispensing of narcotic drugs:**

- (a) A practitioner may administer or dispense directly (but not prescribe) a narcotic [(opioid)] drug listed in [Schedule II] . . . if the practitioner meets both of the following conditions:
 - (1) The practitioner is separately registered with DEA as a narcotic treatment program.
 - (2) The practitioner is in compliance with DEA regulations regarding treatment qualifications, security, [and] records . . . pursuant to the Act.

The chapter goes on to state:

- (d) a practitioner may administer or dispense (including prescribe) any Schedule III, IV, or V narcotic (opioid) drug specifically approved by the Food and Drug Administration for use in maintenance or detoxification treatment to a narcotic [(opioid)] dependent person if the practitioner complies with the requirements of §1301.28 of this chapter.

Therefore, if you receive a prescription for a Schedule II opioid medication (for example, methadone) with a clinical indication of opioid dependence/withdrawal, the prescription is not valid, regardless of whether or not the prescriber has the “X” DEA designation. If you receive a prescription for a Schedule III opioid or above (for example, suboxone) with a clinical indication of opioid dependence/withdrawal, the prescription is valid as long as the prescriber provides the “X” DEA designation.

This and many other DEA tips can be found in the Questions & Answers section of the DEA website at www.deadiversion.usdoj.gov/faq/index.html.

January Deadline Is Here

With the signing of the Drug Quality and Security Act (DQSA) in November 2013, Title II of the DQSA, titled the Drug Supply Chain Security Act (DSCSA), is a 10-year plan to put the industry on a fully interoperable electronic drug product track and trace system. However, by January 2015, pharmacies and dispensers must be compliant with the first wave of the track and trace requirements in paper or electronic formats. A recordable transaction can be defined as transfers of products between persons or agencies that constitute a change of ownership. Distributions that are not considered recordable transactions include (but are not limited to) intracompany distributions; distributions among hospitals or other health care entities under common ownership; distributions for emergency medical reasons, including public health emergencies (a drug shortage is not declared a medical emergency); dispensing a product pursuant to a prescription; and distribution of minimal quantities of a product by a licensed pharmacy to a licensed practitioner for office use. Transaction information that is required includes proprietary or established name of the product; its strength and dosage form; National Drug Code number; container size; number of containers; lot number; transaction date; date of shipment if more than 24 hours after the date of the transaction; business name and address of the person from whom ownership is being

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

System-Based Causes of Vaccine Errors

 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.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that 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. Those 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 a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at www.njconsumeraffairs.gov/press/05012013.pdf.

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.

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transferred; and business name and address of the person to whom the ownership is being transferred.

For more complete information on the DSCSA, please review the DSCSA Implementation Plan page of the Food and Drug Administration website at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm382022.htm.

Single Dose Vials/Ampules

Centers for Disease Control and Prevention (CDC) guidelines call for medications labeled as “single dose” or “single use” to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to health care providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines.

Update on USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

Based on the nature and significance of the public comments received on United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, the chapter is currently being revised and will be republished for public comment. For more information, please visit www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings.

The revised general chapter is targeted to be published in Pharmacopeial Forum 41(2) in March 2015; however, United States Pharmacopeial Convention is currently working to post it on its website at an earlier time. Once it is published, it will be available for access on the USP Compounding Standards & Resources web page at www.usp.org/usp-healthcare-professionals/compounding.

Board Meeting Dates

Please check the Board’s website for the times, locations, and agenda for future Board meetings.

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