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FDA Updates – Initiatives, Programs, and Databases

Did you know that Food and Drug Administration (FDA) writes and films videos just for you? The team of pharmacists at FDA's Division of Drug Information wants their fellow pharmacists to have quick, easy access to information about FDA initiatives, programs, and databases. Last October, the agency announced the release of its brand new videos in the *Drug Info Rounds* series, and the Iowa Board of Pharmacy would like to remind you of these important videos.

The first video in FDA's new series is *Medication Adherence.* In less than three minutes, FDA pharmacists share tips and tools to help you and your patients better communicate about safe medication use, including:

- For you: *www.scriptyourfuture.org* offers wallet cards, posters, door hangers, and more for you to use in your pharmacy.
- For your patients: Stop – Learn – Go – Tips for Talking with Your Pharmacist

Other videos in the series include *Breakthrough Therapy, Antibiotic Resistance,* and *MedWatch Tips & Tools* (tutorial).

The most popular videos from previous seasons include *Accelerated Approval Program, Medication Errors, Disposal of Unused Medicines,* and *Electronic Orange Book.*

Watch the videos online at *http://go.usa.gov/ccfuh.*

Annual CS Inventories: What to Include?

By Jean Rhodes, RPh, Board Compliance Officer

An annual controlled substance (CS) inventory is required to be taken on any date that is within one year plus seven days after the date of the previous annual inventory. The date and time of day (open or close of business) and the signature of the person(s) completing the inventory must be on the inventory record. This task can be delegated, and technicians or pharmacists may complete the inventory record. The inventory must account for **all CS** under the registrant's control. This includes any expired medications, filled prescriptions waiting to be picked up, and drugs in automated dispensing systems or emergency kits that are owned by the pharmacy, including emergency medical service or long-term care emergency kits.

Compounding Convenience Kits

By Sue Mears, MBA, RPh, Board Compliance Officer, and Laura Steffensmeier, Iowa Assistant Attorney General

Over the last few years, companies have been increasingly selling compounding "convenience kits" containing bulk drug ingredients that, when combined in accordance with the instructions, create a compounded drug product. Pharmacists have often posed two questions regarding these kits. First, if a convenience kit is commercially available, do they have to use it to compound the product? The answer is no; a pharmacy is not required to utilize a convenience kit to compound a drug product. A convenience kit is considered a bulk drug ingredient for human prescription compounding by FDA. Convenience kits, on their own, are not considered FDA-approved products (even though they may be labeled with a National Drug Code number), nor are they considered "finished pharmaceuticals." A pharmacy is not required to utilize a convenience kit to compound a drug product for a patient. Second, does the pharmacist still need to complete and maintain a compounding record when making a compounded drug product using a convenience kit? The answer is yes; a pharmacy is still required to complete a compounding record when compounding a drug product using a convenience kit. Because the kit itself is not an FDA-approved product, following the kit's instructions is not considered mixing or reconstituting per the manufacturer label, and is therefore not exempt from the definition of compounding and not exempt from the record-keeping requirements applicable to all compounded drug products.

Can Technicians Perform Drug Identification?

By Terry Witkowski, Board Executive Officer

The identification of medication may be performed by a pharmacy technician as long as the pharmacist-in-charge and the supervising pharmacist agree to permit the technician to perform that function. Policies and procedures should clearly define who can perform the function, when the pharmacist should be consulted (eg, if the technician cannot clearly identify the medication or has questions), the resources to be used to assist in identifying the medication, and the limits of the technician's interaction with the practitioner. For example, the technician may identify the medication to the practitioner but should not advise the practitioner regarding the advisability of the patient's continued use of the medication or the implied diagnosis that prompted the patient's need or use of the medication.

Commonly Found Deficiencies: Vaccine Administration

By Jean Rhodes, RPh, Board Compliance Officer

During any pharmacist renewal period, an authorized pharmacist who engages in the administration of vaccines shall complete and document at least one hour of continuing education (CE) related to vaccines. Please maintain documentation or proof of the following in the pharmacy in which you are administering vaccines: current CPR certification, vaccine administration training, and verification of completion of one CE unit pertaining to the administration of vaccines per pharmacist license renewal cycle.

The pharmacy must have the emergency medications and supplies listed in the protocol. During recent inspections, several pharmacies have not had the listed amount of epinephrine doses for children.

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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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Some have included medications not listed in the protocol, such as ammonia inhalants (smelling salts).

Technician Registration Versus Technician Certification

Pharmacy technicians must be nationally certified by any National Commission for Certifying Agencies-accredited pharmacy technician certification program and examination to obtain, maintain, and renew registration with the Board as a certified technician. Registrations expire on the last day of the technician's birth month and are renewed on a two-year cycle; ie, if a technician's birth month is January and he or she obtains registration in July 2016, that registration would expire the last day of January 2018. Technicians must provide proof to the Board that they have renewed their national certification prior to renewing their registration with the Board.

Technicians: Please remember that you have two items that must be renewed and that those renewal periods may or may not coincide.

USP <797> Compliance Officer Surveys

The Board has recently amended its rules to incorporate United States Pharmacopeia (USP) Chapters <795> and <797> by reference. In an effort to ensure all pharmacies are aware of and are abiding by this requirement, Board compliance officers have been reaching out to pharmacies to schedule surveys of sterile compounding practices. This is an educational opportunity for pharmacists and technicians, and the Board encourages all sites that perform sterile compounding to complete the survey. If you have not had an opportunity for a compliance officer to complete a survey at your facility, please reach out to your compliance officer to schedule a visit. Contact information for compliance officers may be found on the Board's website at *https://pharmacy.iowa.gov.*

2015 Iowa PMP: Annual Report

The number of inquiries from pharmacists processed through the Iowa Prescription Monitoring Program (PMP) in 2015 increased by 32% from 2014. Additionally, requests made by prescribers also increased from 2014, by 38%.

The total number of prescriptions dispensed in 2015 increased by 8%, compared to a 2.6% increase in 2014 and a 0.023% increase in 2013. This increase is most likely due to Drug Enforcement Administration's (DEA) scheduling of tramadol from a legend drug to a Schedule IV drug, which occurred on August 18, 2014.

Hydrocodone and hydrocodone-containing products accounted for 20% (down from 26% in 2014) of all doses dispensed, followed by tramadol (15%), alprazolam (9%), oxycodone (8%), lorazepam (6%), clonazepam (6%), methylphenidates (5%), zolpidem (4%), diazepam (2%), and Vyvanse® (2%).

Since 2010, the number of individuals obtaining Schedule II and III prescriptions from five or more prescribers or pharmacies has been reduced by 85%. Likewise, the number of individuals obtaining Schedule II and III prescriptions from 10 or more prescribers or pharmacies has been reduced by 99%. The PMP continues to gain registered users. Prescriber registrations increased by 15% from 2014, while pharmacist registrations increased by 13%.

The complete annual report is on the Board's website under PMP.

NABP.net: A Wealth of Information

The National Association of Boards of Pharmacy® (NABP®) website, *www.nabp.net,* is chock-full of useful, relevant pharmacy practice information. Want to know how to transfer your license to another state? Unsure if a wholesaler is reputable? Need to check the status of your CE? All of the answers to these questions, and more, can be found on the NABP website.

NABP provides numerous accreditation programs, including: durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); Verified-Accredited Wholesale Distributors® (VAWD®); Verified Internet Pharmacy Practice Sites® (VIPPS®); Veterinary-Verified Internet Pharmacy Practice Sites® (Vet-VIPPS®); and the NABP e-Advertiser Approval℠ Program. Information pertaining to each of these accreditation programs is available at *www.nabp.net.*

Additionally, NABP provides information on its website pertaining to the various examinations and assessments it administers, including the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®), among others.

Finally, if after perusing the NABP website you are still unable to find the answers to your questions, simply click on "Questions? Chat Is Available" and you will be connected to an NABP agent who can assist you.

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