MISSOURI BOARD OF PHARMACY

NEWSLETTER

FEBRUARY 2016

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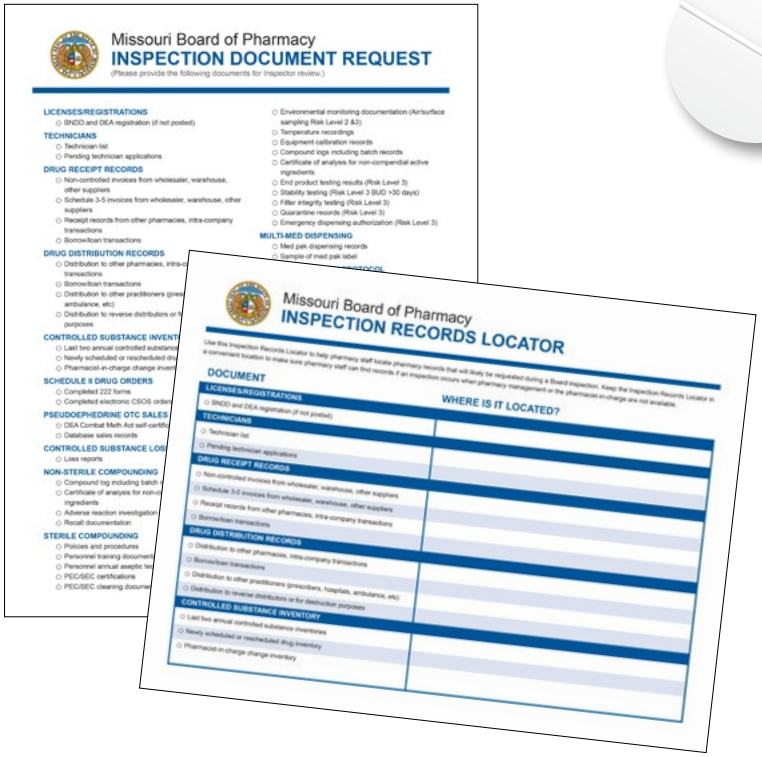
2016 INSPECTION CHANGES

The Board initiated a new pharmacy inspection process that was implemented statewide in January of 2016. The goal of the new inspection program is to focus pharmacy inspection resources on the compliance areas that directly impact patient safety. As part of the new program, the Board has approved a pharmacy "Inspection Checklist" to replace the current inspection Observation Report. The Inspection Checklist contains a detailed list of the most common compliance elements that your inspector will evaluate during an inspection.

The Inspection Checklist is not exhaustive and does not contain all pharmacy compliance elements. The Inspection Checklist simply lists the most common compliance areas. Your inspector may evaluate other areas of compliance based on the pharmacy's activities. The Board encourages licensees to use the Inspection Checklist to assess the pharmacy's compliance before an official inspection. Separate checklists for sterile compounding pharmacies and nuclear pharmacies will be available later this year.

The Board has also issued a new Inspection Document Request Form to assist in the inspection process. The Inspection Document Request Form lists the records inspectors most frequently ask for during an inspection. Your inspector will provide the form to you at the beginning of your inspection and designate the documents he/she will need to review. This process will give licensees time to gather documents and decrease pharmacy interruptions caused by multiple document requests.

Despite multiple newsletter articles, pharmacy inspections often take longer than anticipated because pharmacy staff cannot find required documents. To assist licensees, the Board has issued an Inspection Records Locator Form. The Inspection Records Locator Form lists the commonly requested records and provides space to write down where the record can be found. The Board encourages licensees to share the Inspection Records Locator Form with appropriate staff to make sure staff knows where to find records if the pharmacist-in-charge is absent during an inspection.


Missouri Board of Pharmacy
INSPECTION DOCUMENT REQUEST
(Please provide the following documents for inspector review.)

LICENSES/REGISTRATIONS
TECHNICIANS
DRUG RECEIPT RECORDS
DRUG DISTRIBUTION RECORDS
CONTROLLED SUBSTANCE INVENT
SCHEDULE II DRUG ORDERS
PSEUDOEPHEDRINE OTC SALES
CONTROLLED SUBSTANCE LOG
NON-STERILE COMPOUNDING
STERILE COMPOUNDING
MULTI-MED DISPENSING

Missouri Board of Pharmacy
INSPECTION RECORDS LOCATOR
DOCUMENT
WHERE IS IT LOCATED?
LICENSES/REGISTRATIONS
TECHNICIANS
DRUG RECEIPT RECORDS
DRUG DISTRIBUTION RECORDS
CONTROLLED SUBSTANCE INVENTORY

INSPECTION RESOURCES

The Inspection Checklist, the Inspection Document Request Form and the Inspection Records Locator Form are available on the Board's website at http://pr.mo.gov/pharmacists-pharmacies.asp.

INTRODUCING OUR NEW BOARD MEMBERS

The Board welcomes the following new Board members who were confirmed by the Missouri Senate in January of 2016:

VICE-PRESIDENT

Christian S. Tadrus, Pharm.D.
Original Appointment: 6-11-15
Current Term Expires: 6-10-20

Dr. Christian Tadrus is an owner of independent, community-based pharmacies in Missouri providing prescriptions, compounding, long-term care services, hearing aids and durable medical equipment. He received his undergraduate degree in Business Administration and Management from Boston University and both a Bachelor of Science and a Doctor of Pharmacy from the St. Louis College of Pharmacy. He is a lead developer of the Missouri Pharmacists Care Network - a pharmacist-led, provider network facilitating adoption of innovative pharmacist care models throughout Missouri. Dr. Tadrus is certified to provide immunizations as well as medication therapy management, is credentialed to enter into advanced practice protocols and is a nationally-certified Asthma Educator. Dr. Tadrus previously served as an Adjunct Clinical Instructor for both the University of Missouri School of Pharmacy and the St. Louis College School of Pharmacy. He is a past-President of the Missouri Pharmacy Association, a vice-president of the National Community Pharmacy Association and a member of other state and national pharmacy and industry organizations. Dr. Tadrus was elected as Vice-President of the Board in 2015.

Douglas R. Lang, R.Ph., Member
St. Louis, MO
Original Appointment: July 21, 2015
Current Term Expires: July 20, 2020

Douglas Lang received his Bachelor of Science degree in 1981 from the Saint Louis College of Pharmacy. He holds licensure as a pharmacist in Arkansas, Delaware Louisiana, Nebraska, and Pennsylvania. Mr. Lang started his pharmacy career at Saint Louis University Medical Center serving as a Staff Pharmacist and Assistant Director of Pharmacy. He then practiced in the area of Home Infusion Pharmacy for over fifteen years and was the Pharmacy Manager of the BJC Home Infusion Program. Currently, Mr. Lang is the Vice President of Pharmacy Compliance for Express Scripts Inc., based in St. Louis, Missouri. He provides compliance oversight to the company's mail-order, specialty, fertility pharmacies and its specialty drug distribution operations. He is a member of the Saint Louis Society of Health System Pharmacists and Missouri Society of Health System Pharmacists. He is a member American Society of Health-System Pharmacists and National Association of Boards of Pharmacy. He is a past recipient of the Saint Louis Society and Missouri Society Pharmacist of the Year Award and a past recipient of the Missouri Research and Education Foundations Thomas Garrison Award. He previously served on the Board from 2002 to 2007.

MEET OUR NEW INSPECTORS

Join us in welcoming our newest Board inspectors:

Elaina Wolzak received her Bachelor of Science degree in 1994 from the University of Missouri-Kansas City School of Pharmacy. Her pharmacy practice background includes sixteen years in retail pharmacy as a pharmacy manager and supervisor. She also spent over five years in the pharmacy technology and automation field engaged with drug and third-party database management. Elaina is also a past member of the Missouri Board of Pharmacy serving from 1999-2010. Elaina's territory includes the Kansas City area that became vacant after Frank VanFleet's recent retirement.

Katie DeBold received her PharmD. Degree from St. Louis College of Pharmacy in 2010. Katie has practiced primarily as a hospital pharmacist and served as the IV room coordinator for a large Missouri hospital. Katie will primarily assist the Board with sterile compounding inspections and investigations throughout the state.

GET READY TO RENEW!

2016 is a pharmacist renewal year. All Missouri pharmacists must renew their licenses before October 31, 2016. It's not too early to begin counting your continuing education (CE). A few CE reminders:

- All Pharmacists are required to complete 30 hours (3.0 CEU) of approved CE in order to renew their license every two years (20 CSR 2220-7.080). For the 2016 renewal, CE must be completed between November 1, 2014 and October 31, 2016, to be eligible. However, your CE must be completed prior to renewing your license. You will have to attest that your CE has been completed when you renew. One continuing education unit (CEU) is the equivalent of ten clock hours of CE.
- Newly Licensed Pharmacists: Pharmacists that are licensed for the first time between November 1, 2015 and October 31, 2016 are exempt from CE for that renewal period. However, other CE requirements may still apply. For example, CE may still be required if you have a MTS certificate, are dispensing blood-clotting products or have filed a Notification of Intent to administer medication by prescription or to immunize by protocol.
- To be considered, all CE must be provided by an ACPE accredited provider or approved by the Board of Pharmacy in advance. Only non-ACPE courses must be pre-approved. The Board will not approve non-ACPE classes that have already been taken.
- Continuing medical education (CME) is not eligible for CE unless pre-approved by the Board.
- CE credit is available for attending an in-person open session Board meeting. The pharmacist must be present for the entire open session or, for longer meetings, attend at least eight (8) hours of open session. Four hours of CE credit will be granted for each open session attended. A maximum of 8 CE hours earned by attending Board meetings may be used to meet the biennial CE renewal requirement.
- Undergraduate or graduate courses taken as a post-graduate at an accredited pharmacy, medical, or dental educational institution of higher learning are eligible for CE. [20 CSR 2220-7.080]. The college credit must be related to the practice of pharmacy and must have been earned during the CE renewal period. One hour of college credit = 5 CE hours.

MARK YOUR CALENDAR

THE 2016 "LUNCH WITH THE CHIEF" WEBINAR SERIES

The series will be hosted from 12 p.m. to 1 p.m. on:

APRIL	AUG	OCT
28	04	25

Webinar topics will be posted closer to the webinar.

UPCOMING BOARD MEETING DATES

The Board's 2016 in-person meetings will be held on:

APRIL	JULY	OCT
05-06	19-21*	26-27

*Tentative Strategic Planning Date

All meetings will be held at the Hilton Garden Inn, 3300 Vandiver Drive, Columbia, Missouri. Visit the Board's website for additional meeting information, including, proposed agenda items.

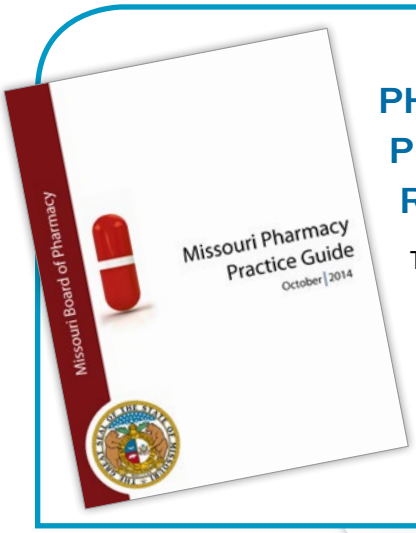
PHARMACIST CE GUIDE

Who?	Number of hours required	CE DATE RANGE (Your CE must be earned in this date range)	Can I use it as part of my 30 hours?	Notes
All Missouri licensed pharmacists (In-state & out-of-state) [20 CSR 2220-7.080]	30	11/1 - 10/31 of EVEN numbered years (e.g., Nov. 1 2014 - Oct. 31, 2016; Nov. 1, 2016 - Oct. 31, 2018, etc.)	Yes	
Pharmacists dispensing/providing patient counseling on blood clotting factor concentrates [20 CSR 2220 - 6.100(3)]	4 hours of approved CE related to blood clotting factor concentrates, infusion treatment or therapy or blood clotting disorders or diseases	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2014 – Oct. 31, 2016; Nov 1. 2016- Oct. 31, 2018, etc.)	Yes	The CE requirement only applies to certain pharmacists dispensing blood clotting factor concentrates and pharmacists who provide patient counseling regarding blood-clotting factor concentrates to bleeding disorder patients. See 20 CSR 2220-6.100(3) for definitions of "blood-clotting product" and a "bleeding disorder patient" and for more information on who needs to comply.
Pharmacist Administering by Prescription Order [20 CSR 2220-6.040(3)	2 hours of approved CE related to administering drugs/vaccines	Must have been completed within the calendar year prior to submitting your NOI.	Yes	The same two hours of CE may be used for pharmacists submitting both a Notice of Intent to Administer Medication by Prescription Order and a Notice of Intent to Administer Vaccines by Protocol.
Pharmacist Immunizing by Protocol [20 CSR 2220-6.050(3)	2 hours of approved CE related to administering vaccines	Must have been completed within the calendar year prior to submitting your NOI.	Yes	See note above
Pharmacists with a Certificate of Medication Therapeutic Services ("MTS Certificate) [20 CSR 2220-6.070]	6 hours of approved CE related to medication therapy management	11/1 - 10/31 of even numbered years (e.g., Nov. 1 2014 – Oct. 31, 2016; Nov 1. 2016- Oct. 31, 2018, etc.)	Yes	The Board will accept approved MTS CE related to any drug therapy or disease state management. These courses generally have an "01" Drug Therapy Related ACPE universal activity number (Example: ACPE Universal Activity Number: xxxx-xxxx-xx-xxx-x01-x).
Intern Pharmacists/ Pharmacy Technicians	NO CE REQUIREMENTS	NO CE REQUIREMENTS	N/A	

COMPLIANCE CORNER

(The following list contains examples of non-disciplinary compliance actions taken by the Board. The information below is provided for educational purposes only and to increase compliance. Each case is reviewed on its individual merits.)

- The Board reviewed a controlled substance loss report that was filed by a Missouri pharmacy after a patient stole a controlled substance prescription that was left unattended on the pharmacy's counter while the pharmacy technician consulted with other pharmacy staff. At another pharmacy, a customer stole a prescription that the technician left on the pharmacy counter when the technician stepped away to answer the customer's question. It appears the question was intentionally asked to divert the technician's attention. *Compliance Tip: Unfortunately, thieves are smart. Never leave medication unattended or in a public access area. Train staff to make sure medication is properly secured and out of public reach at all times.*
- The Board reviewed a recent investigation involving a pharmacy that allowed pharmacy technicians to assist in the practice of pharmacy without proper supervision. Specifically, the pharmacy allowed technicians to open and check-in drug orders without a pharmacist present. *Compliance Tip: This practice could lead to diversion! Pharmacy technicians must be under the supervision of a pharmacist when drug orders are checked in and received.*
- A patient complained that her pharmacist announced in an open waiting area that her Xanax prescription would not be filled. The patient complained the pharmacist used a loud voice that was overheard by everyone in the waiting area. No further action was taken because of insufficient evidence. However, the Board reminds pharmacists of their duty under state and federal law to maintain the confidentiality of patient medical information. *Compliance Tip: Be careful when communicating with patients in open waiting areas. If a private patient consultation space/area is not available, monitor your tone to make sure confidential information is not shared.*
- During a recent diversion investigation, the Board discovered that all of the pharmacy's staff had access to the passwords used to order drugs from the wholesaler and were able to add to or change a drug order independently. Drug orders were frequently received when a relief pharmacist was on duty who did not know or have a way to verify that the order was correct or appropriate. *Compliance Tip: This is another diversion opportunity! If possible, the Board recommends that a pharmacist review all drug orders to make sure they're appropriate. At a minimum, drug orders should be monitored/checked by knowledgeable pharmacy staff who have been trained to identify an unusual or suspicious order.*



PHARMACY PRACTICE GUIDE REVISION:

The Board will be revising the Missouri Pharmacy Practice Guide in 2016. Have suggestions?

E-mail the Board office at MissouriBOP@pr.mo.gov.

MPJE

Beginning April 15, 2016, the National Association of Boards of Pharmacy (NABP) will implement new changes to the Multistate Pharmacy Jurisprudence Examination (MPJE). NABP has issued the following guidance:

- The updated MPJE will be administered beginning April 15, 2016. The number of examination items will increase from 90 (75 scored and 15 pre-test) to 120 (100 scored and 20 pre-test) and the maximum testing time will increase from two hours to two and a half hours. The fee for the new exam will increase from $ 210 to $250. MPJE candidates registering for the exam after April 12, 2016 will be assessed the $250 fee.
- Registration for the current MPJE will remain open through April 3, 2016. Candidates must complete their registration with NABP for the current MPJE by April 3, 2016. These candidates must obtain eligibility from the Board, receive an authorization to test (ATT), schedule with Pearson VUE, and sit for the exam on or before April 10, 2016.
- If a candidate registers for the MPJE by April 3, but does not take the exam on or before April 10, 2016, their registration will be canceled and their fee of $210 will be refunded. The candidate will then need to register for the updated exam and pay the $250 fee on or after April 12, 2016. According to NABP, this will also apply to candidates who have open registrations for the MPJE but have not taken the exam.
- Detailed information on the upcoming MPJE changes is included in the 2016 NAPLEX/MPJE Candidate Registration Bulletin which is available on NABP's website.

INSPECTION TIP

The new year brings another opportunity to assess your pharmacy's compliance and earn two hours of free CE while doing so. The Pharmacy Self-Assessment Form is an online tool that will assist you in conducting your own compliance inspection. Pharmacists-in-charge, pharmacy managers, owners, supervisors, and corporate officers are eligible to earn CE for completing the assessment each calendar year.

AUTHORIZED NALOXONE DISTRIBUTIONS

The Board has recently received questions regarding naloxone distributions/sales to law enforcement agencies. In 2014, § 190.255, RSMo, was enacted which authorizes Missouri licensed drug distributors and pharmacies to sell naloxone to a "qualified first responder agency". A "qualified first responder agency" is defined as "any state or local law enforcement agency, fire department or ambulance service that provides documented training to its staff related to the administration of naloxone in an apparent narcotic or opiate overdose situation." [§ 190.255.2]

Naloxone distributions to a qualified first responder agency should be documented by invoice. Prescriptions cannot be used to document the distribution. Invoices should include:

a) The date of sale;

b) Product name;

c) Quantity distributed;

d) The identity of the qualified first responder agency; and

e) The pharmacy's full address.

Invoices must be maintained in the pharmacy's/distributor's records for two (2) years and filed separately from prescription records.

GOLD CERTIFICATES

The following pharmacists will receive gold certificates in honor of maintaining a pharmacist license with the Board for 50 years. Congratulations to our newest "gold-certificate" pharmacists:

Clifford A. Triplett
Stephen D. Adams
David J. Horejsi
Thomas V. Todd

DISCIPLINARY ACTIONS

PHARMACISTS

Kelly L. Drahota, #2002027551, Drexel, MO. Public censure. As pharmacist-in-charge, administered vaccines without a signed/dated immunization protocol, administration record keeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Mary M. Ellison, #042428, St. Charles, MO. Suspension for three (3) months, followed by Probation for five (5) years. Possessed and consumed controlled substance without a valid patient-specific prescription, used prescriptions meant for her children. Section 338.055.2(5), (6), (13), (15), and (17), RSMo.

Craig Harris, #045232, Kirksville, MO. Probation for three (3) years. As pharmacist-in-charge, no annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; pharmacy permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.

Hillary A. Jackson, #2012013212, Sedalia, MO. Suspension for two (2) years, followed by Probation for five (5) years. Misappropriation of controlled substances from employer for personal use, created and filled controlled substance prescriptions not authorized by her healthcare providers for herself, worked while impaired. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Shannon M. Krieg, #2005000313, O'Fallon, MO. Two (2) additional years of probation. Violation of discipline, tested positive for marijuana, failed to call-in daily to drug testing, and submitted diluted urinalysis samples. Section 338.055.2(5), (6), (13), and (15), RSMo.

Dianne T. Mattix, #043771, Branson West, MO. Public Censure. As pharmacist-in-charge, administered vaccines without a signed immunization protocol, failed to maintain copy of prior protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

Darryl K. Middleton, #028380, Oak Ridge, MO. Probation for three (3) years. As pharmacist-in-charge, created and filled a prescription without prescriber authorization to be used for his pet, misbranding and record keeping violations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Donna J. Neighley, #2006025342, Reeds Spring, MO. Public Censure. Administered vaccines without a signed immunization protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

Dwight K. Nyberg, #028845, Buffalo, MO. Probation for five (5) years. As pharmacist-in-charge, diversion of controlled substances for personal use without a valid, patient specific prescription. Section 338.055.2(5), (13), (15), and (17), RSMo.

David N. Payton, #029753, O'Fallon, MO. Public censure. Administered immunizations without a signed written protocol. Section 338.055.2(5), (6), (13), and (15), RSMo.

Donald S. Sandler, #028168, St. Charles, MO. Public censure. Administered immunizations without submitting a notification of intent to the Board, failed to maintain vaccine administration records, failed to timely notify administration of a vaccine to a patient's primary care provider, and failed to timely notify patient's primary care provider of adverse reaction. Section 338.055.2(5), (6), (13), and (15), RSMo.

Cody R. Steele, #2013026251, St. Joseph, MO. Probation for one (1) year. Dispensing errors, one of which resulted in patient death. Section 338.055.2(5) and (13), RSMo.

PHARMACIES

Nyberg Pharmacy, Inc., #004441, Buffalo, MO. Board Order issued taking no further action due to pharmacy being closed/out of business. Diversion of controlled substances by pharmacist-in-charge/owner; failure to provide adequate security of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.

People's Health Center Pharmacy, #005971, St. Louis, MO. Public censure. Loss of controlled substances, failure to provide adequate security to deter drug theft or diversion of controlled substances. Section 338.055.2(5), (6), (13), and (15), RSMo.

Rider Drug, Inc., #004254, Kirksville, MO. Probation for three (3) years. No annual review/missing sections of sterile products policies/procedures; failure to conduct annual process validation of aseptic technique; compounding log missing information; failure to maintain refrigerator/freezer temperature logs; unsecured storage of controlled substances; permit did not include sterile compounding classification; improper prepackaging; unlawful sharing of CSOS certificate; inaccurate inventory; failure to electronically record receipts of CSOS orders; unsanitary conditions; improper labeling; improper dispensing of controlled substances; and failure to correct Compliance Notice deficiencies. Section 338.055.2(5), (6), (13), and (15), RSMo.

Semo Drugs of Kennett, #006018, Kennett, MO. Probation for three (3) years. Technician theft of controlled substances, failure to maintain adequate security to deter theft of controlled substances. Section 338.055.2(6), RSMo.

Village Fertility Pharmacy, Inc., #2015039678, Waltham, MA. Restricted permit issued on Probation for three (3) years. Shipped into Missouri prior to licensure and disciplinary action in other states. Section 338.055.2(4), (5), 6), and (8), RSMo.

Walgreens #7185, #003418, Chesterfield, MO. Public censure. Technician diversion of controlled substances, pharmacy failed to provide adequate security or effective controls and procedures to detect and prevent drug diversion. Section 338.055.2(6) and (15), RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - 1ST QUARTER 2016

(The following information was provided by the National Association of Boards of Pharmacy and is reprinted with permission of NABP. This information is provided for informational purposes only and does not express or represent the views or opinions of the Missouri Board of Pharmacy.)

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.