Greetings,

Welcome to the February issue of the Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.

I am pleased to announce that the Illinois Department of Financial and Professional Regulation (IDFPR) has enhanced its website to enable licensees to update their contact information at any time. The IDFPR will be using email as a primary notification method for license renewal notifications and other important notifications in the future. The IDFPR is also researching using automated call technology for future licensee notifications. As a result of these new initiatives, it is critical that the IDFPR has the primary email address and phone number for all licensees.

Please follow the instructions below to submit or update your phone number, email address, or address.

1. Visit www.idfpr.com/addressUpdate.asp. (This is the same page where licensees may request paper reprints of their licenses.)
2. Click the link at the top of the screen that says, “Click Here to request a License Reprint or to Change your Address, Email Address or Telephone Number.”
3. Select your profession in the first drop-down box.
4. Make sure that “Change/Verify Address & Contact Info” is selected in the “Reprint Reason” drop-down box.
5. Enter your licensee number, United States Social Security Number, and date of birth.
6. Click “Search.”
7. Once your information has been found, it will be displayed and then updates can be made to the phone number, email, and address fields.
8. Make the desired updates and click “Save and Continue” to lock the changes in the system.

Thank you for taking the time to confirm that the IDFPR has your correct contact information. This will ensure compliance and help better the practice of pharmacy in Illinois.

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov
312/793-3676

New Board Member Appointment

The IDFPR, Division of Professional Regulation – State Board of Pharmacy would like to thank Ronald Weinert for his service and contributions over the past five years to the Board.

Denise Scarpelli was appointed to the Board by Governor Bruce Rauner. She is replacing Ronald, whose term ended in April 2015. Denise will serve a five-year term, which began November 2015 and will expire in 2020.

Denise is a graduate of the University of Illinois at Chicago College of Pharmacy. She is a director of pharmacy and retail for Walgreens Boots Alliance, and has over 19 years of pharmacy experience. Congratulations to Denise in her new advisory role.

Upcoming Board Meetings

The Board is scheduled to meet:
- March 8, 2016 – Springfield, IL, Room 202N
- May 10, 2016 – Chicago, IL, Room 9-040

Chicago location: 100 W Randolph St, 9th Floor
Springfield location: 320 W Washington St

Pharmacy Best Practice and Regulation Review: Self-Inspections, Prescription Monitoring Program, and Immunizations

By Garth K. Reynolds, RPh, IPhA Executive Director

Self-Inspections

As of April 23, 2015, pharmacies of all practice settings are to perform an annual self-inspection of their site. The self-inspection form that is utilized needs to conform with your current practice setting and services provided.
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.


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/Recalls/ucm464072.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/Recalls/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, prefilled, 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.


**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.

Self-inspection forms are available for the following practice settings and services:

- Community pharmacy
- Nonsterile compounding pharmacy
- Nuclear pharmacy
- Onsite institutional pharmacy
- Offsite institutional pharmacy
- Remote prescription-medication order processing pharmacy
- Sterile compounding pharmacy
- Telepharmacy – Remote consultation site pharmacy
- Telepharmacy – Automated pharmacy systems pharmacy
- Telepharmacy – Remote dispensing site pharmacy

The list of practice settings and services may change, so please refer to the most current list and self-inspection forms on the Board website under the “Resources & Publications” section. The Board website is http://ilboard.pharmacy.

Reminder: The self-inspection forms must be made available to pharmacy compliance officers and be maintained at the pharmacy for five years.

Suggestion: To aid in compliance, perform the self-inspection during the same month or time frame of your annual controlled substance inventory and during any change in pharmacist-in-charge (PIC).

Prescription Monitoring Program

As discussed in the November 2015 Newsletter issue, with the passage of Public Act (PA) 99-480 there were changes that affected the Illinois Prescription Monitoring Program (PMP). A major change is the reporting time period, which was amended from within seven days to the end of the next business day. If you have not already started reporting to the PMP under the new time period, please make this change with immediate effect. PA 99-480 went into effect on September 9, 2015, and administrative rule changes are in process to conform to the act.

There have been recent reports from the PMP concerning pharmacies not reporting during the required time frame and/or not reporting required information. There is a $100 per day per facility fine that may be imposed on violating pharmacies. These violations could include further discipline by the Board.

Community and hospital/health-system pharmacies:

Review the dispenser responsibilities for dispensed controlled substances in 77 IAC 2080.100.

Long-term care pharmacies:

Review the dispenser responsibilities for dispensed controlled substances and other required medication classes in 77 IAC 2081.40. A list of required medications may be found in 77 IAC 2081 Appendix A.

Please contact the PMP via its website, https://www.ilpmp.org, if you have any questions regarding compliance.

Immunizations

Since most pharmacists are administering vaccines as part of their provided pharmacist care services, it is important to review some best practices and regulatory points. The administrative rules for immunization care and vaccines may be found in 68 IAC 1330.50.

Review your standing orders with your authorizing physician for all vaccines at least annually and with any change from the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices concerning the specific vaccine(s).

Be sure to maintain your Basic Life Support Certification for Healthcare Providers.

Make sure that you and your pharmacy have available the current copy of or access to the Epidemiology and Prevention of Vaccine-Preventable Diseases (also known as the “Pink Book”).

Review the Vaccine Information Statements to ensure that the most current copy is provided to the patient at the time of administration.

Be sure to maintain vaccine records for five years and, to ensure accurate patient-centered medical home records, report all vaccines to the primary care physician and authorizing standing order physician within 30 days of administration.

Prior to administration, review the patient’s immunization record in the Illinois Comprehensive Automated Immunization Registry Exchange (ICARE). Also, record all vaccines administered for all patients into ICARE.

Garth K. Reynolds, RPh is the executive director of the Illinois Pharmacists Association (IPhA), www.ipha.org. The IPhA is dedicated to enhancing the professional competency of pharmacists, advancing the standards of pharmacy practice, improving pharmacists’ effectiveness in assuring rational drug use in society, and leading in the resolution of public policy issues affecting pharmacists.

New Pharmacy Ticketing Pilot Program Overview

By Alexander Hemsley, Senior Operations Researcher, IDFPR Division of Professional Regulation

This year, the IDFPR will be rolling out a new program in order to increase internal productivity while reducing regulatory burdens placed on pharmacies. The IDFPR is planning to move to a pharmacy ticketing system that will issue non-disciplinary citations (the ticket) for minor pharmacy infractions instead of the current arduous process. The ticket is a streamlining of the formal disciplinary process, allowing IDFPR a faster turnaround time to process these low-level infractions. The ticketing system is completely voluntary, and if requested, a pharmacy can choose the traditional disciplinary procedures to resolve the infraction.

The infractions covered under this ticketing system will be minor violations, reflected by modest monetary fines imposed. Issues such as having a can of soda in the work area, food in the refrigerator where drugs are stored, and one or two unlabeled or expired medications with the active stock will all be covered by tickets. More significant infractions, such as diversion, unlicensed activities, poor record keeping, and security issues will not be eligible.
for the ticketing system. Dr Yashwant Amin, IDPFR’s director of drug compliance, will have a full infraction list published that will be available upon request when the program begins.

The program is not intended to be a significant revenue generating operation for the IDPFR; rather, it is meant to increase IDPFR efficiency, encourage compliance with the law, and allow the IDPFR to spend more time investigating more significant violations of the Pharmacy Practice Act.

For minor infractions, the current process is exceedingly long, often lasting months, with voluminous correspondence between the pharmacy, its attorneys, and the IDPFR, often concluding with public discipline and a small fine paid to the State. It is also consumes a huge amount of time for IDPFR staff, wasting the investigators’ precious hours by having them come in and write a report instead of being out in the field, improving the health of the industry.

So what will the new process look like? Simple – while the investigators perform their duties they may notice one or two easily fixable, small issues. Instead of the investigator telling the PIC to be prepared to receive a complaint from the IDPFR about those violations, they will now provide the PIC with a ticket, making the PIC aware of the charges against the pharmacy and a proposed fine. Signing the ticket at this point is not an admission of guilt, just acknowledgement that the investigator explained the issues he or she saw and made the pharmacy aware of the charges.

From there the pharmacy has two options. First, it can choose to pay the small fine, at which point the ticket and violations will be put into its IDFPR record as a non-disciplinary infraction and the matter will be considered settled. The second option will be to decline to pay the fine, which will revert the process back to the current system, starting with a formal complaint filed by the IDPFR against the pharmacy, followed by settlement negotiations and possibly a full formal hearing. Factoring in the time commitment and legal resources expended, it will likely be more expensive than a ticket, and the discipline will be disclosed on the IDPFR’s monthly disciplinary report and attached to the pharmacy’s license profile on the IDPFR website.

Finally, it should be stressed that this is a pilot program, and the IDPFR will be listening closely to all feedback it receives during the testing of the non-disciplinary ticketing system. The IDPFR wants this program to be effective and useful to all involved, but fully expects there to be some bumps and issues, and is ready to address any potential problems in a quick and effective manner.

continued from page 4