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Minnesota Board of Pharmacy News

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer being included in the *Minnesota Board of Pharmacy Newsletter.* A document that provides information about recent Minnesota Board of Pharmacy disciplinary actions can be found on the Board's website under the "Resources/FAQs" menu item.

Pharmacy Technicians

Registration. Pharmacy technician registration renewals were due on December 1, 2015. Technicians were then given the month of December as a "grace period." The registrations of technicians who failed to renew by December 31, 2015, have expired. Individuals cannot continue working as technicians if their registrations have expired. Pharmacists-in-charge (PICs) are encouraged to verify that technicians working under their supervision have current registrations. That can be done by using the license verification feature on the Board's website. If an unregistered individual performs duties that require a technician registration, the Board can take disciplinary action against that individual, the PIC, and the pharmacy.

Allowed Duties. It has come to the attention of Board staff that some pharmacies may be allowing pharmacy technicians to perform duties that they are not legally allowed to perform. For example, some pharmacies may be allowing technicians to call long-term care facilities (LTCFs) or prescribers to clarify orders for patients who are residing in such facilities, which is not allowed under Minnesota Statutes and Rules. Technicians can obtain demographic information from LTCFs, such as age, birth date, address, and insurance information. They can take refill requests from such facilities so long as the facility is only requesting that existing orders be refilled and no changes are being made to those orders. However, technicians cannot take new orders and they cannot call for clarifications of orders.

Minnesota Statutes §151.01, Subdivision 15a defines "pharmacy technician" as (emphasis added) "a person not licensed as a pharmacist or registered as a pharmacist intern, who has been trained in pharmacy tasks that **do not require the professional judgment of a licensed pharmacist. A pharmacy technician may not perform tasks specifically reserved to a licensed pharmacist."** Minnesota Statutes §151.102, Subdivision 1 states, in part (emphasis added): "A pharmacy technician may assist a pharmacist in the practice of pharmacy by performing **tasks that are not reserved to, and do not require the professional judgment of, a licensed pharmacist."**

Minnesota Rules 6800.3100 specifically reserves the receipt of verbal orders to pharmacists and pharmacist interns, including both new orders and clarification of orders. That rule also reserves verification of the validity and propriety of all prescription drug orders to pharmacists and interns. In addition, the Board considers clarification of orders to require the professional judgment of a pharmacist. Consequently, technicians may not contact LTCFs or prescribers to clarify nursing home orders. Technicians can fax a clarification request as long as a pharmacist or pharmacist intern has prepared the request.

Note that the Board has already disciplined at least one pharmacist for allowing a technician to receive verbal clarification of an order from an LTCF nurse, assessing a $2,500 civil penalty and requiring the completion of additional continuing education. In that case, a patient experienced a significant adverse reaction after receiving a tenfold overdose of a medication.

Board Proposing to Adopt Work Condition Rules

In the September 28, 2015 issue of the Minnesota *State Register,* pages 393-394, the Board published a request for comments that stated, in part:

> The Minnesota Board of Pharmacy requests comments on its possible Adoption of Rules Governing

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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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> Pharmacy Practice, including Pharmacy Work Conditions Related to the Safety of the Public. The Board is considering adopting a new rule that would prohibit a pharmacy that is licensed under *Minnesota Statutes* §151.19, subd. 1, and that is located within the State of Minnesota, from requiring a pharmacist, pharmacy intern or pharmacy technician to work for more than twelve continuous hours per day. The rule would also require that pharmacists, pharmacy interns and pharmacy technicians, working longer than six continuous hours per day, be allowed during that time period to take a 30 minute, uninterrupted meal break and one additional uninterrupted 15 minute break.

The Board is proposing to adopt a new rule (6800.2160) to address pharmacy work conditions that have a direct impact on the safety of the public. The Board originally proposed this rule as a portion of a large package of rules changes that was adopted in 2011. Work on that package of rule changes began several years earlier. The Board withdrew the work condition rule after receiving feedback in 2010 from the Office of Governor Tim Pawlenty. However, the Board remains convinced that this proposed rule is both necessary and reasonable. As noted in the Statement of Need and Reasonableness for this proposed rule:

> It is not unusual for pharmacists, technicians and interns to be required to work shifts in excess of eight hours – usually in the range of 10 to 12 hours, but sometimes as much as 14 hours. It is also not unusual for pharmacists to have no formal breaks – despite working such long shifts. The Board firmly believes that evidence exists which shows that working long hours with no breaks can lead to pharmacists, technicians and interns becoming stressed and fatigued and therefore more likely to make errors, resulting in harm to members of the general public. Consequently, the Board views this proposed rule change as being allowed within its authority and duty under Minnesota Statutes §151.06 to regulate the practice of pharmacy. The Board takes seriously the requirement in Minnesota Statutes §214.001. subd. 2 that no rule shall be imposed unless, among other factors, it is "required for the safety and well being of the citizens of the state." In the judgment of the Board, the proposed rule is, in fact, required for the safety and well-being of the citizens of the state.

The Board heard public comments concerning this proposed rule at its December 16, 2015 meeting. In addition, as of the date of that meeting, the Board had received written comments from approximately 80 individuals, businesses, health care systems, and trade or professional associations. The total number of comments received was slightly larger because a few commenters submitted more than one document that contained comments. Slightly more than half of the comments were in favor of adoption of the proposed rule. Nearly all comments in favor of the rule came from pharmacists. Many of the pharmacists were staff pharmacists, but nearly a dozen were community pharmacy managers. A few comments in favor of the rule came from pharmacy technicians and one came from a physician who was the spouse of a pharmacist. A number of comments were considered to be in favor of the rules, even though the commenter expressed concerns. In those cases, the commenters clearly favored the concepts of allowing breaks and placing limits on the maximum number of continuous hours worked. However, they felt that the Board's proposed rule did not go far enough. Nearly all of the comments considered to be against the adoption of part or all of the rule came from trade and professional associations, health care systems, pharmacy owners, or pharmacy managers.

After considering all of the written and verbal comments, the Board voted unanimously to accept recommendations made by the executive director to modify the proposed language. The Board further directed the executive director to take the additional actions necessary to adopt the rules. It will most likely take several more months to complete those additional actions. The modified language is as follows.

6800.2150. PHARMACIST ON DUTY.

~~A.~~ Subpart 1. **REQUIREMENT TO HAVE A PHARMACIST ON DUTY.** A pharmacy or satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times that the pharmacy is open for the transaction of business except ~~that~~ for brief absences of the pharmacist arising out of and in the course of pharmacy practice. ~~are allowable~~;

~~B.~~ Subp. 2. **LIMITING ACCESS TO PHARMACIES.** When a pharmacy is closed or there is no pharmacist on duty, other individuals shall not be allowed access to the pharmacy except as provided in part 6800.7530. ~~In pharmacies where there are two or more pharmacists on duty, the pharmacists shall stagger their breaks so that the pharmacy is not left without a pharmacist for a temporary period.~~

6800.2160 PHARMACY WORK CONDITIONS.

Subpart 1. **Limitation on continuous hours worked.** A pharmacy licensed under Minnesota Statutes §151.19, subd. 1, which is located within the state of Minnesota, shall not require a pharmacist, pharmacist-intern or pharmacy technician to work longer than 12 continuous hours per day, inclusive of the breaks required under subpart 2.

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Subp. 2. **Requirements for breaks.** (a) A pharmacist, pharmacist-intern or pharmacy technician working longer than six continuous hours per day shall be allowed during that time period to take a 30 minute, uninterrupted break.

(b) A pharmacist, pharmacist-intern or pharmacy technician shall be allowed adequate time from work within each four consecutive hours of work to utilize the nearest convenient restroom.

(c) A pharmacy may, but is not required to, close when a pharmacist is on a meal break. If the pharmacy does not close, the pharmacist shall remain within the licensed pharmacy in order to be available for emergencies. If the licensed pharmacy comprises the entire establishment in which the dispensing area is located, the pharmacist shall remain in close proximity to the dispensing area. In addition, the following apply:

(1) pharmacy technicians, pharmacist-interns and other supportive staff authorized by the pharmacist on duty may continue to perform duties as delineated by that pharmacist while the pharmacist is on break;

(2) no duties reserved to pharmacists and pharmacist-interns under any part of this chapter, or that require the professional judgment of a pharmacist, may be performed by pharmacy technicians; and

(3) only prescriptions that have been certified by a pharmacist, as required by part 6800.3100, may be dispensed while the pharmacist is on break; except that prescriptions that require counseling by a pharmacist, including all new prescriptions and those refill prescriptions for which a pharmacist has determined that counseling is necessary, may not be dispensed while the pharmacist is on break.

(d) In pharmacies staffed by two or more pharmacists, the pharmacists shall stagger their breaks so that at least one pharmacist remains on duty at all times that the pharmacy remains open for the transaction of business.

Subp. 3. **Exceptions for emergencies.** Subp. 1 and subp. 2, paragraph (a) shall not apply in the event that an emergency necessitates that a pharmacist, intern or technician work longer than 12 continuous hours, work without taking required meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.

Interested individuals can find additional information about this rulemaking initiative on the Board's website on the Rules page (scroll to the bottom of the page to find the Rule-Making Docket).

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