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North Carolina Board of Pharmacy News

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Item 2318 – License, Permit, and Registration Renewals

By law, every license, permit, and registration issued by the North Carolina Board of Pharmacy expires annually on December 31. Any pharmacist, technician, dispensing physician, dispensing nurse practitioner, pharmacy permit holder, or device and medical equipment permit holder who has not renewed by the date of this *Newsletter's* publication are now in the 60-day "grace period" during which an unrenewed license, permit, or registration is not yet deemed unlicensed practice of pharmacy.

Those running behind should log on to the Board's website and complete the renewal process. Questions about that process should be directed to the Board's licensing staff.

Item 2319 – Board Enters Into an Agreement With the NCPHP to Serve as an Evaluation and Monitoring Program for Pharmacists and Pharmacy Personnel With Substance Abuse Issues

This past fall, the Board entered into an agreement with the North Carolina Physicians Health Program (NCPHP) to serve as an evaluation and monitoring program for pharmacists and pharmacy personnel with substance abuse issues. NCPHP is well positioned to serve as a resource for professionals and to facilitate early intervention before impairment or other professional consequences occur. Over the coming weeks, current clients of North Carolina Pharmacist Recovery Network (NCPRN) will be transitioned to NCPHP, and more information will be distributed about NCPHP, its team, and its services.

With this transition, the Board is ending its agreement with NCPRN, and the Board does so with extreme gratitude for NCPRN's tremendous work for its clients, the profession of pharmacy, and the public health and safety. The transition to NCPHP ensures that these same services – and more – will continue to be available for pharmacists and pharmacy personnel in North Carolina.

More information about NCPHP may be found at *www.ncphp.org.*

Item 2320 – Amended Rule 21 NCAC 46.1417 Governing Remote Medication Order Entry Was Effective December 1, 2015

After a petition for rulemaking and a period of notice and comment, Board Rule 21 NCAC 46.1417, which governs remote medication order entry services for health care facility pharmacies, was amended effective December 1, 2015. Health care facility pharmacies are now permitted to contract for supplemental remote medication order processing during periods when pharmacists are present in those pharmacies if done pursuant to the applicable law and rules. Before this amendment, the use of remote medication order entry services was permitted only if a health care facility pharmacy was closed.

The text of the amended rule may be found at *www.ncbop.org/LawsRules/rules.1400.pdf.*

Item 2321 – Proposed Amendments to Rule 21 NCAC 46.3101 – Clinical Pharmacist Practitioner

The Board of Pharmacy and the North Carolina Medical Board have jointly proposed rule changes to the clinical pharmacist practitioner rules with two principal purposes: (1) to adjust the supervisory procedures to be more effective in light of experience with the program; and (2) to shift the primary registration/credentialing processing function to the Board of Pharmacy.

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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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The comment period on the proposed changes is open through 5 PM, March 14, 2016. Written comments should be sent to Jack W. "Jay" Campbell IV, executive director, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517; by fax to 919/246-1056; or by email to jcampbell@ncbop.org. The Board is interested in all comments pertaining to the proposed rule. All persons interested and potentially affected by the proposal are strongly encouraged to read this entire notice and make comments on the proposed rule.

The Board will also host a public hearing on March 14, 2016, at 5 PM at the North Carolina Board of Pharmacy office, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

More information, including the text of the proposed amendments, is found at *www.ncbop.org/LawsRules/3101CPPNoticeOfTextandPropLanguageNov2015.pdf.*

Item 2322 – Northern and Western District Board Seat Elections This Spring

The next Board member elections are scheduled for spring 2016. Two district seats will be up for election: (1) the Western District, which consists of Alexander, Alleghany, Ashe, Avery, Buncombe, Burke, Caldwell, Catawba, Cherokee, Clay, Cleveland, Gaston, Graham, Haywood, Henderson, Jackson, Lincoln, Macon, Madison, McDowell, Mitchell, Polk, Rutherford, Swain, Transylvania, Watauga, Wilkes, and Yancey counties; and (2) the Northern District, which consists of Alamance, Caswell, Forsyth, Guilford, Orange, Person, Rockingham, Stokes, Surry, and Yadkin counties. These two seats are presently held by Board members Bill Mixon and Carol Yates Day, respectively.

Pharmacists interested in running for either the Western District or Northern District seats should feel free to contact Board staff. To be eligible, the candidate must be a licensed pharmacist residing in one of the counties that comprise the district at the time of election. Candidates who wish to stand for election must submit a petition signed by 10 pharmacists residing in the relevant district to the Board by March 10, 2016.

Board staff will host question-and-answer sessions in January.

- The first session was held on Thursday, January 7, 2016, at the Proximity Hotel in Greensboro, NC, at 7 PM. Pharmacists living in the Northern District who might be interested in running were invited to attend this session.
- The second session will be on Thursday, January 28, 2016, at Aloft Asheville Downtown, in Asheville, NC, at 7 PM. Pharmacists living in the Western District interested in running for this seat are invited to attend.

Board staff will be available to answer questions and discuss what it means to serve on the Board. For ease of planning, please email Kristin Moore at the Board office if you plan to attend, or call 919/246-1050, ext. 209.

All pharmacists licensed in North Carolina and residing in the state as of March 15, 2016, will be eligible to vote in this election. Details concerning voting procedures will follow in the spring. **Again, all pharmacists licensed and residing in the state as of March 15, 2016, are eligible vote. Voting is not limited to pharmacists who reside in the Northern and Western Districts.**

Item 2323 – North Carolina Drug Control Unit Letters to Prescribers

The North Carolina Department of Health and Human Services Division of Mental Health, Developmental Disabilities and Substance Abuse Services Drug Control Unit, which administers the North Carolina Controlled Substance Reporting System (NC CSRS), has begun sending unsolicited educational letters to **prescribers** regarding their patients who have reached a predetermined threshold of obtaining controlled substances (CS) from various pharmacies and prescribers.

The letter instructs the prescriber to review the patient's CS prescription history report available at the NC CSRS practitioner access website, *https://nccsrsph.hidinc.com.* If the prescriber is not registered with the NC CSRS, the notification contains instructions on how to register in order to access the patient's report.

More information concerning this program may be found at *www.ncbop.org/PDF/NCDCUUnsolicitedLtrsToPrescribers111915.pdf.*

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