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Delaware State Board of Pharmacy News

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http://dpr.delaware.gov/boards/pharmacy/index.shtml

Pharmacy Issues

Automated Pharmacy Devices

The following automated pharmacy devices have been approved by the Delaware State Board of Pharmacy.

Name of System	Model
Accudose Cabinet	ACUDOSERX-MAIN
Baker (Prata) Cell	
First Dose	ACS/ACM Med Management Sol
McKessin Robotic	3000
MedCarousel	SYS-180-1516.25-NT-UL
MedDispense	
MTS MedLocker 96	90481-02
Omnicell	05104RXCT/MDA-FRM-001
PacMed	ARP-400SL
Pyxis	Med Station 3000 Med Station 3500 Cardinal Health 53-03928 Pyxis 4000 Pyxis 3500 Anesthesia device
Robot-Rx	APS-2
Robotic IV Automation (RIVA)	RIVA
RxNow	
ScripPro	SP-100 SP-200 Rapid Script 200
Yuyama	TR-EV1
Yuyama (mini)	TR-EV 120

Please note that any new automated pharmacy system must be presented to the Board for approval prior to installation in the state. A pharmacy wishing to install an automated pharmacy system previously approved by the Board will provide the Board with **prior** written notice of the installation or substantive changes of automated pharmacy systems. Furthermore, the Board shall also be notified prior to removal of an approved automated pharmacy system. Regulation 15.5.1.2 requires that records must be maintained by the pharmacy and must be readily available to the Board. Such records must be maintained for a period of three years and shall include:

- Identity of the system accessed;
- Identification of the individual accessing the system;
- Type of transaction;
- Name, strength, dosage form, and quantity of the drug accessed;
- Name of the patient for whom the drug was ordered; and
- Such additional information as the pharmacist-in-charge may deem necessary.

Please refer to Board Regulations 15 and 16 for complete requirements regarding automation.

Controlled Substance Issues

Refilling Controlled Substance Prescriptions Early

The Board office has recently had numerous calls related to the early refilling of controlled substance (CS) prescriptions. There is no easy way to determine how early a CS refill may be filled. Our patients have a whole host of events that would require early refills including, but not limited to, vacations, medication loss, and waste. However, when the request for an early refill begins to be repeated and routine, the pharmacist should contact the practitioner to alert him or her of the patient's reasoning for early filling and to ensure practitioner knowledge of the repeated event. Documentation of the practitioner contact should be kept on file. A pharmacy written policy and procedure including proper documentation of the handling of the early refill is suggested.

Controlled Substance Records and Inventory Requirements

As a reminder, CS inventories must be taken at least biennially after the initial inventory is taken. The biennial inventory may be taken on any date that is within two years of the previous biennial inventory date.

The initial inventory date is an inventory of all stocks of CS on hand on the date the registrant first engages in the manufacture, distribution, or dispensing of CS. In the event a person commences business with no CS on hand, he or she shall record this fact as the initial inventory.

Each inventory shall contain a complete and accurate record of all CS on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.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 part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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transcribed. CS shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered. In the event CS in the possession or under the control of the registrant are stored at a location for which he or she is not registered (eg, interim box in a nursing home), the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

Holiday Greetings

The Board members and staff would like to join in wishing everyone happiness and all the best in celebrating the holidays and for the coming year.

Susan Esposito, RPh.....President, Professional Board Member
Hooshang Shanehsaz, RPh.....Vice President, Professional Member
Jay Galloway.....Public Board Member
Julia Wheatley.....Public Member
Ken Sellers.....Public Board Member
Joli Martini, RPh.....Professional Board Member
Bonnie Wallner, RPh.....Professional Member
Kimberly Robbins, RPh.....Professional Member
Tejal Patel, RPh.....Professional Member
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Latonya Brown.....Administrative Specialist II
Virginia Jackson.....Administrative Specialist II
Sherry Clark.....Administrative Specialist II
Melanie Alexander.....Administrative Specialist II
Samantha Nettesheim, RPh.....Pharmacist Administrator
Michelle McCreary, RPh.....Pharmacist Compliance Officer
Eileen Kelly, Esq.....Board Deputy Attorney General
David W. Dryden, JD, RPh.....Executive Secretary

Newly Licensed Pharmacists

80 Issued From July 1, 2015, to September 30, 2015

A1-0004763 – Babatunde Seun Bolarinwa; A1-0004764 – Jeremy D. Hess; A1-0004765 – Chelsea Ann Hawkins; A1-00004766 – Jason W. Guy; A1-0004767 – Daniel S. Hoffman; A1-0004768 – Ferdinand Patrick Ngonga; A1-0004769 – Julianne Deborah Gardner; A1-0004770 – Kemeisha N. Taylor; A1-0004771 – Sarah Catherine Maheady; A1-0004772 – Jordan R. VanAuken; A1-0004773 – Patrick C. Kupcha; A1-0004774 – Kenneth Calvin Wiley; A1-0004775 – Rebecca Lynn Pepper; A1-0004776 – Judy E. Balcombe; A1-0004777 – Robert Lee Curtis Okwemba; A1-0004778 – Leah J. Milton; A1-0004779 – Jennifer Lyn Murray; A1-0004780 – Ye Chan Yoon; A1-0004781 – Richard J. Debartolo; A1-0004782 – Zhiwei Mai; A1-0004783 – David N. Lewinter; A1-0004784 – Alexis Hannah Gross; A1-0004785 – Anjana Patel; A1-0004786 – Gayleen Anyango Philips; A1-0004787 – Yu Song; A1-0004788 – Kenza Zahri Elliot; A1-0004789 – Jennifer Kim Do; A1-0004790 – Hasan Khairullah atta Al Hasani; A1-0004791 – Antonella S. Frattarelli; A1-0004792 – Debra A. Remner; A1-0004793 – Tram Anh Dan; A1-0004794 – Gillian Ndi; A1-0004795 – Nicholas James Szalejko; A1-0004796 – Tiffany Tess Liu; A1-0004797 – Marija Ruzic; A1-0004798 – Seth Joel Aaron; A1-0004799 – JungMin Hwang; A1-0004800 – Costadina Aneziris; A1-0004801 – Allegra Kate Spiezio; A1-0004802 – Bhavesh Rameshbhai Patel; A1-0004803 – Thomas Joseph Crum; A1-0004804 – Jarjeet Giovonni Singh; A1-0004805 – Michelle Louise Link; A1-0004806 – David A. Gajdosik; A1-0004807 – Jonathan Calvert Feathers; A1-0004808 – Beth E. Koven; A1-0004809 – Rushita Y. Patel; A1-0004810 – Ali I. Alqaisi; A1-0004811 – Oghenekevwe L. Aziza; A1-0004812 – Selorm Kodzo Woadzro; A1-0004813 – Mercy Fonyi Mudoh; A1-0004814 – Barbara Kwakye-Safo; A1-0004815 – Bronessa Sylvia Fernandes; A1-0004816 – Michael A. Rabinowitz; A1-0004817 – Brenda L. Matthews; A1-0004818 – Daniel J. Purzycki; A1-0004819 – Kelsey Alyssa Trichilo; A1-0004820 – Darci Mukendi; A1-0004821 – Calvin Tran; A1-0004822 – Elizabeth Colleen Stancliffe; A1-0004823 – Theresa Donkor; A1-0004824 – Carl H. Gerdine; A1-0004825 – Bethran C. Nnorom; A1-0004826 – Christine Ly; A1-0004827 – Chelsea O'Brien; A1-0004828 – Rachael Elizabeth McWilliams; A1-0004829 – Michelle Adamczyk; A1-0004830 – Miral M. Patel; A1-0004831 – Andrew Thomas Johnson; A1-0004832 – Lauren Ashley Muller; A1-0004833 – Trisha Rose Hernandez; A1-0004834 – Desiree N. Massari; A1-0004835 – Bhumy Brandon Dicorato; A1-0004836 – Alena S. Tarabrina; A1-0004837 – Elizabeth Wathiri Ikiki; A1-0004838 – Jason H. Chan; A1-0004839 – Chelsey M. McIntyre; A1-0004840 – Bozena Karikowska; A1-0004841 – Deenaz A. Narvel; A1-0004842 – Joseph A. Lofaro

Distributor Permits

25 Issued From July 1, 2015, to September 30, 2015

A4-0002105 – A.P.I. Solutions, Inc; A4-0002216 – SCA Pharmaceuticals, LLC; A4-0002217 – The Proctor & Gamble Distributing, LLC; A4-0002218 – Metrics, Inc, dba Mayne Pharma; A4-0002219 – Wal-Mart Pharmacy Warehouse 45; A4-0002220 – Henry Schein Animal Health; A4-0002221 – Intermed Distributors, Inc; A4-0002222 – Den-Mat Holdings, LLC; A4-0002223 – Dental Health Products, Inc; A4-0002224 – B&B Pharmaceuticals, Inc; A4-0002225 – The Hilsinger Company dba HILCO; A4-0002226 – Pharmaceutical Credit Company, LLC; A4-0002227 – PharmaGenetico, LLC; A4-0002228 – Ritedose Pharmaceuticals, LLC; A4-0002229 – Cypress Medical Products, LLC; A4-0002231 – Alvix Laboratories, LLC; A4-0002232 – BioRx; A4-0002233 – RecoverCare, LLC; A4-0002234 APL Logistics Warehouse Management Services, Inc; A4-0002235 – APL Logistics Warehouse Management Services, Inc; A4-0002236 – Blessings International; A4-0002237 – Legacy Pharmaceutical Packaging, LLC; A4-0002238 – Pharmacia & Upjohn Company, LLC; A4-0002239 – Letco Medical, LLC; A4-0002240 – Cerilliant Corporation

In-State Pharmacy Permits

Four Issued From July 1, 2015, to September 30, 2015

A3-0000987 – Delaware CVS Pharmacy, LLC; A3-0000988 – Delaware CVS Pharmacy, LLC; A3-0000989 – Metro Pharmacy, Inc; A3-0000990 – Shayona Health, Inc, dba Greenhill Pharmacy

The *Delaware State Board of Pharmacy News* is published by the Delaware State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation™ (NABPF™) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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