December 2016

News

Delaware State Board of Pharmacy

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Announcement From David Dryden

By David W. Dryden, Past Executive Secretary, Delaware State Board of Pharmacy/Director, Delaware Office of Controlled Substances

It is with mixed emotions that I announce my retirement from my position as executive secretary of the Delaware State Board of Pharmacy/director of the Delaware Office of Controlled Substances and move on to new challenges. These 20 years have been an unforgettably wonderful experience of my life. If not for your support and cooperation, I could not have made it to where I am today. You would not believe just how much the job has changed over the years. When I first began, the Office of Narcotics and Dangerous Drugs was still using typewriters and carbon paper to make copies. At that time the two most prescribed medications were Zantac® and Dyazide®. Now, we use computers and the two most prescribed medications are oxycodone and hydrocodone. I know many of you cannot remember a time before computers, but believe me, work still went on without them. Things change over the years. You take the good with the bad. Changes are part of the deal and are even necessary, but one thing that will never change is the good wishes and appreciation I have for each of you. I would like to thank all of those both in health care and in state staff who assisted me over the years. I wish I could thank each of you personally, but unfortunately there is not enough time and space to complete the task. I will miss you all very much. Please try to stay in touch, and until we meet again, may God hold you in the palm of his hand.

Pharmacy Issues

Board Meetings Scheduled for Year 2017

With the exception of July and December, the Board meets monthly to discuss pharmacy business as well as to preside over any disciplinary matters. These meetings are open to the public, except when the Board might enter into Executive Session. The Board welcomes your contributions and attendance. The meetings will routinely be held on the third Wednesday of each month at Conference Room A, Cannon Building, Dover, DE, but the location is subject to change and should be confirmed. The meetings begin at 9:30 AM and are scheduled for the following dates in 2017:

- January 18
- February 15
- March 15
- April 19
- May 17
- June 21
- August 16
- September 20
- October 18
- November 15

Mandatory Reporting of Immunizations

The Delaware Department of Health and Social Services requested we send the following to all licensed pharmacists. The Immunization Program would like to remind pharmacists that all vaccines administered in Delaware are required to be reported to the Immunization Registry. This includes vaccines administered to adults.

Please see Regulation 7.1.14.1, available at *http://regulations.delaware.gov/AdminCode/title16* under Division of Public Health – Health Promotion and Disease Prevention. Then, select 4202 Control of Communicable and Other Disease Conditions.

There are three ways to report immunizations to the program. You may fill out and send to the program an immunization reporting form for each vaccine; the form is located at *www.dhss.delaware.gov/dph/dpc/files/ir_form.pdf*. This form can be used so that the pharmacy can immediately start reporting to the program. Please be sure to fill out the form completely with all requested information. Paper forms are only being accepted by the Immunization Program until fall 2017. After that date, immunizations can only be reported via direct data entry into the registry or Health Level Seven (HL7) electronic reporting. For those interested in exploring HL7 reporting, please contact Cheryl Oliver-Knight at 302/744-4793 or Fred Bailey at 302/744-1209.

Any pharmacy interested in being trained to do direct data entry into the registry should contact Laura Gannon at the Immunization Program at 302/744-1159.

Controlled Substance Issues

Controlled Substance Regulation Amendments

Pursuant to 16 Del. C. §4731, the Delaware Controlled Substance Advisory Committee, with the approval of the secretary, has enacted revisions to the controlled substance (CS) rules and regulations. Subsection 4.10.1 addresses the requirement that a pharmacist must verify the identification of the receiver of a CS prescription by reference to valid photographic identification. The regulation is amended to provide that federal, including military, identification meets this requirement. In addition, Subsection 4.10.1.5 is added to provide an exemption to the photographic identification requirement where the person receiving the CS prescription is a patient at an inpatient

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FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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facility or has been discharged from an inpatient facility and is obtaining the CS from the facility's outpatient pharmacy immediately upon discharge. For further review, please see Controlled Substance Rules and Regulations at *www.dpr.delaware.gov.* Should you have any questions regarding this information, please contact the Board office.

Medications That Optometrists Are Authorized to Prescribe

24 Del. C. §2101 defines the practice of optometry as it relates to pharmaceutical agents. This statute has been amended and now permits a prescription for the use of an oral steroid with a limitation not to exceed a single six-day methylprednisolone dose pack, includes the use of an epinephrine auto-injector to counteract anaphylaxis, excludes prescription for oral immunosuppressives except for the use of oral steroids reference 7(b), excludes the prescription of oral antifungals, excludes the prescription of oral antimetabolites, excludes the prescription of any substance delivered intravenously or by injection, and excludes any medication used solely for the treatment of systemic conditions outside the scope of an optometrist. In addition to the above, with the proper CS state and federal registration, this statute now permits the prescribing of a Schedule II CS containing hydrocodone, with a limitation on a maximum 72-hour supply, and Schedules III, IV, and V CS, with a limitation on a maximum 72-hour supply. The complete law is available at *http://delcode.delaware.gov/title24/c021/index.shtml.* Should you have any questions regarding this alert, please contact the Board office.

Holiday Greetings

The Board of Pharmacy 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 Member
Hooshang Shanehsaz, RPh.... Vice President, Professional Member
Jay Galloway..... Public Member
Julia Wheatley..... Public Member
Tejal Patel, RPh.....Professional Member
Kimberly Robbins, RPh.....Professional Member
Bonnie Wallner, RPh.....Professional Member
Christine Mast..... Administrative Specialist III
Melanie Alexander.....Administrative Specialist II
Latonya Brown .....Administrative Specialist II
Sherry Clark.....Administrative Specialist II
Virginia Jackson.....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 ..... Former Executive Secretary

Newly Licensed Pharmacists

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Michael D. Reedy – A1-0004950; Jillian Patricia Dougherty – A1-0004951; Dylan Robert Howery – A1-0004952; Dennis Dy Nuguid – A1-0004953; Mahlet Aklile – A1-0004954; John D. Ganther – A1-0004955; Aisha A. Rauf – A1-0004956; Vy Lam Nguyen – A1-0004957; Jeffrey Liu – A1-0004958; Jack W. Williams – A1-0004959; Mary L. Lurwick – A1-0004960; Sejal Marvania – A1-0004961; Nicole J. Lombardo – A1-0004962; Susan Reichenbaugh Sherbin – A1-0004963; Raymond Michael Snyder – A1-0004964; Kyle M. Vaitukaitis – A1-0004965; Michael A. Dryslewski – A1-0004966; Kelsey Colleen McIntyre – A1-0004967; Emily Beth Calloway – A1-0004968; Melissa Elizabeth Buff – A1-0004969; David M. Sharkey – A1-0004970; Roman R. Steiner – A1-0004971; Blair G. Heckel – A1-0004972; Alison Mikell Forrest – A1-0004973; Bess P. Lynch – A1-0004974; Mathew J. Mason – A1-0004975; Ebony R. Cook – A1-0004976; Vivek K. Kataria – A1-0004977; Adrienne Isabella Herman – A1-0004978; Izetta Chaunte' Henry – A1-0004979; Lauren M. Jansing – A1-0004980; William Michael Clifton – A1-0004981; Hao Wu – A1-0004982; Ryan James Hines – A1-0004983; Ryan J. Steiner – A1-0004984; Hue Kim Nguyen – A1-0004985; Marco Lombardo – A1-0004986; Lauren A. Englert – A1-0004987; Matthew Robert Forman – A1-0004988; Christian M. Talla – A1-0004989; Seong K. Kim – A1-0004990; Richard M. Schutzenhofer – A1-0004991; April K. Hartford – A1-0004992; Ronak Y. Modi – A1-0004993; Jun Hao Lee – A1-0004994; Rosa Jisun Lee – A1-0004995; Rebecca Luu – A1-0004996; Cherie Ann Beando – A1-0004997; Tien Nhat Nguyen – A1-0004998; Idayat A. Adewunmi – A1-0004999; Emily Kathleen Sum – A1-0005000; Judith Ann Olivero – A1-0005001; Sarah Adeniran-Obe – A1-0005002; Maxwell Thomas Widdick – A1-0005003; Dawn Marie Bagley – A1-0005004; Kayla Marie Cassada – A1-0005005; Trudy-Ann Marie McMillian – A1-0005006; Sarah Hoira Jung – A1-0005007; Kristen Anne Kas – A1-0005008

Distributor Permits

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Protein Sciences Corporation – A4-0002319; Protein Sciences Corporation – A4-0002320; Noramco, Inc – A4-0002321; VistaPharm, Inc – A4-0002322; Dynasty Pharmaceuticals, Inc – A4-0002323; Optime Care, Inc – A4-0002324; The Proctor & Gamble Distributing, LLC – A4-0002325; Supplies Distributors, Inc – A4-0002326; GenPak Solutions, LLC, dba EthiPak – A4-0002327; Actavis Pharma, Inc – A4-0002328; The Procter & Gamble Distributing, LLC – A4-0002329; HFC Prestige International U.S., LLC – A4-0002330; HFC Prestige International U.S., LLC – A4-0002331; Medical Specialties Distributors, LLC – A4-0002332; Advanced Accelerator Applications USA, Inc – A4-0002333; P&G Prestige Products, Inc – A4-0002334; Midwest Medical Supply Co, LLC – A4-0002335; Airgas USA, LLC – A4-0002336; Airgas USA, LLC – A4-0002337; GM Pharmaceuticals, Inc – A4-0002338; Smith Medical Partners, LLC – A4-0002339; Richmond Pharmaceuticals – A4-0002340; BluPax Pharmaceuticals, LLC – A4-0002341; Medline Industries, Inc – A4-0002342

In-State Pharmacy Permits

Two Issued From July 1, 2016, to September 30, 2016

ShopRite Pharmacy #558 – A3-0000581; Express Pharmacy – A3-0001004

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