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Delaware State Board of Pharmacy News

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Pharmacy Issues

Contacting Delaware State Board of Pharmacy

The following is contact information of pharmacy personnel for the Delaware State Board of Pharmacy.

Catherine Simon.....Phone: 302/677-7301
E-mail: Catherine.Simon@state.de.us
Samantha Nettesheim.....Phone: 302/744-4518
E-mail: Samantha.Nettesheim@state.de.us
Alicia Kluger.....Phone: 302/838-8071
E-mail: Alicia.Kluger@state.de.us
David W. Dryden.....Phone: 302/677-7313
E-mail: David.Dryden@state.de.us

The mailing address and fax number are as follows:

Delaware State Board of Pharmacy
Cannon Building
861 Silver Lake Blvd, Suite 203
Dover, DE 19904
Fax: 302/739-2711

Pharmacist-in-Charge Self-Inspection Report

The Pharmacist-in-Charge (PIC) Self-Inspection Report is now available on the Board Web site at *http://dpr.delaware.gov/boards/pharmacy/forms.shtml.* Please be aware that new pharmacy regulations 3.1.2.7 and 3.1.2.7.1 require PICs to complete an annual PIC Self-Inspection Report by February 1, of each year. New PICs must complete a PIC Self-Inspection Report within 30 days of becoming a new PIC. The PIC Self-Inspection Report should be downloaded from the Board Web site above. **Please do not mail the completed form to the Board office. Keep the completed form on file in the pharmacy for review at the time of a pharmacy inspection.**

The controlled drug audit for the year 2013 should be completed for two of the four medications listed below:

- Oxycodone 30 mg
- Alprazolam 1 mg
- Lorazepam 1 mg
- Suboxone 8 mg Sublingual Film

If a discrepancy resulting from the audit is greater than 3%, PICs must report the discrepancy to the Board within 30 days with an explanation.

Should you have any questions regarding this information, please contact the office.

Controlled Substance Issues

E-Prescribing Update

The days of the paper prescription pad may be numbered. According to a new report from the Office of the National Coordinator for Health Information Technology, community pharmacies that can accept e-prescriptions rose from 76% to 94% from December 2008 through June 2012. Over the same time period, the number of United States physicians using e-prescriptions for non-controlled substances (CS) increased from 7% to 48%. The report also indicates that about 45% of new and renewal prescriptions in 2012 were sent electronically in 2012.

How are we doing here at home? In 2011, Delaware ranked number four in the "Top 10" e-prescribing states for non-CS, up from number five in 2010. Only Minnesota, Massachusetts, and South Dakota ranked higher (results for 2012 are not yet available).

What about CS e-prescribing? Drug Enforcement Administration (DEA) proposed regulations for e-prescribing CS in June 2010. However, CS e-prescribing did not go into effect on a broad scale until the summer of 2012. Before pharmacies and practitioners could transition to e-prescribing CS, technology that would meet DEA's new security and other regulatory requirements had to be developed and implemented. Your Delaware State Board of Pharmacy and Office of Controlled Substances can offer prescribers and pharmacists guidance on DEA's e-prescribing software requirements and on legal issues related to CS e-prescribing in Delaware.

For more information on the DEA regulations for e-prescribing, visit *www.deadiversion.usdoj.gov/ecomm/e_rx/index.html.* For guidance on implementing e-prescribing in

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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Delaware, contact the Board office at 302/744-4500 or e-mail customerservice.dpr@state.de.us.

The Division of Professional Regulation will continue to provide updates as the implementation continues.

Controlled Substance Registrations and Distribution Reminder

The Board of Pharmacy/Office of Controlled Substances has recently been alerted to confusion pertaining to CS registrations and the distribution of scheduled drugs from one registrant to another. As a review of the Code of Federal Regulations, 21 CFR §1301.12 requires separate registrations for separate locations. Part (a) states, "A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person." Thus, a separate CS registration is required for each site that has a different address where CS are being stored, dispensed, and distributed. This would include different practitioner offices as well as different facilities, even if these practitioners and facilities are owned by the same identity.

Furthermore, 21 CFR §1305.03 requires either a DEA Form 222 or its electronic equivalent for each distribution of a Schedule II CS. Schedule III through V may be distributed from one registrant to another via invoice. Thus, if a registered pharmacy distributes Schedule II CS to another registrant, that is either a practitioner or a facility, such as a clinic, then a DEA Form 222 or its electronic equivalent should be utilized as a record of this distribution.

For further information, please see the Code of Federal Regulations or contact David Dryden at 302/677-7313.

Prescriptions Not Meeting Delaware Prescriptive Requirements

Law enforcement and the Board of Pharmacy/Office of Controlled Substances have recently received information of diverters passing prescriptions that do not meet Delaware prescriptive requirements. Specifically, these prescriptions do not meet the requirement whereby scratching the back of the prescription shows the statement "Delaware Security Prescription." Any prescriptions that do not meet this standard should not be filled, should be documented, and copied if possible. Pharmacists who deny prescriptions presented under circumstances similar to those described above may write on the back of the prescription that the prescription was "declined" with the date of the decline, pharmacist's initials, pharmacy name, and contact information.

Should any concerns arise from checked prescriptions, please contact the State Police Drug Diversion Unit or your local police via "911."

Newly Licensed Pharmacists

Twenty-Nine Issued from October 1, 2012 to December 31, 2012

Hiren Shah – A1-0004347; Larry Shuster – A1-0004348; Chimaobi Odumuko – A1-0004349; David Pouchan – A1-0004350; Valerie Duffy – A1-0004351; Nkechi Anako – A1-0004352; Salma Habeeb – A1-0004353; Angela Morris – A1-0004354; Kayla Wolfe – A1-0004355; Hanan Urick – A1-0004356; Tiffany Dichiara – A1-0004357; Trang Bui – A1-0004358; Sora Kang – A1-0004359; Benjamin Rodgers – A1-0004360; Felicia Glenn – A1-0004361; Jennifer DiRenzo – A1-0004362; Frank Prempeh – A1-0004363; Jennifer Empfield – A1-0004364; Vladimir Berkovich – A1-0004365; Wahed Unnisa – A1-0004366; Sola Anagho – A1-0004367; Stephanie Oster – A1-0004368; Walter Spears – A1-0004369; Toni Haskell – A1-0004370; Donald Brown – A1-0004371; Suzanne Ibrahim – A1-0004372; Qian Wu – A1-0004373; Jennifer Denteh – A1-0004374; Peter Grant – A1-0004375.

Distributor Permits

Seventeen Issued from October 1, 2012 to December 31, 2012

Family Enterprises, LLC, dba Preferred Cylinder Services – A4-0001933; Cardinal Health – A4-0001934; Associated Pharmacies dba API – A4-0001935; EMD Millipore Corporation – A4-0001936; Southern Anesthesia & Surgical, Inc – A4-0001937; Hercon Pharmaceuticals, LLC – A4-0001938; Camber Pharmaceuticals Inc – A4-0001939; Henry Schein, Inc – A4-0001940; AbbVie US, LLC – A4-0001941; Alvogen, Inc – A4-0001942; Tri-anim Health Services, Inc – A4-0001943; Exel Inc – A4-0001944; UPS Supply Chain Solutions, Inc – A4-0001945; Cantrell Drug Company, Inc – A4-0001946; Merial Limited – A4-0001947; MPC Newco, Inc – A4-0001948; MPC Newco, Inc – A4-0001949.

In-State Pharmacy Permits

Two Issued from October 1, 2012 to December 31, 2012

Living Well Pharmacy LLC – A3-0000942; Ainsley's Pharmacy LLC – A3-0000943.

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, Inc, 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 the Foundation or the Board unless expressly so stated.

David W. Dryden, JD, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager