



# Delaware State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

Cannon Building • 861 Silver Lake Blvd, Suite 203 • Dover, DE 19904

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

## Pharmacy Issues

### Board Meetings Scheduled for Year 2014

With the exception of July and December, the Delaware State Board of Pharmacy 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 usually 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 January 15, February 19, March 19, April 16, May 14, June 18, August 20, September 17, October 15, and November 19, 2014.

### New Board Members

The Board would like to welcome Bonnie Wallner, Ken Sellers, Susan Esposito, and Tejal Patel as its four new Board members.

Bonnie is not a new face to the Board. She is a past executive secretary and inspector for the Board, bringing a wealth of knowledge and experience. She currently is a staff pharmacist for the Veterans Affairs Medical Center. She is a pharmacy graduate of the North Dakota State University.

Ken has been a trustee for the Health and Welfare Fund for 25 years. He is a business representative for the Plumbers and Pipe Fitters Union. He looks forward to serving on the Board as a public member.

Susan has experience with independent and retail community practice. She currently works for the Nanticoke Memorial Hospital in Seaford, DE. Susan is a graduate from the Philadelphia College of Pharmacy, University of the Sciences. Prior to coming to Delaware, she worked in New Jersey where she was very active in the New Jersey Society of Health-System Pharmacists.

Tejal has retail and hospital experience in pharmacy. She is currently a pharmacy manager for Walgreen Co at the Newark University Plaza location. She obtained her PharmD through the University of Colorado. She also is a Microsoft Certified Systems Engineer and has post-graduate diplomas in business administration and computer application.

### Warning Signs of Abuse and Dependency

We all know that we may see patients who are addicted to drugs or alcohol. Do we recognize it in them? Can we say we would recognize this disease in a colleague? If we do recognize it, then what do we do? Let us begin with a definition and some signs and symptoms. Addiction to drugs, including alcohol, is defined as a primary chronic, neurobiological disease with genetic, psychosocial, and environmental factors influencing its development and

manifestations. It is characterized by behaviors that include one or more of the following:

- ◆ Impaired control over drug use;
- ◆ Compulsive use;
- ◆ Continued use despite harm; and
- ◆ Craving.

#### Warning Signs of Abuse and Dependency Include:

- ◆ **Usage Increase:** Over time, it is common for individuals taking prescription medications to grow tolerant to the effects of their prescribed dose. Increased dosage often indicates that the original amount is no longer providing relief.
- ◆ **Change in Personality:** Changes in a person's normal behavior can be a sign of dependency. Shifts in energy, mood, and concentration may occur as everyday responsibilities become secondary to the need for the relief the prescription medication provides.
- ◆ **Social Withdrawal:** A person experiencing a dependency problem may withdraw from family, friends, and other social interaction.
- ◆ **Ongoing Use:** Patients that complain frequently about "still feeling pain" or request to extend a prescription long after the medical condition has improved should be monitored closely. Those who gripe about doctors refusing to write a prescription show signs of dependency.
- ◆ **Going to Great Lengths to Obtain Prescriptions:** A dependent person may spend large amounts of time driving great distances and visiting multiple doctors to obtain drugs. Preoccupation with a quest for medication demonstrates that the drug has become a top priority.
- ◆ **Change in Appearance:** Personal hygiene may diminish as a result of a drug addiction. Significant weight loss may occur and glazed eyes may be evident.
- ◆ **Desensitized Emotions:** A dependent person may exhibit an attitude of indifference, a lack of emotion, and demonstrate disinterest in things that previously brought him or her pleasure.
- ◆ **Increased Inactivity:** Hobbies and activities no longer provide the enjoyment they used to. Those suffering from dependency may feel lethargic and tend to stop engaging in athletic activities.
- ◆ **Blackout and Forgetfulness:** Another clear indication of dependence is when the person regularly forgets events that have taken place and appears to be suffering frequent blackouts.

*Continued on page 4*



## Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at [www.fda.gov/Safety/Recalls/ucm357909](http://www.fda.gov/Safety/Recalls/ucm357909).

## Barcoding Technology for Community Pharmacy

**ISMP**  
INSTITUTE FOR SAFE MEDICATION PRACTICES

*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](http://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](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology<sup>1</sup> and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006<sup>2</sup> study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.<sup>3</sup> Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at [www.ismp.org/AHRQ/Default.asp?link=sa](http://www.ismp.org/AHRQ/Default.asp?link=sa).

<sup>1</sup>Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

<sup>2</sup>Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

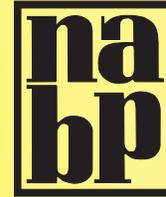
<sup>3</sup>Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

<sup>4</sup>American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: [www.ismp.org/selfassessments/PathwaySection3.pdf](http://www.ismp.org/selfassessments/PathwaySection3.pdf).

## ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at [www.ismp.org/newsletters/longtermcare](http://www.ismp.org/newsletters/longtermcare).



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

## **FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen**

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm).

## **Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors**

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at [www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm](http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm).

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit [www.nabp.net/programs/accreditation/vawd](http://www.nabp.net/programs/accreditation/vawd).

## **Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events**

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

## **Veterinarians Not Eligible for NPIs, CMS Clarifies**

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

- ◆ **Defensiveness:** Abusers who attempt to hide a drug dependency may lash out and become very defensive if they feel their secret is being discovered.

The above article was submitted by Brian Fingerson, RPh, Kentucky Pharmacist Recovery Network.

If you recognize any of these signs and symptoms in a colleague, you may refer him or her to or may contact the Delaware Professionals' Health Monitoring Program (DPHMP) – Dale Kaplan, MSW, MAC, Delaware program manager, at 855/575-9350, ext 9842, dkaplan@reliantbh.com or Christa Lee, MSW, Delaware agreement monitor, at 855/575-9350, ext 9819, cleec@reliantbh.com for assistance. You can find DPHMP information at [www.delawaremonitoring.com](http://www.delawaremonitoring.com).

## 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.

Joli Martini, RPh.....	President, Professional Board Member
Kim Robbins, RPh.....	Vice-President, Professional Board Member
Matthew Maher.....	Public Board Member
Jay Galloway.....	Public Board Member
Ken Sellers.....	Public Board Member
Susan Esposito.....	Professional Member
Bonnie Wallner, RPh.....	Professional Member
Kimberly Robbins, RPh.....	Professional Member
Howard Simon, PharmD.....	Professional Member
Sandra Zaragoza, RPh.....	Professional Member
Tejal Patel.....	Professional Member
Christine Mast.....	Administrative Specialist III
Latonya Brown.....	Administrative Specialist II
Tim Oswell.....	Administrative Specialist II
Sherry Clark.....	Administrative Specialist II
Maggie Strauss.....	Administrative Specialist II
Samantha Nettesheim, RPh.....	Pharmacist Administrator
Alicia Kluger, RPh.....	Pharmacist Compliance Officer
Eileen Kelly, Esq.....	Board Deputy Attorney General
David W. Dryden, JD, RPh.....	Executive Secretary

## Newly Licensed Pharmacists

### 84 Issued from July 1, 2013 to September 30, 2013

Joseph H. Smith – A1-0004421; Ashley L. Lawrence – A1-0004422; Denise M. Needham – A1-0004423; Megan R. Hamilton – A1-0004424; Matthew Willard – A1-0004425; Emily A. Ludvigson – A1-0004426; Michele C. Handzel – A1-0004427; Sarah E. Hallinan – A1-0004428; Ashley M. Hartman – A1-0004429; Kyle D. Odenwelder – A1-0004430; William J. Cooke – A1-0004431; Melissa Giordano – A1-0004432; Sarah Verbyla – A1-0004433; Tenley J. Poulin – A1-0004434; Michael Vuong – A1-0004435; Tiffany H. Benjamin – A1-0004436; Marissa Ann Harrison – A1-0004437; Anna Lvovna Blinova – A1-0004438; Nicholas M. Petrovich – A1-0004439; Jonathan M. Koval – A1-0004440; David L. Bankes – A1-0004441; Mary B. Choi – A1-0004442; Laura A. Schuppert – A1-0004443; Kevin P. Onorio – A1-0004444; Monica Khan – A1-0004445; Lauren Isaacs Karel – A1-0004446; Nabeegha K. Shinwari – A1-0004447; Amy Marie Boyett – A1-0004448; Sindhuri Repaka – A1-0004449; Tawes A. Harper – A1-0004450; Brittany S. Finocchio – A1-0004451; Modupeoluwa O. Omotosho – A1-0004452; Julie A. Gibbons – A1-0004453; Samantha L. Marcelli – A1-0004454; William E. Hallock – A1-0004455; Stephanie V.

Nuyen – A1-0004456; Nicole C. DeMarco – A1-0004457; Kelly M. Luzi – A1-0004458; Sankung Sise – A1-0004459; Kiana Y. Curry – A1-0004460; Zabeena Parveen Shaik – A1-0004461; Tracie N. Sellers – A1-0004462; Sara Ahmed – A1-0004463; David Alan Chamberlain – A1-0004464; Hazel M. Malaluan – A1-0004465; Christopher M. Rock – A1-0004466; Jason P. Skaria – A1-0004467; Kelsey M. Miksic – A1-0004468; Justin N. Markham – A1-0004469; Hua Xiao – A1-0004470; Ronald Vadurro – A1-0004471; Melanie R. McKain – A1-0004472; Alekhya Uppala – A1-0004473; Kim E. Ford – A1-0004474; Jennifer A. Abernathy – A1-0004475; Ryan W. de Lorraine – A1-0004476; Shannon R. Barry – A1-0004477; Christine Skrzypiec – A1-0004478; Aminat A. Adekoya – A1-0004479; Kaylei Marie DeHart – A1-0004480; Rose M. Marese-Smith – A1-0004481; Tamanna Kirit Patel – A1-0004482; DeAngelo L. Price – A1-0004483; Melanie J. Olsen – A1-0004484; Meredith L. Miranda – A1-0004485; Kristen P. Campbell – A1-0004486; Michael T. Holbrook – A1-0004487; Thuy Le – A1-0004488; Hardik A. Shah – A1-0004489; James M. Appio – A1-0004490; Laurel A. Lindberg – A1-0004491; Kareem Adel Karara – A10004492; Gina Yochin Doh – A1-0004493; Craig J. Hughes – A1-0004494; Teresa A. Lee – A1-0004495; Raqueeba A. Hassan – A1-0004496; Shlok N. Prasad – A1-0004497; Krupa Joshi – A1-0004498; Harry B. Rosenman – A1-0004499; Keili Ann Marvel – A1-0004500; Qasim N. Rana – A1-0004501; Ryan P. Mercado – A1-0004502; Steven G. Osgood, Jr – A1-0004503; Emmanuel Y. Asare – A1-0004504.

## Distributor Permits

### 26 Issued from July 1, 2013 to September 30, 2013

Auxilium Pharmaceuticals, Inc – A4-0001360; Arrow International, Inc – A4-0001628; Patterson Veterinary Supply – A4-0001671; Covidien Sales, LLC – A4-0002003; Covidien Sales, LLC – A4-0002004; Nestle Health Science-Pamlab, Inc – A4-0002005; Foundation Care, LLC – A4-0002006; Exel, Inc – A4-0002007; UPS Supply Chain Solutions, Inc – A4-0002008; Paratus Health Systems, LLC – A4-0002009; Medtronic Logistics, LLC – A4-0002011; Exel, Inc – A4-0002012; SmartHealth Distribution Co – A4-0002013; Merritt Veterinary Supplies Northeast, LLC – A4-0002014; Safe Prep International, LLC – A4-0002015; Sharp Corporation – A4-0002016; JHP Pharmaceuticals, LLC – A4-0002017; Cardinal Health – A4-0002018; Sonexus Health Distribution Services, LLC – A4-0002021; Mylan Technologies, Inc – A4-0002022; Central Admixture Pharmacy Services, Inc – A4-0002023; McKesson Medical – Surgical, Inc – A4-0002024; Safecor Health, LLC – A4-0002025; PharmaLink, Inc – A4-0002026; Value Drug Company – A4-0002027; H&H Wholesale Services, Inc – A4-0002028.

## In-State Pharmacy Permits

### Two Issued from July 1, 2013 to September 30, 2013

Cape Pharmacy – A3-0000957; Delaware CVS Pharmacy – A3-0000958.