



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

77 S High St, Room 1702 • Columbus, OH 43215-6126 • Tel: 614/466-4143

Fax: 614/752-4836 • www.pharmacy.ohio.gov

2013 Terminal Distributor Renewals

The 2013 renewal notices for terminal distributor licenses have been sent out by the Ohio State Board of Pharmacy and should have been received by all licensees. If you have not yet received yours, please contact the Board office. If you are the responsible person on the license, you are responsible for seeing that the license is **renewed before January 1, 2013**.

This year's process for renewal is similar to last year's process. The Board will be accepting online terminal distributor renewal applications with payment by a credit card for most licensed sites. Please note that only terminal distributors with **unlimited** licenses will be able to renew online this year. A terminal distributor license cannot be renewed online if any of the following apply: the licensee is a pain management clinic or out-of-state pharmacy, there is a change of address of the licensed site, change of the responsible person on the license, change of the business name, change of business ownership, or a change of the drug category of the license. This is explained on the renewal application and the online renewal screens, which give directions on how to handle these situations. For most renewals, the process should be easy and painless if you read and follow the directions contained in your renewal packet and on the renewal screens. **Do not hit the "back" button after you authorize payment with your credit card!** This will cause your credit card to be charged again, each time you hit the back button. The Board tries to catch those duplicate charges before they get posted to your card. If it does occur, please contact the Board office so the extra charges can be reversed.

New England Compounding Center Update

As many of you know from the Board's recent e-mail blast, the Board announced the summary suspension of the Ohio Terminal Distributor of Dangerous Drugs license for

the New England Compounding Center (NECC) located in Framingham, MA, effective October 9, 2012. The Board has participated in discussions with the Ohio Department of Health (ODH) and the investigation conducted by the Centers for Disease Control and Prevention and the United States Food and Drug Administration (FDA) concerning NECC's contaminated methylprednisolone acetate injections. To date, these products have resulted in a fungal meningitis outbreak that has affected people in 19 states and caused 28 deaths nationwide. Prior to the issuance of the summary suspension, the Board found that there was clear and convincing evidence that the continuation of NECC's professional practice in Ohio presented a danger of immediate and serious harm to others.

The contaminated methylprednisolone acetate injections were administered to 425 people in Ohio. All of these patients have been notified by ODH and as of this writing, 14 Ohio patients have tested positive for the fungal meningitis infection. To date, there have been no deaths in Ohio from this contamination. It appears that four clinics in Ohio received the affected methylprednisolone product. These clinics were located in Cincinnati, Columbus, and Marion, OH. The Board is additionally conducting its own investigation. Due to the amount of product that has been shipped from NECC into Ohio, there is federal concern that NECC was manufacturing products, not compounding medications.

Manufacturing Versus Compounding: Basic Differences

Manufacturing and compounding are two very different practices that are regulated differently as well. Ohio recognizes and enforces federal law that states compounding is performed by a pharmacist in a pharmacy and pursuant to a patient-specific prescription (refer to 21 USCA 353a). Manufacturing does not require a patient-specific prescription, but requires a manufacturing license from

Continued on page 4



AHRQ Toolset Can Assist Pharmacies Using e-Prescribing

A toolset released by the Agency for Healthcare Research and Quality (AHRQ) can assist independent pharmacies with the implementation of e-prescribing and may also provide useful guidance to those pharmacies already using e-prescribing. The toolset for independent pharmacies consists of seven chapters that provide guidance on topics ranging from planning the implementation process and launching the system, to troubleshooting common problems and moving into more advanced pharmacy services, states AHRQ. Flyers for use in communicating the launch to patients, templates for communicating with providers about the launch, tools for assessing pharmacy workflow, and a spreadsheet to determine return-on-investment, among other tools, are also available to pharmacies. The toolset can be downloaded from the AHRQ Web site at http://healthit.ahrq.gov/portal/server.pt/community/health_it_tools_and_resources/919/a_toolset_for_e-prescribing_implementation_in_independent_pharmacies/30595.

FDA Database Provides Information on Pediatric Medications

A Food and Drug Administration (FDA) database provides information on pediatric medications, making it easier for both health care providers and caregivers to locate this information. The Pediatric Labeling Information Database is a one-stop resource, where providers and caregivers can search for information by the product's commercial or chemical name, or by the condition for which it was studied. The database was developed by FDA's Office of Pediatric Therapeutics (OPT), in collaboration with the Center for Drug Evaluation and Research. The OPT also provides a Safety Reporting page with information on products that have been tied to safety problems that specifically relate to children. Additional information and a link to the database is available in the Consumer Updates section of the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm305040.htm.

Inattentional Blindness: What Captures Your Attention?



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.

A pharmacist enters a prescription for methotrexate daily into the pharmacy computer. A dose warning appears on the screen. The pharmacist reads the warning, bypasses it, and dispenses the medication as entered. The patient receives an overdose of the medication and dies.

This error, and many more, have happened because the person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse.¹ People involved in these errors have been labeled as careless and negligent. But these types of accidents are common – even with intelligent, vigilant, and attentive people. The cause is usually rooted in inattentional blindness.¹

Accidents happen when attention mistakenly filters away important information and the brain fills in the gaps with what is aptly referred to as a “grand illusion.”² Thus, in the example above, the brain of the pharmacist filtered out important information on the computer screen, and filled in the gaps with erroneous information that led him to believe he had read the warning appropriately.

Inattentional blindness is more likely to occur if part of your attention is diverted to secondary tasks, like answering the phone while entering prescriptions into the computer, or even thinking about your dinner plans while transcribing an order.

Low workload causes boredom and reduces the mental attention given to tasks, as does carrying out highly practiced tasks, such as counting out medication. We spend a large majority of our waking life functioning with the equivalent of an automatic pilot, with occasional conscious checks to ensure tasks are being carried out properly. This makes us particularly prone to inattentional blindness.

Our past experiences also teach us what is relevant. Errors occur when new or unusual circumstances happen in highly familiar situations. The pharmacist who did not notice important information on a computer warning had rarely encountered a clinically significant computer alert. The pharmacist had subconsciously learned that there was nothing important to see when reading alerts. Nothing had ever happened, so attention was automatically filtered away from the details to conserve mental processing.

Conspicuity is the degree to which an object or piece of information “jumps out” and captures your attention. The best way to achieve this effect is through use of contrast, color, or shape to call attention to differences in packaging or text.

It is difficult to reduce the risk of inattentional blindness, as it is an involuntary and unnoticed consequence of our adaptive ability to defend against information overload. Error-reduction strategies such as education, training, and rules are of little value. Instead, efforts should center on increasing conspicuity of critical information, and decreasing diversions of attention and secondary tasks when carrying out complex tasks.

1. Green M. “Inattentional blindness” and conspicuity. *Visual Expert*. 2004. Accessed at www.visualexpert.com/Resources/inattentional_blindness.html, March 1, 2012.

2. Angier N. Blind to change, even as it stares us in the face. *The New York Times*. April 1, 2008.

Know Your Dose Game Teaches Safe Acetaminophen Use

As part of the Know Your Dose campaign, the Acetaminophen Awareness Coalition has developed an interactive educational game to teach safe use of acetaminophen. The game not only answers some of the most common questions surrounding the safe use of acetaminophen, it gives an engaging face to the issue. The game, available on the

Compliance News

Compliance News to a particular state or jurisdiction should not be assumed. Contact your state board for the law of such state or jurisdiction.)



Know Your Dose Web site at www.knowyourdose.org/game, invites consumers to follow three characters through a typical day of aches and pains while helping the characters learn how to take medicine that contains acetaminophen safely.

Contraception Products Sold Online With No Prescription Required, Endangering Public Health

Health care providers should help to educate patients about the risks of prescription contraceptive products marketed online as “no prescription” and “over-the-counter” products, pharmaceutical security researchers conclude. A study by these researchers found that Google searches returned results for prescription contraceptive products such as injections, oral contraceptives, and patches, as well as intrauterine devices (IUDs). All of these products were marketed as available without a prescription and researchers found that sellers provided links to YouTube videos with IUD instructions. The researchers also found that these products were being promoted on social media channels, including Facebook, Twitter, SlideShare, and Flickr. Researchers Bryan A. Liang, MD, JD, PhD, Tim K. Mackey, MAS, and Kimberly M. Lovett, MD, conclude that such online contraceptive sales represent patient safety risks and also suggest that policy makers should “employ legal strategies to address these systemic risks.” The study, “Suspect Online Sellers and Contraceptive Access,” is available in the May 25, 2012 issue of *Contraception*.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm313768.htm, pharmacists discuss the Accelerated Approval Program and how FDA helps make new, potentially lifesaving drugs available more quickly. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

FDA Resources Help Raise Awareness About Health Fraud Scams

To help raise consumer awareness about health fraud scams, FDA provides numerous educational resources in the Health Fraud Scams section of its Web site. Educating consumers on how to avoid such scams, FDA videos present information on various types of fraudulent products such as fake diet, sexual enhancement, and body building products. Consumers can also access information about specific products that are the subject of FDA warning letters, recalls, public notifications, and safety alerts. FDA news releases related to health fraud are also accessible through this section of the Web site.

NABP Accepting Award Nominations for 109th Annual Meeting

The National Association of Boards of Pharmacy® (NABP®) is currently accepting nominations for the Association’s 2013 awards that will be presented during the 109th Annual Meeting, to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO.

Nominations are currently being accepted for the following awards: 2013 Lester E. Hosto Distinguished Service Award (DSA), 2013 NABP Honorary President, 2013 Fred T. Mahaffey Award, and 2013 John F. Atkinson Service Award.

Nominations for these awards must be received at NABP Headquarters no later than December 31, 2012. New this year, individuals wanting to submit a nomination will be asked to fill out and complete a nomination form, which may be accessed by visiting the Meetings section on the NABP Web site at www.nabp.net/meetings. Criteria for award nominees will also be posted to the Web site. Nomination forms should be sent to the NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056. Directions for electronic submission will be available on the online form. The NABP Executive Committee will review the nominations and select the award recipients.

For more information, please contact the NABP Executive Office via e-mail at exec-office@nabp.net.

NABP Looking for Exam and Assessment Item Writers

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination®, the Multistate Pharmacy Jurisprudence Examination®, the Foreign Pharmacy Graduate Equivalency Examination®, the Pharmacy Curriculum Outcomes Assessment®, and the Pharmacist Assessment for Remediation EvaluationSM. Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply. Interested individuals should e-mail, fax, or mail a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a résumé or curriculum vitae:

- ◆ via e-mail at exec-office@nabp.net;
- ◆ via fax at 847/391-4502; or
- ◆ via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net. Additional information may also be found in the August 2012 *NABP Newsletter*.



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

CPE Monitor™ integration is underway. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your 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.

FDA that enables the company to produce and sell manufactured medications (typically in bulk) again without a patient-specific prescription. To obtain an FDA manufacturing license, the manufacturing site must also pass stringent quality assurance standards (good manufacturing practice) designed to test manufacturing of sterile drug product. Thus, there is much more scrutiny placed on this type of practice (manufacturing) typically due to the large amounts of drug product being made for resale.

Medication compounding, on the other hand, involves the practice of taking commercially available products and modifying them to meet the unique needs of an individual patient pursuant to a prescription from a licensed provider. Our state law defines compounding in Ohio Revised Code 4729.01(C). Also, a pharmacy must follow the compounding requirements pursuant to Ohio Administrative Code (OAC) Rules 4729-5-25, 4729-9-25, 4729-9-21, and 4729-19; current professional compounding standards; and all applicable federal and state laws, rules, and regulations. As required by OAC 4729-19-04, for compounding sterile injectables, the Board would expect to see in your written policies and procedures adherence to United States Pharmacopeia (USP) Chapter 797 guidelines. These guidelines are differentiated by the severity/risk of the type of products being compounded. The Board expects that you review and understand these guidelines to assess your practice prior to compounding sterile injectable prescriptions. For more information regarding the USP Chapter 797 compounding guidelines, visit www.usp.org/store/products-services/usp-compounding. Compounding in Ohio does not require a special FDA manufacturing license and can be performed with no extra licenses other than those required by the Board for pharmacy practice (RPh license for the pharmacist to practice, a terminal distributor of dangerous drugs license for the location, and, if needed, a Drug Enforcement Administration license for controlled substances). No doubt, compounding is a legal and common practice in many Ohio pharmacies and brings incredible value to Ohio patients. However, make sure that your processes meet all standards for compounding and that you are not manufacturing as defined above. The Board has created a great compounding document for review, which can be accessed from the Board's Web site at www.pharmacy.ohio.gov. Click on the "Terminal Distributor (TDDD) Licenses" tab and then on the "Compounding in Ohio" link.

Press Releases

The Board has recently started sending out press releases to communicate major compliance or safety issues that have been identified or resolved as part of our mission to protect the safety of the citizens of Ohio. Jesse Wimberly, Board field agent out of the Dayton, OH, area, is

now functioning as the Board's press information officer in addition to his agent duties. The Board is very proud to share with Ohio pharmacists and the public the accomplishments of the agency. Also, there is a great option on the Board's new Web site to subscribe to these press release updates and stay in tune with what your Board is doing, and you are encouraged to do so. The process to subscribe is very quick and easy and is further elaborated in the "New Web Site" section below.

New Web Site

The Board is pleased to announce that on September 26, the new Board Web site was launched. It includes many more options, forms, and updated licensing applications for the public and current licensees. You are encouraged to check out the new site and also to take advantage of the ability to "Subscribe to Updates," which will automatically e-mail you any time one of the areas of interest that you choose is updated on the site. This new functionality will enable the Board to better notify interested parties regarding things such as the "Sunshine Notice" required to be sent out prior to Board meetings, or press releases of the latest big news going on with the Board as mentioned previously. Also, there are many other topics of interest that you may choose upon registering for this Web service. These examples will allow the Board to minimize the "e-mail blasts" sent out to all pharmacists, and also your subscribing will ensure that e-mail addresses are correct.

New Forms

As part of the new Web site project, the Board also revamped and updated most forms and license applications. Please note that the terminal distributor of dangerous drugs and wholesale distributor of dangerous drugs license applications have been updated, including the legal questions. Please discard any old paper or electronic applications or Board forms that you may have on file. The Board will start returning license applications received by the office on the old forms for re-submission using the new forms starting January 1, 2013.

Enforcement Update

Please note that the rules regarding prescribers and pharmacists registering and checking the Ohio Automated Rx Reporting System (OARRS) program have been in effect for a year now. The Board has noticed a great increase in the number of prescribers and pharmacists who are now registered and requesting reports from the OARRS program, which is fantastic. Also, the Board would like to thank the pharmacists who practice their due diligence regarding checking OARRS to assist in making better clinical decisions and preventing diversion of controlled

Continued from page 4

substances and tramadol products in Ohio. However, it is clear as a result of inspections that some prescribers and pharmacists are not running OARRS reports as they should in some cases, thus allowing for potential clinical issues and potential opiate diversion. Please review previous Board *Newsletters* and OAC 4729-5-20 via the Board's Web site (under the "Laws & Rules" tab) at www.pharmacy.ohio.gov. The Board is also finding that some pharmacies are failing to comply with the OARRS weekly submission of data rule (OAC 4729-37-03). Both of these compliance issues are being enforced; therefore, please review your processes to ensure that you and your pharmacy are complying with these issues. If you have any questions regarding the OARRS data submission process, please contact the OARRS Department at 614/466-4143, option 1.

Disciplinary Actions

Anyone having a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, www.dental.ohio.gov

State Medical Board – 614/466-3934, www.med.ohio.gov

State Nursing Board – 614/466-3947, www.nursing.ohio.gov

State Optometry Board – 614/466-5115, www.optometry.ohio.gov

State Pharmacy Board – 614/466-4143, www.pharmacy.ohio.gov

State Veterinary Medical Board – 614/644-5281, www.ovmlb.ohio.gov

Drug Enforcement Administration – 800/882-9539, www.deadiversion.usdoj.gov

Page 5 – November 2012

The *Ohio State Board of Pharmacy News* is published by the Ohio 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.

Kyle W. Parker, MBA, RPh - State News Editor

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

Larissa Doucette - Communications Manager
