

November 2011

News



# Ohio State Board of Pharmacy

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## **Time for a Change – Personal Note From Bill Winsley**

At the August Ohio State Board of Pharmacy meeting, I announced my intention to retire from the Board at the end of this year. Therefore, this will be the last *Newsletter* I will write as the executive director. I want to take this opportunity to thank all of the pharmacists and others throughout Ohio for the support and encouragement you have given me over the 13 years I have served as executive director and the total of 23 years I have spent working for the Board. As in every job, there have been high points and low points, but I am fortunate to be able to say that the high points far outnumber the low ones. The support I have received from the Board members, staff, and from people all over Ohio has been tremendous and is the reason I can make that statement. Thank you.

The Board has selected Kyle Parker, currently the Board's licensing administrator, as my replacement. I hope everyone will give him the same support and encouragement that they have given me.

## **Terminal Distributor Renewals**

By the time this *Newsletter* is published, renewal notices for terminal distributor licenses will have been sent out by the Board and should have been received by all licensees. If you have not yet received yours, please contact the Board office as soon as possible. If you are the responsible person on the license, please remember that you are responsible for seeing that the license is renewed before January 1, 2012.

This year's process for renewal is similar to last year's renewal 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. Also, a terminal distributor license cannot be renewed online if any of the following applies: change of address, change of responsible person, change of business name, change of business ownership, and/or change of

drug category of the license. This is all explained on both the renewal application and the online renewal screens, which give directions on how to handle these situations. For ordinary renewals, however, the process should be as easy and painless as possible, **if** you read and follow the directions contained in your renewal packet and on the renewal screens. Please also note – **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 last few years, the Board has had several pharmacists whose cards were charged multiple times because they were not patient enough to wait for the card processing to occur. In other words, if that happens, it is because you hit the “back” button, not because the system had a problem. The Board tries to catch those mistakes before they get posted to your card, but the Board is not always successful. If it does occur, please contact the Board office so the extra charges can be reversed.

## **Proposed New and Changed Rules**

On October 14, 2011, the Board filed several new and changed rules that had an effective date of October 27, 2011. A copy of those rules showing the changes is posted on the Board's Web site under “What's New” and the text of the rules that are listed under “Laws & Rules” has been revised to reflect current language. As usual, the most current version of the Board rules is always available on the Board's Web site in the “Laws & Rules” section.

Due to the passage of HB 93, dealing mainly with pain management facilities, the Board was required to promulgate rules addressing mandatory access to the Ohio Automated Rx Reporting System (OARRS). In the past, pharmacists and prescribers were not required to use OARRS and were not liable if they did or did not obtain reports. That has changed with HB 93. Prescribers and pharmacists now have to review OARRS reports under conditions defined by the licensing boards. The Medical and Pharmacy Boards were each required to promulgate rules defining the reasons that

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## 2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm), and information about the ACIP recommendations are available on the CDC Web site at [www.cdc.gov/media/pressrel/2010/r100224.htm](http://www.cdc.gov/media/pressrel/2010/r100224.htm).

## Another TEASpoon – mL Mix-Up



*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).*

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 TEASpoonfuls of a liquid antibiotic for 10 days instead of 3.5 mL. The medication was dispensed in a 60 mL bottle. The child was given 3.5 TEASpoonfuls each day for three days. By the fourth day only one TEASpoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" ([www.ismp.org/Newsletters/acute/articles/20000628\\_2.asp](http://www.ismp.org/Newsletters/acute/articles/20000628_2.asp)). ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of TEASpoonful and other non-metric measurements to prevent errors ([www.ismp.org/pressroom/PR20090603.pdf](http://www.ismp.org/pressroom/PR20090603.pdf)). In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the

labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses ([www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm](http://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm)). Unfortunately, the guidance still mentions both TEASpoon and TABLESpoon. The Consumer Healthcare Products Association has also published guidelines ([www.chpa-info.org/scienceregulatory/Voluntary\\_Codes.aspx#volumetricmeasure](http://www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)) to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL and the "TEASpoonful" equivalent (eg, 5 mL (1 TEASpoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of TEASpoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

## 'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched [www.KnowYourDose.org](http://www.KnowYourDose.org), a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

## Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-



nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever.” FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at [www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table](http://www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table), and advises that “Methylene blue should generally not be given to patients taking serotonergic drugs.” Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at [www.fda.gov/Drugs/DrugSafety/ucm263190.htm](http://www.fda.gov/Drugs/DrugSafety/ucm263190.htm).

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at [www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table](http://www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table), and advises that “Linezolid should generally not be given to patients taking serotonergic drugs.” Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at [www.fda.gov/Drugs/DrugSafety/ucm265305.htm](http://www.fda.gov/Drugs/DrugSafety/ucm265305.htm).

## **NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA**

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- ◆ Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- ◆ Assess safe and accurate preparation and dispensing of medications
- ◆ Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- ◆ Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- ◆ Licensure, registration, certification, and operational requirements
- ◆ Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- ◆ Basic biomedical sciences
- ◆ Pharmaceutical sciences
- ◆ Social/behavioral/administrative pharmacy sciences
- ◆ Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- ◆ Basic biomedical sciences
- ◆ Pharmaceutical sciences
- ◆ Social, behavioral, and administrative pharmacy sciences
- ◆ Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at [exec-office@nabp.net](mailto:exec-office@nabp.net); or via fax at 847/391-4502.

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](mailto:custserv@nabp.net).

## **Clarification Regarding Pradaxa Storage and Handling Requirements**

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News*. As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm) provides more details, and the manufacturer’s Pradaxa safety information is available at [www.pradaxa.com](http://www.pradaxa.com) by clicking on the link for “Important Storage & Handling Information” at the top of the page.

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their respective licensees would have to access OARRS and review the resulting reports. For the pharmacy Board, those conditions are found in rule 4729-5-20 – **Prospective drug utilization review**. Paragraph D (below) was added to the rule to address when a report should be run and how often it should be repeated:

- (D) Prior to dispensing a prescription, at a minimum, a pharmacist shall request and review an OARRS report covering at least a one year time period and/or another state's report, where applicable and available, if a pharmacist becomes aware of a person currently:
- (1) Receiving reported drugs from multiple prescribers;
  - (2) Receiving reported drugs for more than twelve consecutive weeks;
  - (3) Abusing or misusing reported drugs (i.e. over-utilization, early refills, appears overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks);
  - (4) Requesting the dispensing of reported drugs from a prescription issued by a prescriber with whom the pharmacist is unfamiliar (i.e. prescriber is located out-of-state or prescriber is outside the usual pharmacy geographic prescriber care area); or
  - (5) Presenting a prescription for reported drugs when the patient resides outside the usual pharmacy geographic patient population.

After obtaining an initial OARRS report on a patient, a pharmacist shall use professional judgment based on prevailing standards of practice in deciding the frequency of requesting and reviewing further OARRS reports and/or other states' reports for that patient.

In the rare event a report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to receiving and reviewing a report.

If your pharmacy does not have Internet access to allow you to obtain an OARRS report, it will be necessary for that to change. Pharmacists will be held accountable if they fail to comply with the requirements in this rule.

Please review the OARRS reports carefully before you reach any conclusions about a patient. Please remember that the OARRS report is **not** evidence, but is merely a compila-

tion of data submitted by pharmacies (and now prescribers) that the OARRS system **thinks** all belong to the same patient. If you find a report that causes you to question whether or not you should fill the prescription, please take the time to verify the data before you act on it. Because there is no positive identification of the patients (eg, no fingerprints, Social Security numbers), the system relies on matching names, addresses, and dates of birth (with allowances for typing and spelling errors as well as nicknames). As a result, it is possible that there might be more than one patient represented on a report. Please take the time to discuss things with the patient, prescribers, and/or other pharmacies on the report before you make a final decision.

If you are not yet registered with OARRS so that you can obtain reports, please do so at once. Sign on to the OARRS Web site ([www.ohiopmp.gov](http://www.ohiopmp.gov)) and click on "Register" at the top right of the screen. Fill out the registration form online, print it out, and sign it in front of a notary public. Send in the registration form, a copy of your pharmacist's ID card that you receive from the pharmacy Board, and a copy of your driver's license. The OARRS system will send you a confirmation e-mail that requires a response from you to prove that the e-mail address is valid. Shortly after you confirm the e-mail address, you will receive your user name by e-mail and your password to access the system by United States mail. Once you have both a user name and password, you may begin to access the OARRS database.

Please note that when you run OARRS reports, you now have the option to also see if the patient has any prescriptions listed in the Indiana prescription monitoring program as well as in OARRS. Just select the box for Indiana when you ask for an OARRS report and you will get back one report containing both states' data organized by date. Michigan has completed a memorandum of understanding to participate in this system and is expected to be available for you to search in December of this year. Virginia is currently in a test status, but should also be available statewide soon. Several other states are in the process of joining in this effort, so it should not be long before you will be able to search multiple states with just one request to OARRS.

### **Other Changes as a Result of HB 93**

HB 93 made several other changes in addition to requiring OARRS reports. One major change is that prescribers may no longer personally furnish (ie, dispense) controlled substances to their patients for more than a 72-hour period at one time. Furthermore, if prescribers do provide reported drugs (controlled substances, tramadol, and carisoprodol) to their patients, they are now required to report that dispensing to OARRS. In the past, pharmacies reported, but prescribers did not. You should begin to notice some prescriber dispensing information on the OARRS reports in the near future, if you have not already.

Wholesalers are now required to report all sales of reported drugs to OARRS. In the past, they only reported sales to prescribers. Now they will be reporting pharmacy sales as well. As a result, the OARRS database will have a more complete picture of the balance between the reported drugs purchased as well as the reported drugs dispensed, if it should prove necessary to review that.

### **Electronic Prescribing of Controlled Substances**

As discussed several times in past *Newsletters*, Drug Enforcement Administration (DEA) published an interim final rule, effective on June 1, 2010, allowing prescribers and pharmacies who wish to engage in the electronic transmission of controlled substance prescriptions (including Schedule II prescriptions) to do so, **but only after the prescribing and pharmacy systems can meet the requirements set forth in the rule.**

In order to show that the system has met the requirements, each system must undergo an independent (third party) audit by either of the following:

1. A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.
2. A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

As has been said in these *Newsletters* repeatedly, the Board expects that some vendors will soon be able to complete their audits and transmit or receive controlled substance e-prescriptions. However, as of the time this *Newsletter* was written and as frustrating as it is, the Board is still saying the same thing. The Board still does not know of any systems in Ohio that have met the DEA requirements and are able to transmit or receive controlled substance prescriptions.

**As a result** – Until you receive notice that your pharmacy computer system has successfully completed the DEA required audit, you may **not** accept electronically transmitted controlled substance prescriptions, even if the prescribing system has been successfully audited.

### **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](http://www.dental.ohio.gov)

**State Medical Board** – 614/466-3934, [www.med.ohio.gov](http://www.med.ohio.gov)

**State Nursing Board** – 614/466-3947,  
[www.nursing.ohio.gov](http://www.nursing.ohio.gov)

**State Optometry Board** – 614/466-5115,  
[www.optometry.ohio.gov](http://www.optometry.ohio.gov)

**State Pharmacy Board** – 614/466-4143,  
[www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

**State Veterinary Medical Board** – 614/644-5281,  
[www.ovmlb.ohio.gov](http://www.ovmlb.ohio.gov)

**Drug Enforcement Administration** – 800/882-9539,  
[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)