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News

Ohio State Board of Pharmacy

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Do You Have Your New Terminal Distributor's License?

Please check the Terminal Distributor of Dangerous Drugs (TDDD) license at your facility to be sure you have received your 2010 TDDD license from the Ohio State Board of Pharmacy. The TDDD license is the license required for all pharmacies, hospitals, clinics, EMS squads, etc. If you have not renewed or received your 2010 TDDD license, please call the Board office immediately. The 2009 TDDD licenses expired on December 31, 2009.

Jurisprudence Continuing Pharmacy Education Note

Since we are not mailing the *Newsletter* anymore, the Board's annual Jurisprudence Quiz is not attached to this *Newsletter* as before. Instead, it is posted on the Board's Web site (*www.pharmacy.ohio.gov*). Click on "C.P.E. News and S.B.N." The questions in the quiz relate to the topics covered in this *Newsletter* as well as the May, August, and November 2009 issues. If you need them, copies of the previous *Newsletters* can be found on the Board's Web site by clicking on "C.P.E. News and S.B.N."

Please note that the deadline for submission of the completed quiz is **March 31, 2010.** Any answer sheets postmarked after March 31, 2010, will not be accepted.

Final CPE Reminder

This is a final reminder to those pharmacists whose license numbers begin with 03-1. This is the year for you to report your continuing education. It will be due in the pharmacy Board office **no later than May 15, 2010.** The continuing pharmacy education (CPE) report notice should be arriving in the mail sometime early in March, while your renewal instructions will not be arriving until mid summer. If you have not received your CPE report notice by the end of March, please notify us at the Board office so we can get you a replacement. The CPE report form is also available on the Board's Web page under "Forms." You can print it, fill it out, sign it, and mail it to the Board office.

You will need to attest to a total of six CEUs (60 hours) of continuing education credit. **0.3 CEUs (three hours) of those must be in Board-approved jurisprudence.** Please make sure that the jurisprudence courses are Board approved. The approved list is on the Board's Web site. There are a large number of courses coded as law that are not approved by the Board for use in meeting this requirement. The other 57 hours may be in any approved category that you wish.

You may use certificates dated on or after March 1, 2007, that you did not use when reporting in 2007. In addition, **please be sure that you have the certificates in hand before you certify your compliance with the CPE requirements on the form.** Every year, we have a few pharmacists who submit the form before receiving certificates from the continuing education provider because they assume they must have been successful. Sometimes, that certificate then fails to arrive because they did not pass the exam. Even if you do get the certificate after you submit the signed CPE form to the Board, **any certificates dated after the date you signed the CPE form will not be accepted if you are audited.** Falsifying the CPE report form is something that the Board does not take lightly. As long as you have the originals in your possession when you complete the report form, you should have no problem with this reporting period. If you fail to submit a CPE form in a timely manner, you will be subject to Board action on your license. (Rule 4729-7-02(C) states "A pharmacist shall be subject to further action of the board if the continuing pharmacy education report forms are not filed by the date indicated on the continuing pharmacy education report form, or if the hours submitted are incomplete.")

Why Am I Getting Those E-mails?

Now that the Board is renewing your pharmacist license online, we have collected an e-mail address for almost every pharmacist licensed with us. The good news is that we can now communicate with you quickly, efficiently, and cheaply if we need to. A good example of this is the e-mail we sent out about the Florida "pain" clinics and their prescriptions. The response we got from the pharmacists in Ohio was overwhelming and gratifying. As a result, we have several of the people involved in the Florida scheme under indictment in Lancaster, OH, and there may well be more indictments on the way. In addition, we now use e-mail to notify everyone of the availability of this *Newsletter* on our Web site.

The bad news is that Ohio has one of the most liberal Open Records laws in the country and we have to make most of your information available to anyone who asks. We can protect your Social Security number and any grade transcripts we may have. In addition, if we were to have any health records for you (not likely), we could probably protect them. Other than that, your record is open to anyone who asks. Furthermore, if we fail to provide the information requested in a timely manner, we can be fined for each occurrence of delay. That can get pretty expensive.

We have requests on a regular basis from employment agencies, attorneys, news media, continuing education providers, and others who have asked us for information on a pharmacist or for lists of Ohio pharmacists. The end result is that you are getting some mail or e-mail that you regard as spam or junk mail. Please understand

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

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 a 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.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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that, unlike private companies, we are not able to keep your contact information private. It is a source of frustration to us as well as it is to you. Many of the Board's members and staff receive those same solicitations.

If you receive e-mails from Ohio continuing education providers, attorneys, or employment agencies that you do not want to hear from, you might ask them to stop sending you information. Most of the legitimate individuals will make every effort to comply with your wishes. Just be careful when asking to be removed from mailing lists and make sure the source is a legitimate business. As most people already know, asking to be removed from a spam site just verifies that your e-mail address is current. That makes it more likely that your spam will increase rather than decrease.

About ISMP's Recent Attacks on the Ohio Board

Many of you have read the series of articles published by the Institute for Safe Medication Practices (ISMP) about the Eric Cropp case and have commented about them to the Board office. Those who know the facts of the case have been as outraged by the misinformation being published by ISMP as those of us with the Board. On the other hand, people around the country who, like ISMP, have never made any effort to find out the facts and who, like ISMP, are basing their opinions on news articles and fantasy have sent us some of the most vitriolic e-mails that we have ever received. The troubling thing about ISMP's articles and the e-mails of those who are criticizing us so strongly is that they are based on personal opinion and ignorance rather than on facts. Pharmacy is a profession based upon science and fact. That is a basic premise of the training we all received as pharmacists. We all learned that there is no excuse for basing our practice of pharmacy on fantasy and personal opinion in the absence of fact and it would be hoped that this training would carry over to our daily lives. Instead, ISMP and many of the people criticizing the Board are doing so without ever making any effort to determine the facts. While it is pretty common for the news media to be more interested in impact than facts, it is disappointing that ISMP feels it necessary to act in the same way. Despite offers to meet with ISMP at the Board office to review the entire case with them, thereby providing them with facts, there has been no response from ISMP at the time of the writing of this *Newsletter*.

ISMP was formed to perform an important and much needed function. The health and safety of the patient is what should be the ultimate focus of our practice and ISMP was formed to help us reach that goal. In order to do that, it would be expected that ISMP would remain impartial and make every effort to determine and publish facts. In that way, pharmacists would be able to learn from each other and would be able to adjust their individual practices to improve the care provided to patients. However, since ISMP has published such outlandish and false statements on this particular case, it calls into question their commitment to the basic premise of their formation and it also calls into question their credibility. That is an unfortunate situation for them and for the profession as a whole.

The Board does not expect everyone to agree with every one of its actions. Discussion and debate are necessary if we are going to make progress in our ultimate goal of patient protection. However, when an organization with influence, such as ISMP, makes absolutely no effort to determine the facts of a situation like the multiple medication errors in this case and instead contents itself with publishing fantasies and opinions, it does nothing but add fuel to a debate that is already too polarized.

The offer to meet with ISMP remains open. It will be up to them to decide whether they are interested in facts or would prefer to continue publishing articles based on their personal fantasies.

Disciplinary Actions

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency 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*

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