



# Minnesota Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Disciplinary Activity**

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of September 20, 2009 and December 2, 2009.

**Anderson, Dean A. License #111928.** Mr Anderson petitioned the Board for reinstatement of an unrestricted license. The Board had placed conditions on his license in November of 2004 after he admitted to diverting controlled substances from his employer for his personal use. The Board granted Mr Anderson's petition and issued an order of reinstatement at its December 2, 2009 meeting.

**Washburn, Robert A. License #110491.** Earlier this year, Mr Washburn's license was suspended because he had been discharged from the Health Professionals Services Program (HPSP) for noncompliance and because he had admitted to consuming controlled substances that were not prescribed for him. The suspension was stayed, conditional on his enrollment in HPSP, adherence to his HPSP participation agreement, and his abstaining from the use of mood-altering substances. Although he did enroll in HPSP, Mr Washburn was subsequently discharged for noncompliance. Consequently, the Board suspended his license indefinitely at a special meeting held on November 2, 2009. Mr Washburn will have to demonstrate that he has maintained sobriety for a minimum of 12 months, as well as meeting several other conditions, before he can petition the Board for reinstatement of his license.

The following **pharmacy technicians** voluntarily surrendered their registration or had their registration revoked between the dates of September 20, 2009 and December 2, 2009: **Buko, Janet L. Registration #706317; Tiedemann, Patricia Registration #705829.**

## **Joint Statement on Pain Management**

The Minnesota Boards of Medical Practice, Nursing, and Pharmacy recently issued an updated *Joint Statement on Pain Management*, which was first issued in 2004. The *Statement* notes that in "2009, it was estimated that more

than 33 million Americans – men, women, and children – were living with serious pain that lasted one year or more" and that "thirty to fifty percent of patients undergoing cancer treatment experience pain." The three boards believe that Minnesota physicians, nurses, and pharmacists must work cooperatively and effectively to address the problem of untreated and under treated pain and to provide maximum pain relief with minimal side effects. To that end, the *Statement* provides a list of activities that physicians, nurses, and pharmacists should be involved in and also provides many references concerning pain management. The *Statement* is available on the Board's Web site.

## **Pharmacy Technician Registration Renewals**

All pharmacy technicians should have renewed their registrations for 2010 by this time. Any technicians who have not yet renewed their registrations will have to pay late fees when they do renew and are not allowed to practice as technicians until they renew. The pharmacist-in-charge of each Minnesota pharmacy is responsible for making sure that all of the pharmacy technicians employed in his or her pharmacy have current technician registrations posted.

## **Pharmacist Renewals**

In early December, e-mail renewal notices were sent to every pharmacist for whom the Board has an e-mail address. Those who did not renew prior to the end of December were sent renewal notices by regular mail. Pharmacists are encouraged to use the Board's online services to renew their licenses. However, pharmacists can also print renewal invoices after logging onto the online services portion of the Web site or contact the Board office to request a paper renewal application. Pharmacists should either renew their licenses online or complete and return renewal forms to the Board by February 1. Pharmacist licenses expire on March 1 of each year and a late fee is assessed for any renewal received after February 28. Pharmacists are not allowed to practice after February 28,

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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](http://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](http://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](http://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](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 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](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).*

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](http://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<sup>®</sup> Arthritis and Tylenol<sup>®</sup> 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](http://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](http://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](http://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](http://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](mailto:custserv@nabp.net).

unless they have renewed their license. The pharmacist-in-charge of each Minnesota pharmacy is responsible for making sure that all of the pharmacists employed in his or her pharmacy have current licenses posted.

## **Pharmaceutical Waste**

### **Health Care Initiative of the Minnesota Pollution Control Agency and Minnesota Technical Assistance Program**

The Board adopted the following rule concerning disposal of pharmaceutical waste in May 2007:

Minnesota Rule 6800.2350 Pharmaceutical Waste. Hazardous pharmaceutical waste disposal shall comply with chapter 7045 as enforced by the Pollution Control Agency (MPCA) and other authorized state agencies.

This rule was meant to remind pharmacists that they have an obligation to comply with state and federal pollution control laws and rules regarding the proper disposal of pharmaceutical products. Penalties for failing to comply with those laws and rules can be significant.

The MPCA recently sent a letter to the state's dentists, long-term care facilities, medical clinics, pharmacies, and veterinarians concerning this issue. MPCA is partnering with the Minnesota Technical Assistance Program (MnTAP) on a statewide health care initiative that started in 2002. According to MPCA, all Minnesota hospitals and surgery centers have been, or are currently being, brought into compliance with state and federal hazardous waste rules through an inspection process. The initiative is now focusing on dental clinics, long-term care facilities, medical clinics, pharmacies, and veterinary practices.

The initiative consists of Web-based guidance materials, Webcasts, and workshops that will be held in locations around the state during the first six months of 2010. An online self-assessment will be available from April to July 2010. The initiative provides waste reduction guidance and an opportunity to self-disclose and correct violations. Beginning in 2010, all health care facilities will be subject to full enforcement of hazardous waste regulations and may incur financial penalties for noncompliance. Initiative resources can be accessed at [www.mntap.umn.edu/healthcarehw/index.html](http://www.mntap.umn.edu/healthcarehw/index.html). Pharmacists who have questions regarding hazardous waste regulatory compliance may contact Brandon Finke, of the MPCA, by telephone at 651/757-2358 or by e-mail at [Brandon.finke@state.mn.us](mailto:Brandon.finke@state.mn.us).

## **Pharmaceutical Take-back Programs**

Pharmaceutical take-back programs are designed so that members of the public can bring unused or expired drugs to a central location for appropriate disposal. Some Minnesota pharmacies and pharmacists have already become involved with such programs and others have expressed an interest in them. Pharmacists should be aware of several things before participating in take-back programs:

- ◆ Minnesota Rule 6800.2700 prohibits pharmacies from "accepting from patients or their agents for reuse, reissue,

or resale any drugs, prescribed medications, chemicals, poisons, or medical devices." (There are exceptions that allow for the return and redispensing of unopened, unit-dose drugs from certain long-term care facilities and jails.) Consequently, if a pharmacy were to accept drugs from patients or members of the public, those drugs would be considered pharmaceutical waste and would have to be disposed of in compliance with the laws and rules enforced by the Minnesota Pollution Control Agency.

- ◆ Federal controlled substance laws and rules prohibit a pharmacy from receiving controlled substances from anyone who is not a registrant of the United States Drug Enforcement Administration (DEA). (With limited exceptions involving drugs that are the subject of a manufacturer's recall or that were dispensed by the pharmacy in error.) That means that pharmacists are not allowed, with the exceptions just mentioned, to accept controlled substances from patients or members of the public.

DEA does have a process in place through which a local law enforcement agency can get permission to conduct take-back programs. The law enforcement agency may then work with a pharmacy or pharmacist to conduct the take-back program. Law enforcement officials must be present during a take-back event because there is no way to guarantee that controlled substances will not be brought to the collection site. Pharmacists typically assist by identifying controlled substances so that they can be handled separately from other drugs that are collected.

In summary, no pharmacist should be involved in a pharmaceutical take-back program unless he or she is working with a law enforcement agency that has received DEA approval to conduct such a program. The pharmaceuticals collected must be disposed of in accordance with the relevant laws and rules that are enforced by the MPCA.

## ***In Memoriam – Retired Board Surveyor Byron Opstad***

As was announced in the last edition of this *Newsletter*, Pharmacy Board Surveyor Byron Opstad retired in early July. Byron had ably served the Board and the public as a surveyor for almost 14 years and had been the chief pharmacist at the Minneapolis Veteran's Medical Center prior to his employment with the Board. Byron passed away on December 6, 2009. His funeral service was held on December 11, at Community of the Cross Lutheran Church in Bloomington, MN, with internment at Fort Snelling National Cemetery.