



Alaska Board of Pharmacy

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Prescription Drug Monitoring Program

The state of Alaska has been awarded a \$400,000 grant to implement a prescription drug monitoring program (PDMP).

A PDMP is a database of all controlled substances dispensed in Alaska pharmacies.

Currently 32 states have operational PDMPs and six states are in the start-up phase. Drug Enforcement Administration (DEA) has been a long time proponent of PDMPs due to the proven effectiveness in curtailing the diversion and abuse of controlled substances. The program is not intended to be used to target subjects for investigation, but rather to identify illegal activity such as prescription forgery, indiscriminate prescribing, and to deter "doctor shoppers." Health care providers will have access to review the data online through a secure server once the data has been collected, but are not required to access the database prior to writing or dispensing a prescription for a controlled substance.

Data submission will be mandatory for all controlled substances dispensed. Data will be collected online via a data dump via an interface (like online insurance judicator) and the information will be transferred to the database so there should be minimal time required to submit the information. The database will be updated monthly by a third-party vendor, therefore it will not be real time with up-to-the-minute information. Annual maintenance costs vary on the frequency of the data collection, the use of a third-party vendor, the number of prescriptions submitted, and the use of official forms when required. The average operating costs for PDMPs range from \$100,000 to nearly \$1 million. The goal is for the state of Alaska to fund the annual operating costs.

At the next Alaska Board of Pharmacy meeting we will discuss how to implement the PDMP, which third-party vendor to utilize, etc. We hope to get this implemented in 2010.

Pharmacist Collaborative Practice Agreements

Pharmacist collaborative practice agreements are a tool pharmacists can use to initiate or modify drug therapy via an approved written protocol authorized by a collaborating practitioner endorsed to prescribe legend drugs under AS 08. The therapies most commonly addressed by collaborative practice agreements are anticoagulants, travel medication, emergency contraception, hypertension management, and immunizations. The latter of these compromise approximately two-thirds of approved agreements. Recently, due to the H1N1 influenza virus, immunization collaborative practice agreements have increased in order to allow pharmacists to safely meet the need for vaccinating the public.

Advanced nurse practitioners are often the principal prescribing practitioner partnering with pharmacists to create the agreements. When a physician is the principal prescribing practitioner, the collaborative practice agreement must also be approved by the Alaska State Medical Board prior to implementing the therapy. The regulations for collaborative practice agreements are fully described in 12 AAC 52.240 and related definitions are listed in 12 AAC 52.995.

Licensing Statistics

Pharmacist licenses issued September 1, 2009 through December 15, 2009, include Gaston Ewing, William Long, Anand Vora, Maria Reyes, Mark Johnson, Casey Johnson, Billie Marseilles, Christopher Pratt, Laura Anderson, Christine Kathmann, Patricia Church, Robin Cooke, Andrew Bersu, and Jude Fabius.

Also licensed during this period were 83 pharmacy technicians, 22 interns, 15 out-of-state pharmacies, two retail pharmacies, and one drug room.



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.

Proposed New Regulations

If you would like to receive notice of proposed regulations, please write to the regulations specialist and request your name be added to the pharmacy interested parties list. Contact information is as follows:

Jun Marquis, Regulations Specialist
Division of Corporations, Business, and
Professional Licensing
Department of Commerce, Community, and
Economic Development
PO Box 110806
Juneau, AK 99801-0806
E-mail: jun.marquis@alaska.gov

Alaska Board of Pharmacy News

We currently have a vacant public member Board seat. Public members serve a valued role and contribute to our mission. They bring the consumer perspective into the practice of pharmacy and represent the population we serve. Public Board members may not be engaged in the practice of pharmacy or be legally associated with a person who is. Board members are entitled to transportation expenses and per diem. Each term is four years and a member can serve up to two consecutive terms. The full regulations for public members are noted in Section 08.01.025 of the Centralized Licensing Statutes. Please refer potential candidates to contact the Board via phone at 907/465-2589 or via e-mail at license@commerce.state.ak.us/occ.

2010 Board Meeting Schedule

- ◆ February 18-19: Anchorage
- ◆ May 13-14: Anchorage
- ◆ September 23-24: Anchorage

Alaska Board of Pharmacy Members Officer Positions Through February 19, 2010

Leah Handley.....Public Member (Homer)
Richard Holm, RPh..... Vice Chair (North Pole)
Steve R. Johnson, RPh Secretary (Palmer)
Christopher J. Kim, RPh Member (Anchorage)
Mary D. Mundell, RPh.....Chair (Wasilla)
Dirk W. White, RPh Secretary (Sitka)
Vacant.....Public Member

The Alaska Board of Pharmacy staff includes Investigator JoAnna Williamson (Anchorage), Licensing Supervisor Sher Zinn (Juneau), and Licensing Examiner Mary Kay Vellucci (Juneau).

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