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Inspections in 2009

By Richard Burton, RPh, Inspector/Compliance Officer

Each year the Wyoming State Board of Pharmacy requires the inspectors to list results of their yearly inspections. The results from these inspections will vary from year to year but a number of the discrepancies or findings reappear each year. There seems to be a correlation between the reappearance in some of these findings and the changing of the pharmacist-in-charge (PIC) at the pharmacies. The PIC does carry more responsibility, but the main responsibility is supervision of the pharmacy staff and making sure they do their job. When you read the listing below of inspector findings for 2009, you will find that each infraction is covered by rules in the Wyoming Pharmacy Practice Act or Wyoming Controlled Substance Act. These rules apply not just to the PIC but to each pharmacist and technician. Each pharmacy staff member has a responsibility to comply with the rules that govern the practice of pharmacy.

Major Findings for the 2009 Inspections

- Failure to sign and date controlled substance invoices when order received
- Failure of reconciliation of Schedule II perpetual inventory
- Technicians working with no license posted in the pharmacy
- Failure to separate controlled substance invoices from non-controlled substance invoices
- Expired drugs on active drug shelf
- Daily log book not current or signed
- Schedule II prescriptions not signed or dated when filled
- Technicians working without name tags
- Product ID on prescription with incomplete identification
- Pharmacists not displaying pharmacy license in the pharmacy
- Failure to complete Drug Enforcement Administration (DEA) Form 222 when order received

Methadone Deaths on the Rise

By Amanda Thompson, PharmD Candidate

Methadone, an opioid analgesic traditionally used as an agent for management of opioid, heroin, and morphine addiction, is now increasingly being prescribed for pain relief. According to the Centers for Disease Control and Prevention (CDC), "methadone has become one of the most widely prescribed opioid pain relievers, with 4 million prescriptions written for pain relief in 2006 alone." The CDC also states that deaths from opioid use have tripled since 1999 with 4,000 deaths in 1999 and 13,800 deaths in 2006, and methadone deaths, specifically, have increased from 790 to 5,420 respectively. Methadone's increasing use for pain management has made the medication more available for therapeutic and non-prescribed use. Its increased availability, lack of knowledge amongst providers and patients about methadone's potential hazardous effects, and lack of adequate monitoring all contribute to the rise in methadone related deaths.

The shift to methadone use from other opioids, such as OxyContin®, is partly due to the increased concern of OxyContin's abuse potential and high price. Methadone, a cheaper long-acting opioid analgesic, presents with various life threatening effects if not correctly monitored and dosed. Potentially fatal respiratory depression, cardiac effects, and varied range of elimination and drug interactions all add to methadone's risks. When used for management of opioid addiction, methadone is regulated by methadone-specific state and federal laws and closely monitored through the program. Only physicians enrolled in such programs are allowed to prescribe methadone for this use. When prescribed for pain, methadone is regulated by state and federal laws generally applied to all other controlled substances, and any physician is able to prescribe for its use. In this case, methadone could be prescribed by physicians who may not be fully aware of methadone's risks, monitoring needs, and dose individualization.

Most patients are also unaware of the potential risks of methadone. Methadone's pain alleviation lasts from around four to eight hours, and patients seeking adequate pain relief may take more medication than prescribed to them. The potential danger associated with this is that even though methadone's pain alleviation is relatively short, it can remain in the body for up to 59 hours. By continually adding extra doses, patients may find themselves unknowingly overdosing on methadone. Patients may also concomitantly take medications or substances such as benzodiazepines and alcohol that show to be dangerous and possibly fatal when taken with methadone. Patients taking non-prescribed methadone also fall into these risks. Data from DEA shows that nationwide methadone drug loss and theft has more than doubled, from 176 incidences in 2000, to 393 in 2007.

Efforts are being made to increase methadone's safety through physician and patient education, newly revised labels including more safety information for methadone tablets, and prescription drug monitoring program utilization. The state of Wyoming currently does not have any opioid treatment centers. Therefore, methadone prescriptions from physicians in the state will most likely be for pain and could possibly be less strictly monitored than when used for management of opioid addiction. Recorded deaths in Wyoming from methadone use remain extremely low; however, the use, overdose, and abuse of methadone are concerningly on the rise within the United States. Physicans, pharmacists, other health care providers, and patients can all play a role in methadone awareness and overdose and death prevention.

Major Focus of Board Inspectors During the 2010 Inspections

1. PIC responsibilities
2. Format to use for clear reconciliation of Schedule II perpetual inventory

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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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3. Continuing random drug audits of one controlled substance at each pharmacy
4. Patient counseling and medication errors
5. Display of licenses in the pharmacy
6. Checking IDs and addresses on controlled substance prescriptions
7. Checking patient profiles and Drug Use Reviews in compliance with Wyoming Pharmacy Act, Chapter 9
8. Ensuring technicians apply to Board after passing Pharmacy Technician Certification Board examination and posting licenses
9. Utilizing Board Web site to check status of any new licensed personnel
10. Documentation of records in pharmacies administering immunizations
11. Proper documentation of transferred prescriptions
12. Attitude and courtesy
13. United States Pharmacopeia Chapter 797 rules
14. Awareness of new rules adopted in 2009

Medication Donation Program

By Daniel Plaisted, PharmD Candidate

Throughout the state of Wyoming and around the nation, the rising cost of health care has been a topic of great debate. Many people have found that they are no longer able to afford health care and its associated costs. In the state of Wyoming there are over 71,000 people who are uninsured. For many, medications that have been prescribed by a physician seem impossibly expensive. Many wonder where to turn for help. When they come to your pharmacy, what will you tell them? While there are certainly many different programs designed to help patients with the costs of medications, the state of Wyoming has also stepped forward to help develop a solution to the problem.

In 2005, a significant piece of legislation was passed in the state of Wyoming. This legislation developed a program that would allow certain unused medications to be donated to be dispensed to patients who are unable to afford the high cost of their medications. The program is administered through the Office of Pharmacy Services, a division of the Wyoming Department of Health and is called the Wyoming Medication Donation Program. While many other states have passed similar legislation, few actually have programs up and running.

Since the pilot program's inception in 2007, the program has grown significantly. In a single year the number of patients who used the clinic grew by 65%. The program has dispensed over 3,900 prescriptions from January to September of 2009 with a total retail value of more than $446,000, as compared to a total retail value of approximately $336,000 for all the medications dispensed in 2008. While this growth is a sign that people are starting to utilize the program, it is still unknown to many providers, pharmacists, and patients who could potentially benefit from it.

Patients must meet the following criteria to be eligible: be a Wyoming resident, have no prescription insurance, and have limited income (at or below 200% of Federal Poverty Level). The program is not designed to provide medications to patients on a long-term basis but rather to get patients a one or two-month supply while helping them to find long-term assistance through other programs.

The program accepts donations from any person or entity. While a majority of their donations come from nursing homes, they also receive donations from many other sources. Donations are limited to unopened medications in their original sealed bottles, or unit-dosed or individually packaged medications. They also accept donations such as pharmacy supplies (lids, vials, bags, etc), diabetic supplies such as strips and lancets, and other medical supplies (spacers, syringes, etc). The program asks that medications donated be boxed and include a packing list or invoice of what has been donated.

When asked what she would like pharmacy personnel to know about the program, Program Director Donna Artery, PharmD, said, "We just need to get the word out that this program is available. If you have patients who can benefit from the program, give them a brochure or send them to us, just utilize the program."

If you would like to donate time, supplies, or medications, or to see a list of currently available medications, or if you would like more information about the program please contact:

Wyoming Medication Donation Program
A Program of the Wyoming Department of Health
6101 Yellowstone, Suite 259B
Cheyenne, WY 82002
1-800/438-5785
Fax: 307/777-8623
E-mail: donna.artery@health.wyo.gov
Or visit *www.health.wyo.gov/healthcarefin/pharmacy/MedicationDonation.html*

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