Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning pharmacists between the dates of June 11, 2009 and September 19, 2009.

Hayenga, Timothy J., License # 115088. Mr Hayenga admitted to diverting controlled substances from his employer and to the unauthorized personal use of those drugs. At its April 1, 2009 meeting, the Board suspended his license but stayed the suspension on condition that he enter into a participation agreement with the Health Professional Services Program (HPSP), pay a civil penalty in the amount of $300, and comply with all provisions of any court order that is issued in the event that he is convicted of any criminal offenses relating to the diversion of controlled substances. Mr Hayenga violated the terms of his disciplinary order by not entering into an agreement with HPSP and not paying his civil penalty. Consequently, the Board rescinded his previous disciplinary order, suspended his license to practice pharmacy for an indefinite period of time, and imposed a $1,000 civil penalty.

Silivongxay, Phonesagnam J., License # 118456. Dr Silivongxay admitted to diverting controlled substances from his employer and to the unauthorized personal use of those drugs. At its February 18, 2009 meeting, the Board placed him on probation for three years or until successful completion of a participation agreement with HPSP, whichever is later. He was also assessed a civil penalty of $300, required to meet with a Board member on a regular basis, and required to notify any pharmacy employer about his disciplinary order within a specified period of time. Dr Silivongxay violated his disciplinary order by not entering into an agreement with HPSP and not paying his civil penalty. Consequently, the Board rescinded his previous disciplinary order, suspended his license to practice pharmacy for an indefinite period of time, and imposed a $1,000 civil penalty.

The following pharmacy technicians voluntarily surrendered their registrations between the dates of June 11, 2009 and September 19, 2009: Courtney, Michelle L., Registration # 717856; Lafferty, Holyelk, Registration # 717249; and Pasch, Lacey J., Registration # 713507.

New Prescription Monitoring Program

The Minnesota Legislature passed a law in 2007 requiring the Board of Pharmacy to establish a controlled substances prescription electronic reporting system for all Schedule II and III controlled substance prescriptions dispensed in Minnesota. The law was amended in May 2009 to include Schedule IV controlled substances and to allow the Board to contract with a vendor to assist in both the implementation and administration of the program. The Board recently signed a contract with Health Information Designs, of Auburn, AL.

The new program will be called the Minnesota Prescription Monitoring Program (PMP) and will require all dispensers, including nonresidential pharmacies that ship or mail prescriptions into the state, to report certain information concerning Schedule II, III, and IV prescriptions to the Board. Prescribers and pharmacists will be able to enroll in the PMP as users, allowing them to access controlled substance profiles for patients who are currently under their care. The purpose of the program is to help prescribers and pharmacists identify patients who may be engaged in “doctor-shopping.”

Pharmacies will soon receive a Dispenser’s Implementation Guide in the mail. It is imperative that pharmacies provide a copy of the guide to their pharmacy software vendor as soon as possible. Pharmacies may need to make changes to their systems in order to begin reporting by the January 4, 2010 implementation deadline. Pharmacies may want to contact their software vendors even before they receive the guide and let them know that American Society for Automation in Pharmacy 2007 Standards will be used for the PMP. Additional information about the PMP will be made available on the Board’s Web site and on a new Web site dedicated to the PMP.

2009 Legislation Affecting the Practice of Pharmacy

A large number of bills related to the profession of pharmacy or to pharmaceutical manufacturers were introduced this past session. Descriptions of some of the provisions that were enacted into law follow.

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Pharmacy Security and Safety Prove Necessary Component in Pharmacists’ Training

Pharmacy robbery — no one ever thinks it will happen to them, but those who have experienced it know it can happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin®. They left with bags filled with OxyContin and Percocet®, having a retail value of nearly $10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university’s college of pharmacy alumni e-Newsletter. In the article Bryan states, “I crouched down hoping they hadn’t seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery,” he explains. “I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal.”

In December 2008, a safety DVD, Pharmacy Security – Robbery, accompanied the shipments of the National Association of Boards of Pharmacy® 2009 Survey of Pharmacy Law that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

“One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber’s appearance – clothes, height, weight – and not just focusing on the gun,” states Cisneros. He was glad to have received the DVD, explaining that, “it was just the right length, added a lot to the class, and led to great discussions.” Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol® Web site at www.rxpatrol.org. RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at www.partnersagainstpain.com under Pain Education Center.

Concerns with Patients’ Use of More than One Pharmacy

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.

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy...
locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient’s pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM’s computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through SureScripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the $4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbal supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

**CDC Announces Get Smart Week to Help Decrease Antibiotic Resistance**

Centers for Disease Control and Prevention (CDC) is holding Get Smart Week October 5-11 to emphasize CDC’s public health effort to decrease antibiotic resistance, including how pharmacists can become involved. Because antibiotic resistance is one of the world’s most pressing public health problems, CDC launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at [www.cdc.gov/getsmart/](http://www.cdc.gov/getsmart/).

**FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1**

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements).

**ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High**

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

**FDA Takes Actions on Pain Medications Containing Propoxyphene**

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite “serious concerns . . . , the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time.” Additional information can be found at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm).
Changes in Definition of Practice of Pharmacy

As originally introduced, this bill would have clarified that pharmacists can administer influenza vaccines to children 10 years of age and older. It would have also allowed pharmacists working under protocol with certain practitioners to sign legally valid prescriptions. The provision concerning vaccines was removed from the bill due to concerns expressed by the Minnesota Departments of Health (MDH) and Human Services (DHS). Those departments were unaware that legislation was passed last year to allow pharmacists to administer influenza vaccines to individuals under the age of 18. They indicated that allowing pharmacists to give any vaccines to children would put the state in violation of laws and rules concerning a free vaccine program. The Minnesota Pharmacists Association worked with DHS and MDH on that issue and a compromise was reached that allows pharmacists to continue administering influenza vaccines to children who are 10 years of age or older through December 31, 2009. After that date, pharmacists must enroll in the Minnesota Vaccines for Children Program that is administered by MDH if they want to continue administering influenza vaccines to children.

The provision allowing pharmacists to sign legally valid prescriptions proved to be non-controversial and was enacted into law. The relevant new language is as follows: “A licensed practitioner may prescribe a legend drug, without reference to a specific patient, by directing a nurse, pursuant to section 148.235, subdivisions 8 and 9, physician assistant, or medical student or resident, or pharmacist according to section 151.01, subdivision 27, to adhere to a particular practice guideline or protocol when treating patients whose condition falls within such guideline or protocol, and when such guideline or protocol specifies the circumstances under which the legend drug is to be prescribed and administered.”

The Board adopted the following guideline at its June 10, 2009 meeting:

If a pharmacist working per a protocol (as authorized in Minnesota Statutes 151.01, Subd. 27) uses a prescription form, a faxed prescription, or an electronic prescription, the pharmacist should indicate the name of the authorized prescriber who developed the protocol, the name of the pharmacist who is implementing the protocol, and indicate that the prescription is generated per protocol. As an example, the pharmacist might sign a prescription generated per a warfarin monitoring protocol as follows:

“Sven Svenson, RPh, per warfarin protocol with Ingrid Ingridsdottir, MD”

Pharmacists should not fill a prescription signed by a pharmacist unless there is an indication on the prescription that the pharmacist signing the prescription is authorized to do so per protocol. As with all prescriptions, pharmacists should verify any prescription if there is a question as to its validity.

Changes Concerning Pseudoephedrine Sales

One change clarifies that the permitted amounts of pseudoephedrine and other methamphetamine precursor drugs that can be contained in a single package, or that can be sold on a daily or monthly basis, refer to the base form of the drug – as opposed to the salt. Packages must contain no more than 3 g of ephedrine or pseudoephedrine, calculated as the base drug, not the salt. For example, Claritin-D® 24-Hour contains 240 mg of pseudoephedrine sulfate, but only 181.8 mg of the base per tablet. Consequently, 15 tablets contain 181.8 mg * 15 = 2727 mg or 2.727 g of pseudoephedrine base. Two of the 15-count packages of this product would contain about 5.5 g of pseudoephedrine – which is under the 6 g monthly sales limit.

Another change requires pharmacies to retain pseudoephedrine sales logs for at least three years and clarifies that the logs “must at all reasonable times be open to the inspection of any law enforcement agency.”

Changes to State Controlled Substances Schedules

Legislation was passed that requires the Board to annually submit a report to the legislature that specifies the changes that the Board made to the state’s controlled substance schedules during the preceding 12 months. The Board is in the process of amending rules to add a number of federally scheduled drugs to the state schedules. This will have little impact on pharmacists since most of the drugs will be added to Schedule I and since those drugs that will be added to the other schedules must already be handled as controlled substances by pharmacists in order to comply with federal law. However, these changes will make it easier for county attorneys to bring charges under state law for controlled substances violations. The proposed rule changes can be found on the Statutes, Rules, and Guidelines page of the Board’s Web site at www.phcybrd.state.mn.us/Main-sta.htm.

Medication Therapy Management Provision

Legislation was passed that requires a pharmacy benefit manager to “make available medication therapy management services for enrollees taking four or more prescriptions to treat or prevent two or more chronic medical conditions.” The legislation further defines “medication therapy management” to mean the provision of certain pharmaceutical care services by, or under the supervision of, a licensed pharmacist. At its June 10, 2009 meeting, the Board went on record as interpreting the “or under the supervision of” clause to refer only to registered pharmacy interns and that other individuals working under the supervision of a pharmacist may not provide medication therapy management services.

Pharmacy Board Surveyor Retires

Pharmacy Board Surveyor Byron Opstad retired in early July. Mr Opstad served the Board and the public with loyalty, dignity, integrity, and effectiveness for almost 14 years. Please join the Board in recognizing Mr Opstad’s efforts to protect the health and welfare of the public while also serving as an educational resource for the pharmacists of this state. Please also join the Board in wishing Mr Opstad the best in his retirement years. Due to budget constraints, the Board will not be filling the position being vacated by Mr Opstad at this time.