



Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

The Ohio Prescription Monitoring Program – Ohio Automated Rx Reporting System

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Please Note: Throughout this article, the term “drug(s)” refers only to controlled substances (CS) (all schedules), carisoprodol, and tramadol.

In 2002, the Ohio Attorney General’s Office and the Ohio Bureau of Criminal Identification and Investigation conducted a non-scientific survey of Ohio law enforcement agencies that conduct investigations involving prescription drugs and asked specifically about the abuse of OxyContin®. The survey results indicated that between 49% and 78% of individuals arrested used doctor shopping to obtain OxyContin illegally. This statistic is not surprising. Since 1988, the Ohio State Board of Pharmacy has been involved in the arrest of over 2,300 individuals for prescription drug abuse and has documented over 18,000,000 doses of CS diverted for illegal use. Most of the diverted drugs were Schedule III and Schedule IV CS; specifically, the hydrocodone-containing products and the benzodiazepines.

In the War on Drugs, Ohio is still using revolvers while surrounding states have machine guns. Kentucky, Indiana, Michigan, Pennsylvania, and West Virginia have active or pending electronic prescription drug monitoring programs. Since the inception of Kentucky’s monitoring program in 1999, Ohio has seen an influx of Kentucky residents coming to Ohio intending to divert drugs by doctor shopping. These individuals were aware that Ohio did not have a prescription monitoring program (PMP) at the time and, therefore, the chances of being identified and prosecuted were greatly reduced. The Ohio Board recently had cases involving two alleged pain management physicians located in central Ohio. Of the 2,683 patients seen by these physicians, 2,322 patients (86%) were from Kentucky, 188 patients (7%) were from Ohio, 145 patients (5.4%) were from West Virginia, 8 patients (0.3%) were from Indiana, 7 patients (0.26%) were from Michigan, and various other patients came from Tennessee, Virginia, Florida, Maryland, Maine, North Carolina, and Pennsylvania. Not only has the Board of Pharmacy seen an increase in prescription drug diversion and drug abuse attributed to residents from outside the state, but it has also seen an increase in drug diversion among residents of Ohio.

Currently, the only method to investigate a potential diversion case on an individual patient or prescriber is to obtain informa-

tion by physically visiting each pharmacy in an area to obtain drug profiles. This information must then be manually entered into a computer system to be sorted and studied before the actual investigation begins. The investigation of a prescriber can take up to six months just to collect, enter, and review this data. Law enforcement agencies close serious criminal cases every year due to a lack of personnel resources to investigate. Such a time-consuming process is not only expensive, it is also invasive to the pharmacy and potentially damaging to the prescriber if the complaint is unfounded.

In 2002, and again in 2004, Representative Tom Raga introduced legislation to allow the Board to create a PMP. In December 2004, the legislation passed both the House and the Senate and Governor Bob Taft signed it in February 2005. Key provisions of the legislation include (1) collection of prescription data from pharmacies, (2) collection of wholesale transaction data from wholesalers and pharmacies, (3) data analysis by Board personnel, (4) dissemination of data as allowed by the statute, to pharmacists and prescribers who are treating patients, and (5) reporting to the legislature.

Our contractor, Atlantic Associates, Inc, collects the prescription data. Pharmacists submit the data twice a month to Atlantic either directly from the pharmacy or via their agent such as a pharmacy chain headquarters or a software vendor. Atlantic will audit the data to be sure it is readable and it meets the criteria set by the Board. Valid records are accepted and forwarded to the Board. Atlantic will notify the submitting pharmacy of rejected records along with the reason for rejection. The pharmacist must correct the records and resubmit.

Wholesale transactions must be reported directly to the Board office. This affects every pharmacy that sells drugs to a prescriber, clinic, ambulance service, etc. (Note: Pharmacies are allowed to sell drugs directly to prescribers and others even if they do not have a wholesale license. However, the pharmacy must report all sales except sales to other pharmacies, hospitals, wholesalers, or manufacturers.) Data includes the Drug Enforcement Administration numbers of the buyer and seller, date of the transaction, National Drug Code number, and quantity of the drug sold.

The law requires that all reports, prescriptions, and wholesale transactions be electronic and be sent twice a month. Once the prescription data is in the system, pharmacists and prescribers may request reports on their patients.

Prescribers should request a report when:

- ◆ Treatment with a CS is necessary beyond what the prescriber initially anticipated;

Continued on page 4



FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

Continued from page 1

- ◆ A condition is diagnosed that will require treatment with a CS for an extended period of time; or
- ◆ Suspicions of drug abuse, misuse, or addiction arise.

In general, pharmacists should be using PMP data in the same way that physicians use it – to evaluate patients for whom they are providing treatment. A pharmacist should be looking at patient drug histories (within their own pharmacy or chain, depending on how much data is available to them) every time a prescription is filled. He or she may see something in the record or in the patient encounter that leads them to wonder what the patient may be obtaining elsewhere. As you know, pharmacists see many things that the prescriber does not see and the pharmacist may realize that PMP information could be helpful even though the prescriber may not. For example, a patient on hydrocodone/acetaminophen might need to be monitored. Even if there's no misuse of the hydrocodone, the acetaminophen consumption can be a health risk if combined with other products that contain acetaminophen. The information gained is utilized in the same manner as information obtained through traditional sources – to consult with prescribers and patients in order to provide appropriate patient care.

The Ohio law limits prescribers and pharmacists to obtaining reports on their own patients. Therefore, a pharmacist cannot request a report on a person who is not his or her patient, even if a physician asks them to do so. A pharmacist who obtains a report and discusses the information with the physician should not release the written report to the physician due to liability issues. The treating physician should obtain his or her own report.

How to Obtain a Report

Register to obtain access to the secure Web site. Information and forms will be available on the Web site; however, the process will require mailing a notarized application and supporting documents.

1. Check the Board's Web site for details.
2. Log in to the Web site with your registration information.
3. Enter patient's identifying information – full name, address, date of birth, and telephone number.
4. You will receive an e-mail when the report is ready. Go back to the Web site and view or print the report.
5. Treat the report like all protected health information and protect it from unauthorized disclosure.

Additional details, that were not available at press time, will be posted on the Web site. Check the Board's Web site, www.pharmacy.ohio.gov, after July 1, 2006.

Physicians and law enforcement officers will be able to obtain information in a similar manner.

In addition to providing patient utilization reports, the Board staff is required to analyze the data for potential violations of law and refer those cases to the appropriate licensing board or law enforcement agency.

The Board is very excited about this new tool that is available to pharmacists, prescribers, and law enforcement. Based on the experience of other states, it has great potential to improve the health care provided to legitimate patients who take CS and to minimize the abuse and misuse of these drugs.

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 – 1-800/230-6844, www.deadiversion.usdoj.gov

Page 4 – May 2006

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