



Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Prescription Monitoring Program

The 1997 Idaho Legislature mandated that the Idaho State Board of Pharmacy shall create, operate, and maintain a controlled substances (CS) prescriptions database for the purpose of assisting in identifying illegal activity and providing information to patients, practitioners, and pharmacists to assist in avoiding inappropriate use of CS. All CS dispensed for humans shall be filed with the Board electronically, including prescriber dispensings. In fiscal year 2013, 2,795,356 CS dispensings were reported to the Board, which collated the data into patient and prescriber profiles, available for use by authorized users. In 2008, the prescription monitoring program (PMP) went online 24 hours a day, seven days a week, available for use by prescribers who are considering prescribing CS to a particular patient and pharmacists who are considering dispensing CS to a particular patient or who are providing pharmaceutical care services.

Unsolicited Reports

The Board has traditionally received CS dispensing data and made the data available to authorized users. The Board has not traditionally studied the data itself; however, the Board is statutorily allowed to provide PMP data to the appropriate law enforcement agency, Medicaid or Medicare agency, or licensing board to further investigate or for administrative enforcement use. The Board often sends law enforcement agencies reports on forgeries and forwards licensing boards public complaints of overprescribing. Occasionally, the Board sends Medicare or Medicaid insurance fraud information. As of July 1, 2013, the Board received statutory authority to expand the provision of unsolicited PMP reports. Each month since July 1, 2013, the Board has sent a cover letter and a patient history to each prescriber who prescribed CS to a patient that was also prescribed CS by at least four other prescribers that month. In fiscal year 2013, the average number of letters sent per month was 377, and an average of 329 prescribers received letters each month, indicating that an average of 48 prescribers received multiple letters. Prior to the provision of unsolicited reports, 65% of the prescribers who received unsolicited reports were registered for online PMP access. This has increased to 82%. Prior to the provision of unsolicited reports, 9% of prescribers who received an unsolicited report checked the PMP prior to prescribing and still prescribed, indicating a true need, such as a cancer patient. This has increased to 18%. Currently, 38% of the prescribers who hold CS registrations are registered for online PMP use.

Who Receives Unsolicited Reports?

- ◆ Physicians receive 62% of the unsolicited reports distributed.
- ◆ Physician assistants receive 18%.
- ◆ Advanced practice nurses receive 10%.
- ◆ Dentists receive 9%.
- ◆ Podiatrists and optometrists combine to receive the remaining 1%.

Who Orders CS?

- ◆ 90% of the CS dispensings are issued by 16% of the prescribers in or into Idaho.
- ◆ 90% of the CS dispensed (by quantity) are issued by 13% of the prescribers in or into Idaho.

Board Mailings and Attributed Results

In May 2013, the Board mailed a letter to all prescribers encouraging PMP use, signed by several agencies, boards, associations, and legislators. The two-year average number of new online PMP users per month was 64, and the four-month average since the mailing is 127; a 98.4% increase. The two-year average number of monthly profiles generated was 11,285, and the four-month average since the mailing is 21,156; an 87.5% increase. In October 2013, the Board mailed to every prescriber and pharmacy a brochure explaining the PMP and window clings that state "We participate in the Prescription Monitoring Program administered by the Board of Pharmacy. The system collects prescription data on controlled substances dispensed in or into the state of Idaho. The program is mandated pursuant to Idaho Code 37-2730A." The Board encourages the use of these items and is pleased with said increased PMP usage.

Potential Future Idaho Legislation

- ◆ 13 states require mandatory registration for PMP online use.
- ◆ 16 states require some sort of mandatory PMP access prior to prescribing CS to a particular patient.

New Operating System

The Board expects its new PMP online operating system to be in place sometime soon after the printing of this *Newsletter*. The new system will have much greater functionality for the Board, pharmacists, and practitioners. Operations manuals are available on the Board's Web site and will be mailed to all prescribers and pharmacists. The system is provided to the Board by the National Association of Boards of Pharmacy® (NABP®) and will be able to interstate data share with other states who share this same functionality through NABP PMP InterConnect®. Currently 21 states interstate data share through NABP InterConnect, with bordering states Nevada, Utah, Montana, and Wyoming expected to share data with Idaho authorized users in the near future. The new system is also capable of receiving daily dispensing data, and Board rule authorizes the Board to collect data "weekly, or more often." Please be advised that the Board may require daily CS dispensing data submission in the near future.

Data Integrity

The Board's staff spends a great deal of time "scrubbing" data submitted to the PMP by dispensers, as the data often arrives with errors. The new system will reject certain data that does not conform to nationally established standards. Such data will be required to be

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

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 an 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology¹ and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006² study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also

revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.³ Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.asp?link=sa.

¹Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." *Joint Comm J Qual Pt Safety*. 2007;33(5):293-301.

²Ukens C. "New study sheds light on medication errors." *Drug Topics*. 2002;146(21):33.

³Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." *J Amer Pharm Assoc*. 2006; 46(2):154-160.

⁴American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at: www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR*, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised

to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/vawd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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corrected by the dispenser and resubmitted. In addition to these technical issues, the Board's staff has identified numerous CS prescription drug orders that have been dispensed in conjunction with incorrect prescriber Drug Enforcement Administration (DEA) registration numbers. Not only are these dispensings a violation of labeling rules and Idaho State Board of Pharmacy Rule 500 for "failing to follow the instructions of a prescriber," but these dispensings create incorrect PMP data, which is used to create unsolicited reports, which are then distributed in error. Reasons for such dispensing errors include two prescribers with the same last name, choosing a prescriber that is prescribing from the same office as the true prescriber, and choosing a prescriber's DEA number that has expired, as opposed to the prescriber's new DEA number. Such violations are subject to discipline, from warning letters up to and including license revocation. In these cases, the Board believes that the pharmacy should be disciplined for submitting incorrect PMP data, in addition to the filling pharmacist. Please submit accurate PMP data.

Lapsed Licenses

Idaho Administrative Code, 27.01.01 Rule 017.04 states, ". . . failure to submit a renewal application prior to the expiration date will cause the license or registration to lapse and will result in the assessment of a late fee and possible disciplinary action (if you work). A lapsed license or registration is invalid until renewal is approved by the Board and if not renewed within thirty days after its expiration will require reinstatement." **Section 54-1718(2), Idaho Code states,** "The Board of Pharmacy shall require all applicants for . . . reinstatement of licenses or registrations to submit to a fingerprint-based criminal history check. . ." Fingerprint results often take two to six weeks to be processed by the Federal Bureau of Investigation and Idaho State Police. Thus, if you fail to renew for more than 30 days, a \$75 late fee is assessed, the cost of fingerprinting is currently \$41.50, you are restricted from working while your fingerprints clear, and you may be subject to disciplinary action.

Future Board Meetings

The following dates and locations are tentative. Please check the Board's Web site for potential updates.

- ♦ January 21, 2014, in Boise, ID. Location to be determined.
- ♦ March 13, 2014, at Idaho State University (ISU), Pocatello, ID.
- ♦ May 29, 2014, at the Coeur d'Alene Resort, Coeur d'Alene, ID, as part of the Northwest Pharmacy Convention.

ISU Announces Spring Continuing Pharmacy Education Schedule

The following dates and locations are subject to change and will include law jurisprudence.

- ♦ March 12, 2014: ISU, Meridian, ID
- ♦ March 16, 2014: ISU, Pocatello
- ♦ April 13, 2014: North Idaho College, Coeur d'Alene

Recent Board Discipline

B.C., RPh: Due to diversion, license and CS registration restricted, requiring compliance with the Pharmacy Recovery Network (PRN) for five years.

S.J., DDS: Due to diversion, CS registration restricted as to not order, store, administer, or dispense CS for two years.

K.B., NP: Due to diversion, CS registration restricted as to not order, store, administer, or dispense CS and as to not issue verbal orders for CS.

L.V., PA: CS registration revoked for diversion.

M.R., MD: CS registration restricted pursuant to Board of Medicine order.

D.P., RPh: Fined \$500 and license restricted as to not be pharmacist-in-charge for two years for intentional misrepresentation on an application.

S.G., Pharmacy Technician: Fined \$1,000 for intentional misrepresentation on applications.

E.R., Pharmacy Technician: Due to unprofessional conduct and moral turpitude, registration restricted, requiring PRN compliance for five years.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book*, for future reference.

Know a Pharmacist in trouble with drugs/alcohol or mental health problems?
Please contact the Pharmacist Recovery Network for help.
www.SouthworthAssociates.net 800.386.1695
24 HOUR CONFIDENTIAL Toll free Crisis Line
866.460.9014