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Prescription Drug Monitoring Program

By Nancy Bishop, RPh, Assistant State Pharmacy Director, Alabama Department of Public Health

The Prescription Drug Monitoring Program (PDMP) became operational in 2006, and has collected data from almost 1 billion filled prescriptions, including new and refilled prescriptions. The law requires all pharmacies that hold an Alabama retail license with the Alabama State Board of Pharmacy to report any dispensed controlled substance (CS) to the database within seven days of dispensing. If no CS are dispensed, a "zero" report must be submitted every seven days. Zero reporting can be done via an online account. A list of pharmacies not reporting or under-reporting is given to the Board every six months.

Some pharmacy software vendors offer automatic uploading to the PDMP at no charge or for a small fee.

It is important that a change in Drug Enforcement Administration (DEA) number is reported to the Board, to the PDMP, and to the pharmacy's dispensing software vendor. The PDMP database identifies the pharmacy by the DEA number. Any questions can be directed to the PDMP help-desk at 1-800/225-6998, option 8, or to the PDMP staff at 1-877/703-9869.

Identification Required to Purchase Pseudoephedrine in Alabama

Code of Alabama 1975, Title 20, Chapter 2, Alabama Uniform Controlled Substances Act 1407, §20-2-190. **Penalties; sale of ephedrine, etc.; Alabama Drug Abuse Task Force,** reads in part:

(5)a. Each pharmacy selling an over-the-counter product in compliance with paragraph b. of this subdivision shall require the purchaser of the product or products:

- ♦ to be at least 18 years of age,
- ♦ to provide
  - ◊ a valid, unsuspended driver's license or nondriver identification card issued by this state,
  - ◊ a valid, unsuspended driver's license or nondriver identification card issued by another state,
  - ◊ a United States Uniformed Services Privilege and Identification Card, or
  - ◊ a United States or foreign passport, and
- ♦ to sign a record of each transaction.

The customer hotline to inquire about rejections from purchasing is 1-888/520-6384. The customer will be asked to provide information from the rejection notice, which should be given to him or her by the pharmacy.

Please refer to §20-2-190 to confirm this information or to obtain more information about the purchase of pseudoephedrine.

This program is administered by the Alabama Criminal Justice Information Center. For more information send an e-mail to Avery Morris at Avery.Morris@alacop.gov.

Continued Use of a CS for the Purpose of Weight Reduction or Treatment of Obesity

Alabama Board of Medical Examiners Rule 540-X-17-.05:

(1) A physician should not prescribe, order or dispense a controlled substance for the purpose of weight reduction or treatment of obesity in an amount greater than a thirty-five (35) day supply.

(2) Within the first thirty-five (35) days following initiation of a controlled substance for the purpose of weight reduction or treatment of obesity, the patient should be seen by the prescribing physician, a physician assistant supervised by the prescribing physician, or a certified registered nurse practitioner collaborating with the prescribing physician, and a recording should be made of weight, blood pressure, pulse, and any other tests which may be necessary for monitoring potential adverse effects of drug therapy.

(3) Continuation of the prescribing, ordering, dispensing or administering of a controlled substance to a patient for the purpose of weight reduction or treatment of obesity should occur only if the patient has continued progress toward achieving or maintaining medically established goals and has no significant adverse effects from the medication.

(4) A patient continued on a controlled substance for the purpose of weight reduction or treatment of obesity should undergo an in-person re-evaluation at least once every thirty-five (35) days. Once medically established goals have been met for an individual patient, it is strongly recommended that reduced dosing and drug holidays be implemented for those patients who need maintenance medication.

(5) If the re-evaluation is delegated to a physician assistant or certified registered nurse practitioner, then the prescribing physician should personally review the resulting medical records prior to the continuance of the patient on a controlled substance for the purpose of weight reduction or treatment of obesity.

(6) For the prescribing of only the drug, Qsymia(TM), the following applies:

(a) Refills of Qsymia(TM) are allowed after an initial Qsymia(TM) prescription and one follow up visit for an in-person re-evaluation.

(b) Continued prescribing/refills of Qsymia(TM) must be in accordance with the Risk Evaluation and Mitigation Strategy (REMS) required by the Federal Food and Drug Administration (FDA) for Qsymia(TM).

(c) Refills allowed pursuant to this rule are specific for the brand name drug Qsymia(TM), and refills are not allowed

Continued on page 4

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

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 technology[1] 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 2006[2] 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.*

[1]*Cochran 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.*

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

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

[3]*American 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.*

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."

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Continued from page 1

for generic substitutes or for individual prescriptions of phentermine or for individual prescriptions of topiramate.

Technician Renewals for 2014/2015

To start the renewal process, visit the *www.albop.com* homepage and click on "Online Renewals" in the list on the left side. It will ask for your license number (including the "T" at the start) and the last four digits of your Social Security number.

This is the Board's first renewal period to register all technicians online and it will not accept any paper applications except in cases of a recent disciplinary action. All renewals must be completed by December 31, 2013, at midnight. After that time, there will be a $30 non-disciplinary penalty for late renewals.

There are three things you need to know before you begin:

1. You have to **scroll down** to see the application page.
2. When you enter a phone number, key in only the 10 numbers. Do not enter dashes or parentheses.
3. If you change your employer, you will need the permit number of the pharmacy.

Online credit card payment is the **only** option. You will need a **Visa, MasterCard, American Express, or Discover Card** at the end of the application. **Do not mail in checks.**

When the file update is complete and your payment is accepted, the Board will mail your new registration to you. The Board will mail it to the address shown in your file.

The Board is not collecting proof of your continuing education (CE) hours at this time. However, it will audit CE after the first of the year using your National Association of Boards of Pharmacy® e-Profile ID.

680-X-2-.36 Continuing Education for Pharmacists (in Part).

(1) Pharmacists shall complete fifteen (15) hours of continuing education every year as a condition of licensure renewal. By submitting the biennial renewal, a pharmacist is representing their compliance with this requirement by the end of the relevant calendar year.

(2) In order to receive credit for continuing education, the continuing education shall be previously approved by the Board. Any requests for approval of continuing education shall be submitted to the Board no less than thirty (30) calendar days prior to offering of the continuing education. A condition of approval shall be that the continuing education is pertinent to the practice of pharmacy. However, this requirement shall not apply to [Accreditation Council for Pharmacy Education] ACPE approved continuing education courses for which a program number is available.

(3) Continuing Education may be completed by either attendance or by distance based program, video or by publications; however, a pharmacist must complete at least three (3) hours of live continuing education through attendance at a course(s).

(8) A pharmacist may carry over and receive credit for twelve (12) hours of continuing education in the succeeding calendar year; however, a pharmacist must obtain in each calendar year no less than three (3) hours live by attendance. For purposes of this rule, attendance shall mean participation in any course where real-time interaction with the presenter is possible.

680-X-2-.37 Continuing Education for Pharmacy Technicians (in Part).

(1) Pharmacy Technicians shall complete three (3) hours of continuing education every year as a condition of registration renewal. By submitting the biennial renewal, a pharmacy technician is representing their compliance with this requirement by the end of the relevant calendar year.

(2) In order to receive credit for continuing education, the continuing education shall be previously approved by the Board. Any requests for approval of continuing education shall be submitted to the Board no less than thirty (30) calendar days prior to offering of the continuing education. A condition of approval shall be that the continuing education is pertinent to the practice of pharmacy. However, this requirement shall not apply to ACPE approved continuing education courses for which a program number is available.

(3) Continuing Education may be completed by either attendance or by distance based program, video or by publications; however, a pharmacy technician must complete at least one (1) hour of live continuing education through attendance at a course(s).

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program helpline at 205/981-2273 or 251/866-5585. The Board Wellness Program e-mail address is bopwellness@gmail.com. All communications are confidential.

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