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Alabama State Board of Pharmacy News

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Alabama State Board of Pharmacy Wellness Program; Mentor Program

There are many ways a pharmacist or pharmacy technician who has become impaired gets to treatment. His or her workplace may report him or her, his or her family may seek help for him or her, or he or she may seek help for him or herself. While in treatment, he or she is in a safe, almost cocoon-like environment. This presents a major obstacle in returning to his or her family and workplace after his or her treatment is finished. The first several months are very crucial to the long-term successful recovery of the individual. This is the time for a pairing of the individual with a concerned pharmacist or technician so that a caring relationship can be established as quickly as possible.

Having a peer in a position to listen and advise has been the mainstay and a singularly essential part of the professional's early recovery. The mentor is usually someone who has been through the same type of process that the impaired person has, but is not limited to that identity. Any pharmacist or technician who is willing to help a recovering individual over an extended period of time is qualified. He or she must be a good listener and be able to give advice when necessary. He or she must be willing to report, if necessary, any concerns he or she has to the program manager of the Alabama State Board of Pharmacy Wellness Program. This mentoring program has been very successful in helping recovering health professionals across the country.

Being a mentor is not for everyone, but if you are interested in becoming a committee member and a mentor, the Board wants you to know it needs your help. The Board and your state and/or local pharmacy associations have a vested interest in returning professionals to optimum health and in assuring that they can practice with reasonable skill and safety. The mentor provides a necessary and important link between the professional and the Board Wellness Committee.

Send an e-mail to Dr Michael Garver (bopwellness@gmail .com) if you are interested. He can talk with you and see if you can help him and someone in your area. **"Peers helping peers."** It is the way it works!

Supervising Pharmacists

At the February 20, 2013 Board business meeting, the Board members discussed two of Tuesday's administrative hearings in which there were two technicians that had stolen in excess of 22,000 pills out of the pharmacy. It was agreed that the Board's attorney will begin to draw up a statement of charges and notice of hearing, and it will be served on the supervising pharmacist and possibly the permit holder in order to charge them with being responsible for their pharmacy and employee(s).

At every interview for licensure candidates, the Board members emphasize to the candidates to make sure when a controlled substance (CS) order comes into the pharmacy/facility that the pharmacist verify that he or she has received what he or she ordered, the pharmacist sign the invoice, and the pharmacist make sure everything is as it should be. Obviously this is not being done because the Board continues to get cases where huge quantities of drugs are being stolen through the check-in process.

In the past, the Board inspectors have dealt with the district managers and/or supervisors, but the supervising pharmacist is ultimately the one responsible for the record keeping. The supervising pharmacist has never been addressed in the issue and that is inherently wrong in the whole process. It is not necessarily that if somebody had a really good scheme of stealing drugs, the supervising pharmacist is going to be punished, but the supervising pharmacist needs to make sure he or she is paying attention to his or her responsibilities for record keeping.

Clarification of Schedule II Prescriptions

> The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

Board Policy 20100825; Adopted August 25, 2010.

Manner of Issuance of Prescriptions

> All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

21 CFR §1306.05(a).

Schedule II CS Rules and Regulations

Schedule II prescriptions for a resident of a long-term care facility may be transmitted by the practitioner or the practitioner's agent via facsimile. The facsimile serves as the original written prescription.

21 CFR §1306.11 (f); Code of AL §20-2-58(c); 680-X-3-.10(1) (b).

Schedule II prescriptions for patients under hospice care may be transmitted by the practitioner or the practitioner's agent via facsimile. The facsimile will act as the original written prescription.

21 CFR §1306.11(g); 680-X-3-.10(1) (b).

FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

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.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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'Pre-Populated' Refill Requests

At the February 2013 business meeting of the Board and after further consideration, it is the opinion of the current members of the Board that there is no statute or rule that prohibits "pre-populated" refill requests for non-CS. Therefore, the Board's opinion is there is nothing that prohibits a pharmacy from submitting a refill request, via fax, that is pre-populated with the previous prescription information for non-CS.

National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank

The National Practitioner Data Bank (NPDB) and the Healthcare Integrity and Protection Data Bank (HIPDB) are flagging systems run by the federal government and are jointly referred to as the Data Bank.

The information in the NPDB assists state licensing boards, hospitals, and other health care entities in conducting extensive, independent investigations of the qualifications of health care practitioners they seek to license, hire, or grant medical staff membership or clinical privileges. The information in the HIPDB identifies health care practitioners, providers, and suppliers involved in acts of health care fraud and abuse.

Section 1921 of the Social Security Act expanded the information that the NPDB collects and discloses on pharmacists and other practitioners. It enhances NPDB's ability to serve as a valuable pre-employment and pre-licensing resource for health care entities by collecting negative actions taken against all licensed health care practitioners, including pharmacists.

Which pharmacists are reportable to the Data Bank? Reportable pharmacy professionals are licensed or certified by their state and generally distinguished by their practice setting. They include but are not limited to community pharmacists, clinical and hospital pharmacists, government and military pharmacists, and nuclear and research pharmacists. Pharmacy technicians, pharmacy interns, and pharmacy assistants who are regulated by their state are also reportable to the Data Bank.

What is reportable? Medical malpractice payments; state licensure actions; other negative actions or findings by state licensing authorities; Medicare/Medicaid exclusions; Drug Enforcement Administration actions; negative actions or findings by peer review organizations and private accreditation organizations; health care-related criminal convictions; and health care-related civil judgements.

You can visit *www.npdb-hipdb.hrsa.gov,* and under "Practitioners" click on "Start a Self-Query" to run a report. There is a charge for this service.

680-X-2-.31 Regulation of Daily Operating Hours

Any person who receives a community pharmacy permit pursuant to §34-23-30, and commences to operate such an establishment shall, for the benefit of the public health and welfare, keep the prescription department of the establishment open for a minimum of twenty (20) hours per week. A pharmacy may apply to the Board for a waiver or exception under special circumstances. A representative from the pharmacy may be required to appear before the Board in order for this waiver or exception to be considered. A sign in block letters not less than one inch in height shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. Such sign shall state the hours the prescription department is open each day.

Author: Kenny Sanders, R.Ph., President

Statutory Authority: Code of Alabama 1975, §34-23-92

History: Adopted 17 December 2004; Effective 18 January 2005; Amended: 20 March 2013; Effective 29 April 2013.

Reminder

Please notify the Board, in writing, of any change of address or employment.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Alabama State Board of Pharmacy Wellness Program help-line 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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