



Alabama State Board of Pharmacy

1 Perimeter Park South, Suite 425 South
Birmingham, AL 35243
Tel: 205/967-0130 Fax: 205/970-6846

Published to promote voluntary compliance of pharmacy and drug law.

New Alabama State Board of Pharmacy Executive Secretary

The Alabama State Board of Pharmacy recently hired Louise Foster Jones as the executive secretary. Louise was most recently pharmacy services director for the Alabama Medicaid Agency. She has been associated with state pharmacy programs since 1999 and was instrumental in developing and implementing the Preferred Drug Program as well as serving as a lead negotiator for Medicaid's Drug Discount Program. Her leadership and organizational development has been recognized statewide, as she has facilitated administrative savings while cultivating strategic partnerships to address policy issues. Louise is married to Doug Jones and they have two children, Rachael (13) and Britton (10).

Article 10 Controlled Substances Prescription Database

§20-2-210 Legislative Findings

The Alabama Legislature hereby finds that the diversion, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama. The Legislature further finds that establishment of a controlled substances prescription database to monitor the prescribing and dispensing of controlled substances will materially assist state regulators and practitioners authorized to prescribe and dispense controlled substances in the prevention of diversion, abuse and misuse of controlled substances prescription medication through the provision of education and information, early intervention, and prevention of diversion, and investigation and enforcement of existing laws governing the use of controlled substances.

§20-2-211. Definitions

Reads in part . . .

- (3) DEPARTMENT. The Alabama Department of Public Health.
- (5) PHARMACY. A retail establishment licensed by the Alabama State Board of Pharmacy.
- (6) PRACTITIONER or AUTHORIZED PRACTITIONER. A medical, dental, podiatric, optometric, or veterinary medical practitioner licensed to practice in this state and authorized to prescribe, dispense, or furnish controlled substances under the Alabama Uniform Controlled Substances Act.
- (7) STATE HEALTH OFFICER. The executive officer of the Alabama Department of Public Health.

§20-2-212. Controlled Substances Prescription Database Program; Powers and Duties of Department; Trust Fund

Reads in part . . .

- (3) To enter into one or more contracts with the State Board of Pharmacy for the performance of designated operational functions for the controlled substances prescription database, including, but not limited to, the receipt, collection, input, and transmission of controlled substances prescription data and such other operational functions as the department may elect.
- (4) The committee shall consist of one representative designated by each of the following organizations:
 - a. The Medical Association of the State of Alabama.
 - b. The Alabama Dental Association.

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretinoin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.



Metronidazole and Metformin: Names Too Close for Comfort

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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®



(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association (JAMA)* published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at <http://www.connectlive.com/events/genericdrugs/>.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

- c. The Alabama Pharmacy Association.
- d. The Alabama Veterinary Medicine Association.
- e. The State Health Office, or his or her designee.
- f. The Alabama Hospital Association.
- g. The Executive Director of the Alabama State Board of Pharmacy.
- h. The Executive Director of the Board of Medical Examiners.
- i. The Alabama Optometric Association.
- j. One representative from each of the certifying boards established under the Alabama Controlled Substance Act.
- k. The Alabama Independent Drug Store Association.
- l. The Alabama Podiatry Association.

§20-2-213. Reporting Requirement

Reads in part . . .

- (a) . . . pertaining to all Class II, Class III, Class IV, and Class V controlled substances. . . .
- (b) The following entities or practitioners are subject to the reporting requirements of subsection (a):
 - (1) Licensed pharmacies, not including pharmacies of general and specialized hospitals, nursing homes, and any other healthcare facilities which provide inpatient care, so long as the controlled substance is administered and used by a patient on the premises of the facility.
 - (2) Mail order pharmacies or pharmacy benefit programs filling prescriptions for or dispensing controlled substances to residents of this state.
 - (3) Licensed physicians, dentists, podiatrists, optometrists, or veterinarians who dispense Class II, Class III, Class IV, and Class V controlled substances directly to patients, or in the case of veterinarians, for administration to animals, but excluding sample medications. For the purposes of this article, sample medications are defined as those drugs labeled as sample, not for resale under the laws and regulations of the Federal Food and Drug Administration. Controlled substances administered to patients by injection, topical application, suppository administration, or oral administration during the course of treatment are excluded from the reporting requirement.
- (c) The manner of reporting controlled substance prescription information shall be in such manner

and format as designated in regulations of the department.

- (e) In addition to any other applicable law or regulation, the failure of a licensed pharmacy or pharmacist or a licensed practitioner to comply with the requirements of this section shall constitute grounds for disciplinary action against the license of the pharmacy, pharmacist, or licensed practitioner by the appropriate licensing board or commission, and the imposition of such penalties as the licensing board or commission may prescribe. The department shall report to the appropriate licensing board, agency, or commission the failure of a licensed pharmacist or a licensed practitioner to comply with the reporting requirements of this section. Any report made by the department to a licensing board, agency, or commission shall be deemed a formal complaint and shall be investigated and appropriate action taken thereon.

§20-2-214. Limited Access to Database Permitted for Certain Persons or Entities

Reads in part . . .

The following persons or entities shall be permitted access to the information in the controlled substances database, subject to the limitations indicated below:

- (1) Authorized representatives of the certifying boards, provided, however, that access shall be limited to inquires concerning the licensees of the certifying board.
- (2) A licensed practitioner approved by the department who has authority to prescribe, dispense, or administer controlled substances, provided, however, that such access shall be limited to information concerning a current or prospective patient of the practitioner. Practitioners shall have no requirement or obligation to access or check the information in the controlled substance database prior to prescribing, dispensing, or administering medications or as part of their professional practice.
- (3) A licensed pharmacist approved by the department, provided, however, that such access is limited to information related to the patient or prescribing practitioner designated on a controlled substance prescription that a pharmacist has been asked to fill. Pharmacist[s] shall have no requirement or obligation to access or check the information in the controlled substances database prior to dispensing or administering medications or as part of their professional practices.
- (4) State and local law enforcement authorities. . . .
- (5) Employees of the department and consultants engaged by the department for operational and review purposes.

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§20-2-218. Reimbursement of Certain Cost Incurred in Compliance with Article

The department is authorized to grant funds to participating pharmacies for the purpose of reimbursing reasonable cost for dedicated equipment and software incurred by pharmacies in complying with the reporting requirement of this article. Such grants shall be funded by gifts, grants, donations, or other funds appropriated for the operation of the controlled substances prescription database. The department is authorized to determine standards and specifications of any equipment and software purchased by the authority of this section.

§20-2-19. Financing of Development, Operation, etc, of Database

The controlled substances prescription database shall become operational within 12 months after the State Health Officer certifies to the certifying boards in writing that the department has sufficient funds to finance the development, implementation, and operation of the database.

§20-2-220. Liability for Reporting

Any person or entity required to report information concerning controlled substance prescriptions to the department, or to its designated agent, pursuant to the requirements of this article shall not be liable to any person for any claim of damages as a result of the act of reporting the information and no lawsuit may be predicated thereon. (Act 2004-443, 2nd Sp. Sess., p.781, §11. Effective August 1, 2004.)

Administrative Hearings – December 2004 Through February 2005

Technicians: Tiffany Coral Smith #T10609, William Anthony Lowe #T02197, James Nathan Bullard #T09252, Rickey Darnell Smith #T01705, Jennifer Dawn Thren #T01982. Action – Registrations revoked, administrative and hearing cost \$850.

Technicians: Corey Dewayne Ware #T16005, Amanda D. Wilkins #T14855, Jenny Brianna Burson #T09703, Ara Marie Burton #T06450, Amanda Joelen Doedtman #T14641, Heather Ricketts Garrison #T13012, Veronica Synett Gibson #T05991, Jennifer Power Harris #T05585, Tamika Malone #T13925, Angela Martin Bullard #T16364, Melissa Dianne Deese #T10656, Jennifer Adams Johnson #T08464, James Rickey King #T12082, Tova Blackwood Lindsey #T03974, Latricia Horace Thomas #T02907 – Registrations revoked.

Technician Applicants: Rosetta S. Weary, Sherry Lynn Hill, Champalle T. Jordan – Registrations denied.

Intern: Charles I. Storey, IV #7545 – Failure to appear. Obtained a pharmacy intern permit by fraudulent means. Action – Registration revoked, hearing cost \$250.

Pharmacist: James Henry Hurley, Jr #6457 – Failed to ensure compliance with the Pharmacy Practice Act,

Code of Alabama (1975), the Alabama Uniform Controlled Substance Act, Code of Alabama (1975), and the Rules of the Alabama State Board of Pharmacy. Action – License revoked, administrative fine \$11,000.

Pharmacy: C & S Pharmacy #111516 – Permit failed compliance with the Pharmacy Practice Act, Code of Alabama (1975), and the Alabama Uniform Controlled Substance Act, Code of Alabama (1975). Action – Permit revoked, administrative fine \$11,000.

The Alabama State Board of Pharmacy Web Site Has a New Look

Stay informed of current law, rule, and regulation changes. Visit www.albop.com for current Board updates and compliance tips. Applications and forms are now online for easy access to information needed from the Alabama State Board of Pharmacy. Refer to the continuing education (CE) menu www.albop.com



to register for the September 11, 2005 Huntsville location and the October 2, 2005 Montgomery location for three (3) free live hours of **law CE** given by the State Board of Pharmacy. Registration is available **online**.

680-X-3.08 Annual Inventory of Controlled Substances

Every pharmacy shall take an initial inventory of all controlled substances on hand on January 15 or the alternative fixed date approved by the Board.

Internet Pharmacy

The actual physical location of the pharmacy that purchases, stores, and dispenses controlled substances pursuant to prescription orders processed by the Internet site must be registered with Drug Enforcement Administration (DEA). The Web site itself would not require a separate registration unless it is the same physical location, since the Web site does not store or dispense controlled substances. For example, some Internet pharmacies maintain a central pharmacy warehouse site and offices where prescriptions are verified and substances shipped; this location must be registered with DEA as a retail pharmacy. Other Internet sites allow patients to pick up their prescriptions for controlled substances from a local pharmacy; these pharmacies must be registered with DEA. In the case, the Internet “pharmacy” has no obligations under DEA regulations because the responsibility for assuring compliance with DEA regulations

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rests with the actual pharmacy where controlled substances are dispensed.

The pharmacy must have a license from the state in which the controlled substances are stored and dispensed and, in most instances, from any state in which you plan to conduct business with customers. Pharmacists should also be aware that many states require licenses for the Web site itself since these sites often provide services like patient counseling. Being an Internet pharmacy does not change the pharmacy's responsibilities under DEA regulations. The pharmacy is still authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner who issued the prescription in the usual course of his or her professional practice.

A pharmacist may dispense a Schedule II controlled substance only after the patient or prescriber provides an original signed prescription prior to dispensing. The label on the prescription filled must indicate the location that dispensed the controlled substance.

Some Internet pharmacies have doctors who prescribe substances based on an online questionnaire. Federal law requires that, "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his [or her] professional practice" (21 CFR 1306.04(a)). Every state separately imposes a similar acting requirement under its laws. Under federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.

For the purpose of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication

that the legitimate doctor/patient relationship has been established:

- ◆ A patient has a medical complaint;
- ◆ A medical history has been taken;
- ◆ A physical examination has been performed; and
- ◆ Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

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Joyce C. Altzman, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor
Reneeta C. "Rene" Renganathan - Editorial Manager

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National Association of Boards of Pharmacy Foundation, Inc
1600 Fehamville Drive
Mount Prospect, IL 60056
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