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Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Registration and/or Licensure – Do Not Take It For Granted

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As a health care profession, pharmacy is regulated legislatively both on the federal and state level. Regulation is deemed necessary in order to protect the public health, safety, and welfare and to ensure that the public has confidence in the profession and likewise that the profession merits confidence. In all health care regulation, a regulatory body is also created to ensure compliance with the obligations of those who are regulated.

As a registered technician, licensed pharmacist, or a permitted pharmacy, there are many benefits that are both obvious and numerous. With these benefits are also obligations and consequences for not fulfilling those obligations.

One of the obligations is to ensure that any required registration, license, or permit is renewed **in a timely manner**. As to pharmacists and pharmacies, that includes either a license or permit in order to practice or operate and a registration in order to dispense controlled substances (CS). A license to practice or permit to operate is distinct and separate from a registration to dispense CS, but all have in common the necessity for timely renewal. For a technician, renewal means registering with the Alabama State Board of Pharmacy to work in a permitted pharmacy under the supervision of a licensed pharmacist.

Not renewing a necessary registration, license, or permit in a timely manner in and of itself is not a violation of either the Alabama Pharmacy Practice Act or the Alabama Uniform Controlled Substances Act except to the extent there is a penalty for late renewal. On the other hand, performing technician duties, practicing pharmacy, operating a pharmacy or dispensing CS without renewing in a timely manner is a violation, this determination having been made by the legislature and not by the Board. In addition, there are

no exceptions nor is a violation conditional upon how long one has performed technician duties, practiced, or owned a pharmacy or the number of days one was late.

The Board takes no pleasure in having to impose discipline when the circumstances justifying discipline could have been so easily avoided. With that in mind, the Board vehemently urges you to do the following:

1. Complete the renewal process early. Do not wait until the last minute.
2. It is the responsibility of the holder of any required registration, license, or permit to ensure that there is timely renewal. Do not rely on others.
3. You will receive evidence of renewal of any required registration, license or permit. For those whose responsibility includes ensuring that a technician, pharmacist, or pharmacy is properly licensed or permitted, insist on seeing the documentary evidence of renewal.
4. Check the Board's Web site, www.albop.com, for updates or information concerning any new requirements dealing with a renewal. Carefully read the *Newsletter* or other communications received from the Board not only as to renewals but all other pertinent topics.
5. If you have any doubts or questions, remember that asking for forgiveness rather than permission is not a valid assumption when dealing with your license. The Board has a very capable compliance person, a pharmacist, who is available to answer any questions.

Another condition of renewal is the documentation and completion of a minimum amount of continuing education (CE) hours. When renewing your registration to perform technician duties or your license to practice pharmacy, you are promising the Board that you have complied. The Board

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

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

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

NIH Develops Community Drug Alert Bulletin

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

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

Implementation of the Anabolic Steroid Control Act of 2004

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

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

The changes to the definition include the following:

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

FDA Unveils New Package Insert Format

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

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

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

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

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is taking your word that you have done so. Please maintain your records of compliance with CE so in the event you are the subject of a random audit, you can submit evidence of your compliance. Your failure to either complete the required CE or to document such completion will subject you to disciplinary action.

You worked hard to initially obtain your pharmacist license – continue to do so. Treat your registration and/or license and your ability to practice without adverse consequences, with the same commitment and attitude exhibited in obtaining your education and initial registration or licensure. Your failure to expend the minimal effort it takes to renew in a timely manner any required registration, license, or permit is no one's fault but your own. Ensuring renewal is an act of personal responsibility. Please make the Board's job easier and your life easier by timely compliance with all requirements. If you choose not to do so or wait until the last minute, do not blame the adverse consequences that may follow on anyone other than yourself.

Legislation: 680-X-2-.32 Prescriptions by Electronic Means

- (1) The following requirements shall apply to any prescription, as that term is defined in Code of Alabama (1975) §34-23-33 (1)(21), for non-controlled legend drugs transmitted by electronic means.
 - (a) The prescription must include the patient's name and address, the drug prescribed, strength per dosage unit, directions for use, and the name of the prescriber or authorized agent. To the extent not include[d] above, the prescription must comply with any applicable provisions of the Alabama Pharmacy Practice Act or Board Rule now existing or later amended or changed.
 - (b) Prescriptions may be transmitted directly to the pharmacy or transmitted over an e-prescription network approved by the Board. All such transmissions must ensure appropriate security and authenticity to include the following:
 1. An electronic signature process enabling the pharmacy to ensure the identity of the prescriber;
 2. Date and time stamp;
 3. Transmitting system identifier;
 4. Prescriber internal sender identification; and
 5. Pharmacy internal receiver identification.
 - (c) Any pharmacy receiving a prescription shall comply with all requirements for record keeping and prescription information

mandated by the provisions of the Alabama Pharmacy Practice Act or Board Rule now existing or later amended or changed except that for the purpose of the substitution of drugs or brands of drugs as set forth in Code of Alabama (1975) §34-23-8, a prescription transmitted by electronic means shall not be considered a written prescription.

- (d) Prescriptions for CS, whether scheduled pursuant to state or federal law shall not be authorized until the Drug Enforcement [Administration] has adopted applicable regulations, at which time all prescriptions for [CS] must comply with the provisions of any such regulation or any later amendments or changes thereto.

Author: James S. Ward

Statutory Authority: Code of Alabama 1975, §34-23-1 (21) and §34-23-92(6)

History: New: Filed October 20, 2005; **Effective February 17, 2006.**

680-X-2.24 Precursor Drugs

- (1) LISTED PRECURSOR CHEMICALS:
 - (a) All substances listed as precursor chemicals in any regulation set forth in the Code of Federal Regulations shall be considered and designated as a precursor chemical with the exception of those precursor chemicals designated or deleted as such under federal law to which the Board objects, after notice, in the manner provided in Code of Alabama (1975), §20-2-181(c), all precursor chemicals listed in any federal regulation shall be considered and designated as precursor chemicals pursuant to the provisions of Code of Alabama (1975), §20-2-180, et seq.
- (2) LICENSE
 - (a) An annual license must be obtained from the Alabama State Board of Pharmacy by any individual, corporation, partnership, association or other entity who is a manufacturer, wholesaler, retailer or other person who sells, transfers, manufactures, purchases for resale or otherwise furnishes any listed precursor chemical as defined or designated by law or rule of the Alabama State Board of Pharmacy. The license shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall contain information as required by and con-

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form with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

- (b) An annual license fee in the amount of \$250 shall be paid by all licensees to the Alabama State Board of Pharmacy.

(3) PERMIT

- (a) A permit must be obtained from the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity having a legitimate need for using any listed precursor chemical as defined or designated by law or rule of the Alabama State Board of Pharmacy obtains such chemical(s). The permit shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

- (b) A permit fee in the amount of \$35 shall be paid to the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity obtains any listed precursor chemical.

Author: James S. Ward

Statutory Authority: Code of Alabama (1975), §34-23-92(6) and §20-2-181

History: Adopted: October 7, 1991; Effective January 1, 1992; Amended: Filed September 4, 1992; Effective October 9, 1992; Amended September 4, 1999; Effective November 1, 1999; Amended: Filed October 20, 2005; **Effective February 17, 2006.**

§20-2-58. Dispensing of Controlled Substances in Schedule II; Maintenance of Records and Inventories by Registered Pharmacies

- (g) In an emergency situation, a pharmacist may dispense a Schedule II [CS] for a resident of a long-term care facility, a patient receiving hospice services, or a patient receiving home health care services pursuant to an emergency oral prescription transmitted by the practitioner to the dispensing pharmacy. The quantity dispensed pursuant to an emergency oral prescription shall be limited to the amount adequate to treat the patient during the emergency period not to exceed 72 hours.

The practitioner, within seven days of the emergency oral prescription, shall provide the dispensing pharmacy with a written prescription for the quantity prescribed. (Acts 1971, No. 1407, p. 2378, §308; Act 1995, No. 95-732, p. 1565, §1; Act 98-617, p. 1358, §1, Effective 8-1-1998 Act 2006-183, **Effective March 7, 2006.**)

680-X-.33 Internet Pharmacies

A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should have known under the circumstances, that the order for such drug was issued on the basis of an [I]nternet-based questionnaire, an [I]nternet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

Author: James S. Ward, JD

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

New: History: Filed December 19, 2005; **Effective April 21, 2006.**

680-X-2-.34 Fees for Applicants for Pharmacist License and Biennial License Renewal

- (1) The fee for licensure examination shall be \$300.
- (2) The fee for initial registration for licensure shall be \$100.
- (3) The fee for biennial renewal of a pharmacist license will be \$100.
- (4) All fees required above shall not be refundable.
- (5) Penalties for late renewal of a pharmacist license shall be governed by the provisions of the Alabama Pharmacy Practice Act.

Author: Louise F. Jones, Executive Director

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

History: Filed January 20, 2006. **Effective April 21, 2006.**

680-X-2-.35 Fees for Initial Pharmacy Permits, Biennial Permit Renewal, and Transfer of Ownership

- (1) The application fee for a new pharmacy permit shall be \$200.
- (2) The fee for biennial renewal of a pharmacy permit shall be \$100.
- (3) The fee for transfer of ownership of a pharmacy permit shall be \$50.

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- (4) All fees required above shall not be refundable.
- (5) Penalties for late renewal of a pharmacy permit shall be governed by the provisions of the Alabama Pharmacy Practice Act.

Author: Louise F. Jones, Executive Director
 Statutory Authority: Code of Alabama 1975, §34-23-92.
 History: Filed January 20, 2006. **Effective April 21, 2006.**

680-X-3-.03 Time and Method of Payment; Refund

Registration fees shall be paid at the time the application furnished by the Alabama State Board of Pharmacy for registration is submitted for filing. Payment shall be made payable to the Alabama State Board of Pharmacy and shall be due October 1 of each even-numbered year and delinquent after the last day of December of each even-numbered year.

In the event the application is not accepted for filing or is denied, the payment shall be refunded to the applicant.

Author: Louise F. Jones, Executive Director
 Statutory Authority: Code of Alabama 1975, §34-23-50(b)
 History: Adopted: November 27, 1973; Effective: January 1, 1974. Filed June 1, 1982; Emergency rule filed December 22, 2005; effective December 22, 2005; Filed January 13, 2006. **Effective April 21, 2006.**

Board of Pharmacy Licensing Statistics As of February 2006

Open Pharmacy Report

Chain.....	618
Clinic	12
Community	707
Distributor of Chemicals	82
Hospital.....	164

Mail Order	101
Manufacturer/Wholesaler/Distributor	1,008
Non-Resident Pharmacy	425
Nuclear.....	14
Parenteral	4
Retail Medical Oxygen Supplier	385
Total	3,520

Pharmacist Status Report

Active.....	6,198
Deceased.....	154
Inactive (no current license)	1,289
Probation.....	95
Revoked	9
Suspended.....	47
Total	7,792

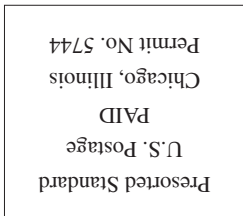
Alabama Technicians

Registered	approximately 10,000
Registered and Pharmacy Technician Certification Board	2,302

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