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Arkansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Season's Greetings from the Arkansas State Board of Pharmacy

2003.21 – Regulation Changes from the October Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulations at the October 2003 Board Meeting:

Regulation 02 – Pharmacists: The amendments require criminal background checks on all new pharmacist and pharmacy intern applicants after March 1, 2004. (Effective November 15, 2003)

Regulation 03 – Pharmacy Technicians: The amendments require criminal background checks on all new pharmacy technician applicants after March 1, 2004, and further define the duties of a pharmacy technician who engages in reconstitution, bulk compounding, and/or preparation of parenteral products and the training requirements for expanded roles of the pharmacy technician. (Effective November 15, 2003)

Regulation 04 – Pharmacy: The amendments specify the form that will be used for an application for a pharmacy permit and include buprenorphine in the list of drugs that a Methadone Clinic Specialty Pharmacy can dispense. A new section was added to Regulation 04 that defines and recognizes central fill pharmacies. (Effective November 15, 2003)

Regulation 07-02 – Compounding: The Board permanently approved the amendments mentioned in the previous *Newsletter* from the emergency regulation change in June 2003. Those amendments require sterility, pyrogen, and potency testing on certain high-risk sterile products and prohibit compounding for office stock for veterinarians except for compounds to be used in life-threatening situations. The Board approved additional amendments to this Regulation at the October Board Meeting that generally prohibit compounding of a drug product that is essentially a copy of a commercially available Food and Drug Administration-approved drug product and that define low-, medium-, and high-risk sterile products, consistent with current United States Pharmacopeia standards. (Effective October 26, 2003)

Regulation 08-02 – Wholesale Distributor of List I Chemicals: The amendments define how the Board may suspend or revoke a registration after notice and hearing and require an applicant for registration as a wholesale distributor of List I chemicals to hold a registration with Drug Enforcement Administration as a retail distributor of List I chemicals. (Effective November 15, 2003)

Regulation 11 – Criminal Background Checks: This new regulation defines and recognizes the process of criminal background checks for new pharmacist, pharmacy intern, and pharmacy technician applicants after March 1, 2004. The new regulation will establish the process that the Board will use to obtain the criminal history of the applicants and how the information will be used in the application process.

This is a brief summary of the changes to each Regulation. The complete regulation can be obtained from our Web site at www.state.ar.us/asbp in the "Pharmacy Law Book" section. Please contact the Board Office at 501/682-0190 if you have any questions about these changes.

2003.22 – Regulation Changes from the June 2003 Board Meeting

The Board of Pharmacy approved changes to the following regulations at the June 2003 Board Meeting:

Regulation 02-04-0002 – Defining Unprofessional or Dishonorable Conduct: The amendment changed item (r) to reflect the change in the Board of Pharmacy inspection form from a numerical score to a compliant/noncompliant system.

Regulation 07-04-0006 – Theft or Loss of Controlled Drugs: The amendments require a license holder to immediately notify by phone or fax Drug Enforcement Administration (DEA), the Arkansas Health Department Drug Control Division, and the Arkansas State Board of Pharmacy upon discovery of a theft or loss of controlled drugs and require a license holder to deliver a completed DEA Form 106 to each of the above named agencies within seven days of the occurrence or discovery of a theft or loss of controlled drugs. The DEA Form 106 may be amended at a later date if additional losses are identified during an ongoing investigation.

As stated above, this is a brief summary of the changes to each regulation. The complete regulation can be obtained from our Web site at www.state.ar.us/asbp in the "Pharmacy Law Book" section. Please contact the Board Office at 501/ 682-0190 if you have any questions about these changes.

2003.23 – Immunization Administration (Injectable and Inhalation)

This is a good time of the year for all pharmacists with the Authority to Administer to review the section of the law that allows for the practice of giving immunizations. The Authority to Administer is discussed in Board Regulation 09-00-0002 and ACA §17-92-101 (16) and ACA §17-92-101 (22) (B). Here are a few things to remember:

- The administration of medications shall not include the administration of medications to any person under the age of eighteen (18).
- The administration of medications shall be limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications.
- An Authority to Administer for immunizations and vaccinations may be a general protocol.

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- An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year.
- Only persons who have met all of the requirements set forth in the statute and Board Regulation 09-00-0002 (b) (4) may administer immunizations and vaccines, regardless of the route of administration (injectable or inhalation).

Please contact the Board office at 501/682-0190 if you have any questions about vaccinations, immunizations, or the Authority to Administer.

2003.24 – Correct Prescriber on Controlled Substance Prescriptions

It is very important that you put the correct prescriber on all prescriptions that you fill, especially controlled substance prescriptions. If you cannot read the signature, please call to verify who signed the prescription. There have been several instances in which investigators with the Arkansas Health Department, Drug Enforcement Administration, or the Board of Pharmacy have found the incorrect prescriber listed on printouts obtained from a pharmacy. This incorrect information can adversely affect the investigative process. Despite repeated notifications regarding this issue, the Board continues to deal with complaints.

2003.25 – Compounding Respiratory Products

We have received several questions in the Board Office about how the recent changes to the compounding regulation (see article 2003.21, page 1) will affect compounding of respiratory drugs. Please refer to §07-02-0001 (a) (3) for the definition of high-risk sterile products. If the products you are compounding are considered high-risk sterile products, they must be compounded in one of the environments listed in 07-02-0001 (j), and if the storage requirements exceed the time periods listed in 07-02-0001 (a) (3) (E), they must pass a sterility test. Please contact the Board Office at 501/682-0190 if you have any questions about compounding respiratory products.

Consistent with other compounded products, compounding an inhalation drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available Food and Drug Administration (FDA)-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the prescribing physician of a patient-specific medical need or if the drug product is not commercially available. The unavailability of such drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

2003.26 – Act 1653 of 2001 Requires Disclosure of Board Actions for Public Guidance

Ark. Code Ann. §25-19-108 (Act 1653 of 2001), a new section added to the Freedom of Information Act (FOIA), identifies certain information that must be made available for public guidance and provides that such materials created after July 1, 2003, shall be made accessible to the public via the Internet. Consequently, to comply with this law, the Arkansas State Board of Pharmacy has made changes in the manner in which Board actions pertaining to pharmacists, pharmacies, pharmacy technicians, and all other entities licensed or permitted by the Board are reported. The Findings of Fact, Conclusions of Law, and Order regarding all aforementioned proceedings will be published on the Arkansas State Board of Pharmacy Web site (www.state.ar.us/asbp). This information has been available and accessible through FOIA requests in the past, but not published on the Internet.

Arkansas Pharmacy Support Helpline – 870/636-0923

Special Notice About This Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter*'s contents. Please contact the Board Office (501/682-0190) if you have questions about any of the articles in this *Newsletter*.

The *Arkansas State Board of Pharmacy News* is published by the Arkansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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