Recent Regulation Changes

7-00-0006 – Non-equivalent Drug Product List

If a product is listed on the Arkansas Non-equivalent Drug Product List and the Food and Drug Administration (FDA) approves a competitive product as bioequivalent and publishes that product with an “A” (AA, AB, AN, AO, AP, and AT) rating in the FDA Approved Drug Products with Therapeutic Equivalence Evaluations (“The Orange Book”), Arkansas pharmacists, or any pharmacist dispensing drugs to patients in Arkansas, may substitute that product consistent with law until this list is revised. Conversely, if the drug product is “B” rated, is changed from an “A” rating to a “B” rating, or is not rated, the pharmacist may not substitute without the consent of the prescribing practitioner.

When a substitution is made, the pharmacist shall continue the patient on the same product unless that manufacturer’s product is not available. When a pharmacist substitutes a bioequivalent drug product for the drug prescribed, the prescribing practitioner and the patient shall be notified of the substitution by a pharmacist involved in the dispensing process.

A prescription written for any brand name drug listed can be only changed with prior consent of the prescribing practitioner.

Note: The effect of this amendment to Regulation 07-00-0006 is to delete warfarin sodium tablets; theophylline capsules, controlled release and tablets; quinidine gluconate oral; phenytoin sodium tablets and capsules; and leucovorin tablets. The only drug remaining on the Non-equivalent Drug Product List is levothyroxine tablets.

03-00-0007 – Pharmacist-to-Pharmacy Technician Ratio

A. Retail Pharmacy Setting

(1) Each pharmacist on duty in a pharmacy may utilize one pharmacy technician to assist the pharmacist. In addition, a pharmacy may utilize one additional pharmacy technician per shift.

(2) In addition to the technician(s) described in paragraph A (1), above, a pharmacist shall not also supervise more than one student intern. A graduate intern will not affect the ratio.

B. Hospital Setting

(1) Pharmacy technicians used in assisting the pharmacist in pharmaceutical services for inpatients of the hospital shall be permitted to perform under the direct supervision of a licensed pharmacist within the following conditions:

- The number of pharmacy technicians employed by the Pharmacy Department shall not exceed a ratio of one pharmacy technician to each pharmacist on staff plus one additional pharmacy technician per shift. The one-to-one ratio is governed by the number of employees and is not shift-dependent. If the pharmacist-in-charge desires to use more than a one-to-one plus one ratio on a certain shift, the hospital pharmacist in charge shall notify the Board of Pharmacy that the ratio on that shift exceeds one-to-one plus one and include a brief summary of the duties now performed by the pharmacist with emphasis on counseling, quality assurance, drug utilization evaluation, education, and MD/RN interactions, etc. Said request to exceed the standard ratio is subject to approval by the executive director of the Board of Pharmacy. The ratio shall not exceed two pharmacy technicians to one pharmacist on any one shift. This ratio shall not include pharmacy interns counted as either supportive personnel or pharmacists. Also excluded from the count of supportive personnel are those persons whose functions are not related to the preparation or distribution of medication. Such persons include clerks, secretaries, messengers, and delivery personnel. (August 23, 1996, Amended October 2000.)

Note: The effect of this amendment to Regulation 03-00-0007 is to increase the pharmacist-to-pharmacy technician ratio from 1:1 to 1:1 plus one additional technician per shift.

02-01-0003 – Definitions

E. Class A Pharmacy: A pharmacy which has a pharmacy permit with a pharmacist on duty at least 40 hours per week, and no unsatisfactory deficiency, and no more than three non-compliant deficiencies noted on its last Board inspection. (Amended October 2000.)

Note: The effect of this amendment to Regulation 02-01-0003 (Section E) is to change the definition of a Class A Pharmacy from a numerical score to a non-numerical score consistent with the current pharmacy inspection report.

07-00-0008 – Electronic Prescription Processing and Patient Confidentiality

There has been a number of changes to regulations affecting electronic transmission of prescriptions. These changes are made to permit the transmission of information in electronic form by

Continued on page 4
means such as e-mail, electronic devices to computer, computer to computer, in addition to fax transmission. These changes to the Laws and Regulations should be thoroughly reviewed by all pharmacists. Both parties must still ensure the confidentiality of these types of transmissions. According to the Drug Enforcement Administration, these types of prescriptions for controlled substances must be handled as oral prescriptions under their present interpretation. The providing of electronic equipment to a practitioner to achieve a competitive advantage is prohibited in this section. This regulation now specifically recognizes e-mail as an appropriate means of prescription transmittal.

**04-02-0010 – Regulating the Use of Electronic Data Processing in Lieu of Present Recordkeeping Systems in Pharmacies Holding Pharmacy Permits**

The changes in this section are made to allow the storage of required information in electronic form with specific requirements to be able to produce, within 48 hours, a hard copy if requested. These changes will allow the pharmacy to greatly reduce the amount of paper now required for this type of information. The pharmacy is still required to collect this information on a daily basis but can store it electronically. There is also the addition of requiring the use of a bound logbook for the signatures of all pharmacists filling prescriptions on a daily basis. This record must be kept for two years as are all other records, either electronic or hard copy. If you choose the electronic method of storing records you must be sure that your system backs up all information on a continuous or daily basis.

**04-05-0003 – Regulating the Use of Electronic Data Processing in Lieu of Present Recordkeeping Systems in Hospital Pharmacies Holding Hospital Pharmacy Permits**

The changes in this section are also made to allow the storage of required information in electronic form. These changes will greatly reduce the volume of paper records that have been required. These electronic records, along with the required bound log book, must be kept for a period of at least two years. The director of pharmacy should review this section to ensure compliance within his or her software system. These electronic records must also be able to be produced in hard copy within 48 hours if requested.

The complete regulations pertaining to electronic prescription and electronic data processing as they now exist are available online at our Web site at www.state.ar.us/asbp.