PROPOSED REGULATION ARTICLE III F DISPENSING LEGEND DRUGS

- F. Who dispenses legend drugs. Dentists who choose to dispense legend drugs directly to their patients are subject to the following definitions and requirements:
 - 1. A dispensing dentist is a dentist licensed under Ark. Code Ann. 17-82-301 et seq., who purchases legend drugs to treat dental and/or oral conditions to be dispensed to his or her patients for the patients' personal use and administration out5side the dentist's office.
 - 2. The dispensing dentist shall:
 - a. <u>Personally prepare and dispense legend drugs and all the preparation and dispensing of such drugs may not be delegated;</u>
 - b. Keep records of all receipts and distributions of legend drugs.

 The records shall be subject to inspection by proper enforcement authority and shall be readily accessible and maintained in a central registry;
 - c. Affix to the container a label showing:
 - i. The dentist's name, address and telephone number
 - ii. The date of the dispensing
 - iii. The serial number of the prescription
 - iv. The name of the patient
 - v. The trade name of the medication, if any, or the generic name and identity of the manufacturer of the dispensed medication
 - vi. The strength per unit doses of the medication
 - vii. The quantity of the medication
 - viii. Directions for use
 - ix. Any cautionary statements required by law
 - d. The dispensing dentist shall counsel the patient in person ("face to face") to improve therapeutic outcomes and prevent medication errors.
 - Except for dispensing samples without charge, oral rinses or topicals, and emergency or starter dosages for use up to seventy-two (72) hours, no dentist licensed under Ark. Code Ann. 17-82-301, et seq., shall dispense legend drugs without prior approval by the Arkansas State Board of Dental Examiners after application to the Board and upon the showing of need. A dentist shall dispense only to his own patients and only for conditions being treated by that dentist.

- 4. Any dentist desiring to dispense legend drugs which are not exempted by Paragraph 3 of this regulation from the requirement of prior approval of the Arkansas State Board of Dental Examiners shall apply to the board on a form provided for that purpose and shall be required to demonstrate the need for such dispensing of legend drugs prior to receiving approval.
- 5. <u>Violation of this regulation shall constitute "professional misconduct" and shall subject the violator to disciplinary action as provided in Ark. Code.</u> Ann. 17-82-316 and Ark. Code Ann. 17-82-317,
- 6. <u>The Arkansas State Board of Dental Examiners shall enforce the provisions of this regulation.</u>