

04-03-0001—SPECIALTY PHARMACY PERMITS

The Board may issue a specialty pharmacy permit for a facility to provide unique aspects of pharmaceutical care to an identified patient population as provided in Regulation 04-03-0001 *et seq.* Said specialty pharmacies and the pharmacists practicing therein shall comply with applicable federal and state law and regulations, including Arkansas Pharmacy Law, A.C.A. § 17-92-101 *et seq.*, and Board Regulations, including without limitation regulations regarding Retail Pharmacies 04-02-0001 *et seq.*, which are not expressly superseded by the regulation applicable to the specific type of specialty pharmacy.

04-03-0002 METHADONE CLINIC SPECIALTY PHARMACY PERMIT

1. DEFINITIONS:

- a. “Methadone Clinic Pharmacy” means the place in which a licensed professional prepares methadone to be administered and/or dispensed to a patient of the clinic.
- b. “Dispensing Methadone” means the preparation of one or more doses of methadone in properly labeled, patient specific containers and delivery of said drugs to the patient to consume away from the clinic; only a licensed pharmacist or physician holding a dispensing permit issued by the Arkansas State Medical Board shall dispense methadone.
- c. “Administering” means giving a single dose of methadone to a patient to consume on-site; a physician shall administer or supervise the administration of methadone and the clinic pharmacist shall retain appropriate methadone administration records.

2. PERMIT

- a. Applications for methadone clinic permits shall be submitted pursuant to Regulation 04-02-0001.
- b. Any pharmacist shall notify the Board of Pharmacy in writing and ascertain that a Methadone Clinic Pharmacy Permit has been issued to the clinic before beginning practice in that clinic.

3. PHARMACY OPERATIONS

- a. The pharmacist-in-charge shall provide written policies, procedures, and protocols for the operation of the pharmacy and shall obtain the approval of same by the Executive Director of the Pharmacy Board prior to operation of said pharmacy.
- b. A Methadone Clinic Pharmacy shall stock and dispense methadone only.

4. PHYSICAL FACILITIES

- a. The pharmacy shall be a controlled area for the storage, safeguarding, preparation, and dispensing of methadone, a Schedule II narcotic, and shall have adequate facilities for pharmaceutical services including the procurement, storage, distribution, security and control of said drug consistent with all federal and state laws and regulations.**
- b. The pharmacy shall have all equipment necessary to carry out the functions of the Methadone Clinic Pharmacy and is otherwise exempt from Regulation 02-02-0004; the equipment must be identified in the policies and procedures of each Methadone Clinic specialty Pharmacy.**

5. LICENSED PHARMACIST PERSONNEL REQUIREMENTS

- a. A methadone pharmacy shall be open to serve its patients, with a pharmacist or pharmacists on duty, a minimum of 10 hours per week or, if necessary, a greater period of time in order to perform pharmacy duties necessary to ensure patient safety.**
- b. The pharmacy's operating hours must be approved by the Executive Director of the Arkansas State Board of Pharmacy.**