



Arkansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Compounding for a Prescriber's Office Use

Arkansas Pharmacy Regulation 07-02-0002-Good Compounding Practices (section L) allows compounding for a prescriber's office use within defined rules. Item 7 of section L states, "A Retail pharmacy is not precluded from making more than five percent (5%) of its annual sales to licensed practititioners. The pharmacy must, however, obtain a State Wholesale Legend Drug and/or Controlled Substance Distributor Permit."

Any compounding pharmacy licensed in Arkansas that exceeds 5% of its annual sales for office stock must apply for a Wholesale Distributor Permit and be inspected for compliance with Arkansas Regulation 08: wholesale distribution. In addition, if controlled substances are included in office stock compounding, the facility must be inspected by the US Drug Enforcement Administration (DEA) for compliance with 21 CFR 1301.71-.74 (Security Requirements). These storage and security requirements are considerably more stringent than those required for a Retail Pharmacy Permit.

Employee Screening Procedures

Recent issues involving diversion of controlled substances have prompted questions about an employer's responsibility for their employees who have access to controlled substances. According to the US Drug Enforcement Administration (DEA), 21 CFR 1301.90 (Employee Screening Procedures) delineates that the following questions should become a part of an employer's comprehensive employee screening program:

Question: Within the past five years, have you been convicted of a felony, or within the past two years of any misdemeanor, or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses, or military convictions, except by general court martial.) If the answer is yes, furnish details of conviction, offense, location, date, and sentence. **Question:** In the past three years, have you ever knowingly used any narcotics, amphetamines, or barbiturates other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advise: An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right to privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Office-based Opioid Treatment

The Drug Addiction Treatment Act (DATA) of 2000 amended the Controlled Substance Act to allow qualified physicians who have applied for a waiver to prescribe certain Schedule III-V narcotic controlled substances approved by the US Food and Drug Administration (FDA) for use in the treatment of narcotic addiction. To be eligible for a waiver, physicians who meet certain qualifications must submit a written notification to the Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT). CSAT will coordinate the waiver process with the US Drug Enforcement Administration (DEA). Physicians who receive the waiver will be assigned a unique identification number that must be noted on all prescriptions written under the waiver. We have been told that the unique identification will be similar to the physician's DEA number with an "X" in it. Physicians in a "group practice" may have no more than 30 patients for the entire practice.

Subutex® (buprenorphine) and Suboxone® (buprenorphine/naloxone combination) are both sublingual tablets that were just recently approved by the FDA for the treatment of narcotic addiction. Buprenex® is an injectable form of buprenorphine that has been approved by the FDA for the treatment of pain, but it is **not** permitted for the treatment

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of a narcotic addiction. Buprenorphine has been reclassified by the DEA from Schedule V to Schedule III.

In Office-based Opioid Treatment (OBOT), a patient will receive traditional drug treatment and health care services such as routine medical exams and counseling services at an affiliated doctor's office instead of at the patient's traditional Narcotic Treatment Program. Physicians who have applied to CSAT and have received the waiver from the DEA may prescribe Schedule III-V substances and dispense Schedule II substances for narcotic addiction treatment, but they cannot prescribe Schedule II substances for narcotic addiction treatment.

The local DEA office has offered to provide the Arkansas State Board of Pharmacy a list of the physicians in Arkansas who receive the waiver and unique identification number. If you receive a prescription for Subutex or Suboxone, please feel free to contact the Board office at 501/682-0190 to verify the unique identification number.

Biennial Registration Renewal Reminder

The following permits shall be renewed every two (2) years beginning with renewals for the 2003-2004 biennium: all pharmacy technician permits, hospital pharmacy permits, ambulatory care center pharmaceutical services permits, wholesale distributors of legend or controlled substance permits, wholesale distributors of medical equipment, legend devices, and medical gases permits, institutional pharmaceutical services permits, nursing home consultant pharmacist permits, and nursing home consultant pharmacist-at-large permits.

The fee for any biennial renewal term will be the amount of two (2) annual renewal fees for the applicable license, permit, registration, or certification. Renewal notices will be sent on December 1, 2002. Please contact the Board Office at 501/682-0190 if you have any questions.

New Reciprocating Pharmacists

The following is a list of pharmacists who were approved to receive an Arkansas Pharmacist license by reciprocity by the Arkansas State Board of Pharmacy at the June meeting:

Dennis Bean Charles Moore Steven Chang Eric Napier Karen Coleman Barbara Nelson Lynda Doremus Maria Ojeda Paul Elmer Deborah Pechacek Timothy Fincher James Poullard Daniel Garcia Cheryl Pryor Orville Geddes Dawn Rana Robert Rowe Ricky Gilmore Yolanda Haynes George Russman Chad Herlyn Carol Spann Angela Hudson Larry Talley Lisa Thomas Bernard Hukill Kent Kennon Phu Tran Vaughn Kinosian Carl Tunison James Knox Maureen Vance Christi Macaluso Michael Wilson

The Arkansas State Board of Pharmacy would like to welcome all of these pharmacists to Arkansas.

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