

ALABAMA STATE BOARD OF PHARMACY
ADMINISTRATIVE CODECHAPTER 680-X-3
ALABAMA UNIFORM CONTROLLED SUBSTANCES

TABLE OF CONTENTS

680-X-3-.01	Registration Requirements
680-X-3-.02	Registration And Reregistration Fees
680-X-3-.03	Time And Method Of Payment; Renewal And Non-Disciplinary Penalty For Late Renewal Of Controlled Substances Permit
680-X-3-.04	Continuing Education For Reregistration (Repealed 8/10/06)
680-X-3-.05	Recordkeeping By Manufacturers, Wholesalers, Or Distributor Of Controlled Substance And Submission Of Reports To The State Board Of Pharmacy
680-X-3-.06	Surrender Of License And Permits At Termination Of Operation, Inventory And Disposition Of Controlled Substances Drugs
680-X-3-.07	Report Of Theft Or Loss Of Controlled Substances
680-X-3-.08	Annual Inventory Of Controlled Substances
680-X-3-.09	Invoices And Acquisitions Of Controlled Substances
680-X-3-.10	Facsimile Prescription Drug Orders For Controlled Substances
680-X-3-.01	<u>Registration Requirements.</u>

(1) Every person or firm who manufacturers, distributes, or dispenses any controlled substance, or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance, shall obtain annually a registration from the Alabama State Board of Pharmacy, on forms provided by the Alabama State Board of Pharmacy, unless exempted by law. This applies to each individual pharmacist and to each pharmacy, but does not apply to physicians, dentists, or veterinarians, who are registered by their certifying boards.

(2) Only persons actually engaged in such activities are required to obtain a registration; related to affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder of a parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)

Author: James W. McLane

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed June 1, 1982.

680-X-3-.02 **Registration And Reregistration Fees.** Fee amounts.

(a) Effective January 1, 2006 for each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of six hundred dollars (\$600) to be renewed in even-numbered years.

(b) Effective January 1, 2006 for each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of six hundred dollars (\$600) to be renewed in even-numbered years.

(c) Effective January 1, 2006 for each pharmacy registration or reregistration to dispense controlled substances listed in Schedule II through V, the registrant shall pay a fee of three hundred dollars (\$300) to be renewed in even-numbered years.

(d) Effective January 1, 2006 for each pharmacist registration or reregistration to dispense controlled substances listed in Schedule II through V, the registrant shall pay a fee of one hundred dollars (\$100) to be renewed in even-numbered years.

Author: James W. McLane

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed June 1, 1982. **Emergency rule** filed December 8, 1983. **Amended:** Filed December 8, 1983. **Amended:** Filed November 1, 2005; refiled: December 22, 2005; effective December 22, 2005.

680-X-3-.03 **Time And Method Of Payment; Renewal And Non-Disciplinary Penalty For Late Renewal Of Controlled Substances Permit.**

(1) Registration fees shall be paid at the time the application or renewal furnished by the Alabama State Board of Pharmacy for registration is submitted for filing. Payment shall be made payable to the Alabama State Board of Pharmacy and shall be due October 1 of each even-numbered year and delinquent after the last day of December of each even-numbered year. If the application for renewal and appropriate renewal fee is not received in the Board's office by December 31 of any even numbered year but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

(2) This Rule is adopted pursuant to the Board's authority set forth in Code of Ala. 1975, §34-23-33(b) and is in lieu of formal disciplinary proceedings.

Author: Herb O. Bobo, R.Ph., Secretary

Statutory Authority: Code of Ala. 1975, §34-23-50.

History: Filed June 1, 1982. **Amended:** Filed March 17, 2006; effective April 21, 2006. **Amended:** Filed July 8, 2010; effective August 12, 2010; operative September 1, 2010.

680-X-3-.04 **Continuing Education For Reregistration.**

(Repealed)

Author: Jerry Moore, Executive Secretary

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed June 1, 1982. **Amended:** Filed December 10, 1984, October 8, 1987, March 19, 1993. **Amended:** Filed August 23, 1994; effective January 1, 1995. **Repealed:** Filed July 6, 2006; effective August 10, 2006.

680-X-3-.05 **Recordkeeping By Manufacturers, Wholesalers, Or Distributors Of Controlled Substances And Submission Of Reports To The State Board Of Pharmacy.**

(1) Any manufacturer, wholesaler or distributor of controlled substances doing business in the State of Alabama or who proposes to do business in Alabama shall obtain annually a registration by the Alabama State Board of Pharmacy.

(2) Such manufacturers, wholesalers, or distributors doing business in the State of Alabama who sell, furnish, give away, or otherwise dispose of controlled substances drugs

enumerated in Schedule I, II, III, IV, or V or precursor agents used to manufacturer such controlled substances to a registrant other than another manufacturer or wholesaler, shall submit to the Alabama State Board of Pharmacy legible copies of records and reports required by the Drug Enforcement Administration concerning increases in purchases or high or unusual volumes purchased by pharmacies within 30 days.

Author: Vance L. Alexander, RPh, President

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed June 1, 1989. **Amended:** Filed December 8, 1983.

Amended: Filed May 20, 1996; effective June 24, 1996; operative August 15, 1996.

680-X-3-.06 Surrender Of License And Permits At Termination Of Operation, Inventory And Disposition Of Controlled Substances Drugs.

(1) Every pharmacy or manufacturer/distributor of prescription legend drugs, including controlled substances drugs, who is registered with and holds licenses and permits from the Alabama State Board of Pharmacy shall immediately notify the Board any time there is a termination of that operation and shall surrender all licenses and permits to the Board within 10 days of that termination.

(2) Within 10 days of termination of operation of any pharmacy, manufacturer, or distributor registered with the Alabama State Board of Pharmacy, an inventory of all controlled substances on hand at the time of termination of operation shall be furnished the State Board of Pharmacy. Final disposition of all controlled substances on hand at the time of termination shall be reported to the Board as it may occur. Manufacturers and distributors of controlled substances located outside of this state and holding licenses and permits to distribute controlled substances within the state shall be required to furnish inventory and disposition of controlled substances as stated.

(3) The next of kin of any deceased licensed pharmacist owner of a pharmacy shall have a period of 30 days within which to comply with the provisions of this rule during which time no prescriptions shall be filled unless a licensed pharmacist is on duty.

Author: James W. McLane

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed December 8, 1983.

680-X-3-.07 Report Of Theft Or Loss Of Controlled Substances.

(1) A pharmacy shall notify the Field Division Office DEA and the Alabama State Board of Pharmacy of the theft or significant loss of any controlled substances upon discovery of such loss of theft. The pharmacy shall also complete DEA form, "Report of Theft or Loss of Controlled Substances," which may be obtained from the Board of Pharmacy or DEA office.

(2) Four copies must be made of the report. The pharmacy shall keep a duplicate copy for its records, forward two copies, the original and duplicate copy, to the Field Division Office of DEA, and provide one duplicate copy of the Alabama State Board of Pharmacy.

Author: James W. McLane

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed October 10, 1986.

680-X-3-.08 Annual Inventory Of Controlled Substances.

(1) Every pharmacy shall take an initial inventory of all controlled substances on hand on January 15, 1987 and shall take a new inventory of all stocks of controlled substances on hand on January 15th or the alternative fixed date approved by the Board of each year following the date the initial inventory was taken.

(2) The annual inventory may be taken on any fixed date which does not vary by more than six (6) months from the annual date that would otherwise apply. If the registrant elects to take the annual inventory on another fixed date, he must first petition the Board for approval of the alternative fixed date on which the annual inventory will be taken.

(3) A pharmacy registered after any annual inventory date shall take an initial inventory of all stocks of controlled substances on hand on the date it first engages in the dispensing of controlled substances. In the event such pharmacy commences business with no controlled substances on hand, the record shall indicate this fact as the initial inventory. This pharmacy shall take a new inventory of all stocks of controlled substances on hand January 15th or the alternative fixed date approved by the Board of each year following the date the initial inventory was taken.

(4) The inventory by a pharmacy must be taken either as of the opening of business or as of the closing of business. The pharmacy shall indicate on the inventory records whether the inventory was taken as of the opening of business or as of the close of business, the date of inventory was taken, followed by the signature of the person responsible for taking the inventory.

(5) In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the pharmacy shall do as follows:

(a) If the substance is listed in Schedule II, an exact count or measure of the contents shall be made.

(b) If the substance is listed in Schedule III, IV, or V, an estimated count or measure may be made of the contents unless the container holds more than 1000 tablets or capsules in which case an exact count of the contents must be made.

Author: Jerry Moore, RPh, Executive Secretary

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: Filed October 10, 1986. **Amended:** Filed August 23, 1994; effective January 1, 1995.

680-X-3-.09 Invoices And Acquisitions Of Controlled

Substances. In addition to those records required under federal laws and regulations, and under provisions of the Alabama Uniform Controlled Substances Act, all receipts of controlled substances by a pharmacy shall be reviewed and approved by pharmacist. Said review and approval shall be documented by the signature of a pharmacist employed by the pharmacy permit holder on the supplier's invoice or other similar such document.

Author: Vance Alexander, RPh, President

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: **New Rule:** Filed May 20, 1996; effective June 24, 1996; operative August 15, 1996.

680-X-3-.10 Facsimile Prescription Drug Orders For Controlled
Substances.

(1) A prescription drug order which is transmitted by an electronic device which sends an exact copy image to the receiver (pharmacy) over telephone lines.

(2) Faxing Schedule II prescriptions:

(a) Faxing a Schedule II for a home infusion and/or I.V. pain therapy patient - A prescription, written for a Schedule II substance to be compounded for the direct administration to a home infusion patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, may be transmitted directly from the prescribing practitioner, by the practitioner or the practitioner's agent to the pharmacy by facsimile. The facsimile serves as the original written prescription. This exception does not apply to any other dosage forms.

(b) Faxing a Schedule II for a long term care patient - A prescription written for a Schedule II substance, for long-term care patients, which include hospice patients, may be transmitted directly from the prescribing individual practitioner, by the practitioner or the practitioner's agent, to the provider pharmacy by facsimile. The facsimile serves as the original written prescription.

(3) Faxing for a long term care patient to a pharmacy:

(a) A pharmacist may accept a fax prescription for a long term care patient provided:

1. For Schedule II drugs, all requirements of a written prescription are met, including the prescriber's signature on the faxed order and it is faxed by the nurse/person the physician has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.

2. For drugs other than Schedule II, the order is faxed by the nurse/person the physician has designated as his/her "agent" to transmit the order, and must contain the nurse/person's signature.

3. The pharmacist verifies the fax is from the machine of the designated nurse/person.

(4) Faxed prescriptions.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV or V which is a prescription drug, or any legend drug, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile of a written signed prescription transmitted directly by the prescribing practitioner, or the practitioner's agent, to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner, or the practitioner's agent, and promptly reduced to writing by the pharmacist.

(b) All laws and regulations applicable to oral prescription drug orders shall also apply to all facsimile orders including, but not limited to, generic substitution, maintenance of records, information required, etc.

(c) A prescription order transmitted by facsimile device shall contain all prescription information required by federal and state law.

(d) A pharmacist may dispense prescription orders transmitted by fax only when signed by the prescribing practitioner and transmitted from the practitioner's office or a long term care facility in compliance with all sections of this document.

(e) The original fax shall be assigned the number of the prescription dispensed, and maintained in pharmacy records for at least two (2) years.

(f) The receiving fax machine must be in the prescription department of the pharmacy to protect patient/pharmacist authorized prescribing practitioner confidentially and security.

(g) Refill authorizations for prescriptions, other than Schedule II, may be transmitted using a facsimile device.

Author: Jerry Moore, R.Ph., Executive

Statutory Authority: Code of Ala. 1975, §34-23-92.

History: New Rule: Filed January 13, 1999; effective February 17, 1999; operative March 1, 1999.