

Alabama State Board of  
Pharmacy

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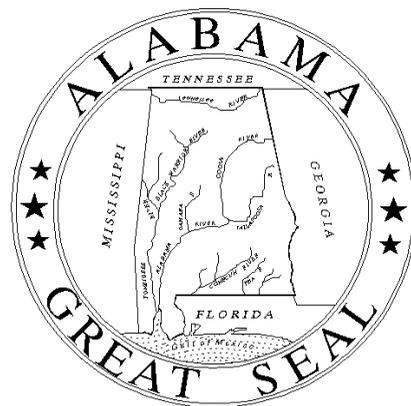
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# Alabama State Board of Pharmacy



## Controlled Substance Rules & Regulations Quick Reference

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*A brief summary of pertinent rules  
and regulations impacting the  
practice of pharmacy*

### Controlled II Substance Rules & Regulations

#### **Requirements of a Rx:**

A Rx for a CII may be transmitted by the practitioner or the agent of the practitioner via facsimile provided the original manually signed Rx is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. **CFR §1306.11 (a); Code of AL §20-2-58(a)**

#### **Refilling CII Rxs:**

The refilling of a Schedule II Rx is **prohibited**. **CFR §1306.12(a)**

#### **Emergency CII Rxs:**

In an **emergency situation**, a pharmacist may dispense a CII for a resident of a long-term care facility, a patient receiving hospice services, or a patient receiving home health care services, pursuant to an emergency oral Rx transmitted by the practitioner to the dispensing pharmacy. The quantity dispensed shall be **limited** to the **amount** adequate to treat the patient during the emergency period not to exceed 72 hours. The practitioner, within **7 days** of the emergency oral Rx, shall provide the dispensing pharmacy with a written Rx for the quantity prescribed. **CFR §1306.11 (d); Code of AL §20-2-58(g)**

In addition, the written Rx shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. Upon receipt, the dispensing pharmacist must attach to the oral emergency Rx that had earlier been reduced to writing. The pharmacist must **notify** the nearest office of the Drug Enforcement Agency (DEA) if the prescribing individual practitioner fails to deliver a written Rx. **CFR §1306.11(4)**

#### **Facsimile Rx for CII medications:**

CII Rxs that are to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent via facsimile. The facsimile will serve as the original Rx. **CFR §1306.11 (e); Code of AL §20-2-58(b)**; This exception does not apply to any other dosage forms. **680-X-3-.10(a)**

### Controlled II Substance Rules & Regulations

CII Rxs for a resident of a Long-Term Care Facility may be transmitted by the practitioner or the practitioner's agent via facsimile. The facsimile serves as the original written Rx. **CFR §1306.11 (f); Code of AL §20-2-58(c); 680-X-3-.10(1) (b)**

CII Rxs for patients under Hospice care may be transmitted by the practitioner or the practitioner's agent via facsimile. The facsimile will act as the original written Rx. **CFR §1306.11(g); 680-X-3-.10(1) (b)**

#### **Partial Filling of CII Rxs:**

Partial filling of CII Rxs is **permissible** if the pharmacist is unable to supply the full quantity called for by the Rx. Notation of quantity supplied must be noted on the face of the original Rx. The remaining portion of the Rx may be filled within **72 hours** of the first partial filling; however, if the remaining portion is not or cannot be filled within this period, the pharmacist shall notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new Rx. **CFR §1306.13(a)**

Schedule II Rxs written for patients residing in a **Long-Term Care Facility (LTCF)** or who have a diagnosis documenting a **terminal illness** may be **partially filled** (see 60 day provision below). The pharmacist must record on the Rx whether the patient is "terminally ill" or "LTCF patient". For each partial filling, the dispensing pharmacist shall record the date of the partial fill, quantity dispensed, remaining quantity along with identification of the dispensing pharmacist. The total quantity dispensed in all partial fillings must not exceed the total quantity prescribed. **CFR §1306.13 (b)**

Schedule II Rxs for patients in LTCF or patients with a medical diagnosis documenting a **terminal illness** shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication. **CFR § 1306.13 (b)**

**Controlled III, IV, & V Substance Rules & Regulations**

**Requirements of a Rx:**

A pharmacist may dispense a controlled substance (Schedule III, IV, & V) only pursuant to: a **paper Rx** signed by a practitioner, **facsimile** of a signed Rx, or an **oral Rx** made by an individual practitioner and promptly reduced to writing by the pharmacist. **CFR §1306.21(a); 680-X-3-.10(a).**

**Refilling of a Rx:**

No Rx for CIII or IV medications shall be filled or refilled more than **6 months** after the date on which such Rx was written or refilled more than **five times**. **CFR §1306.22 (a)**

**Partial filling of a Rx:**

Partial filling of Schedule CIII-V Rxs is **permissible** provided that each partial filling is recorded, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed and no dispensing occurs after **6 months** after the date on which the Rx was issued. **CFR §1306.23(a)(b)(c).**

**Maintenance of records and inventories:**

A pharmacy which employs a computer application for Rxs that permits identification by Rx number and retrieval of original documents by the prescriber name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy Rx with a red "C" is **waived**. **CFR §1304.04 (h)(4)**

**Inventories:**

Every pharmacy shall take an annual inventory of all stocks of CS on hand **on January 15<sup>th</sup>** or the **alternate fixed date** approved by the Board of each year following the date the initial inventory was taken. **680-X-3-.08(1)**

An annual inventory may be taken on any fixed date which does not vary by more than **6 months** from the annual date that would otherwise apply. **680-X-3-.08(2)**

When performing an annual inventory, an **exact count or measure** is required of all CII medications on hand. If the drug is listed in Schedule III-V, an **estimated count or measure** may be made; if the container holds more than **1,000** tablets or capsules in which case an **exact**

**count** of the contents must be made. **680-X-3-.08(5b)**

**Transfer of CIII-V Rxs between pharmacies:**

The transfer of original CIII-V Rxs is permissible between pharmacies on a **one-time basis only**. However, pharmacies **electronically** sharing a real-time, online database may transfer up to the maximum allowable refills permitted by law. **CFR §1306.25 (a)**

The transfer **must be communicated directly** between two licensed pharmacists. **CFR §1306.25 (1)**

Record on the reverse of the invalidated Rx the name, address and DEA number of the pharmacy to which it was transferred and the name of the pharmacist receiving the Rx. **CFR §1306.25 (2)(ii)**

For paper and oral Rx reduced to writing, the pharmacist receiving the transferred Rx information must write transferred Rx and reduce to writing all information required pursuant to CFR §1306.05 to include:

- Date of issuance of original Rx
- Original number of refills authorized
- Date of original dispensing
- Number of valid refills remaining; date(s) and locations of previous refill(s).
- Pharmacy's name, address, DEA number and Rx number from which the Rx information was transferred.
- Name of pharmacist who transferred Rx
- Pharmacy's name, address, DEA number and Rx number from which the Rx information was originally filled. **CFR §1306.25 (3)(i)(ii)(iii)(iv)(v)(vi)(vii)**

The original and transferred Rx(s) must be maintained for a period of two years from the date of last refill. **CFR §1306.25(5)(c)**

**Drugs; statement of required warning:**

The label of CII-IV controlled substances **shall contain** the following warning "**Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.**" **CFR §290.5**

**Additon to AL CS Scheduling:**

The Alabama State Committee of Public Health has approved the scheduling of the anesthetic "**Propofol**" to Schedule IV. **Effective 8/27/2012**

**Clarification of CII Rxs:**

The pharmacist may add or change the patient's address upon verification. The pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the Rx. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of these changes to controlled substance Rxs. **Board Policy 20100825; adopted August 25, 2010**

**Manner of issuance of Rx:**

All Rxs for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. **CFR 1306.05(a)**

**Refilling Rxs; issuance of multiple Rxs.**

An individual practitioner may issue multiple Rxs authorizing the patient to receive a total of up to a 90-day supply of a CII Rx. **CFR §1306.12(b)(1);** The individual practitioner provides written instructions indicating the earliest date on which a pharmacy may fill each Rx. **CFR §1306.12(b)(1)(ii)**

**Sale of ephedrine, etc:**

It shall be unlawful for any person, business, or entity to knowingly sell any ephedrine or pseudoephedrine, their salts or optical isomers, or salts of optical isomers unless sold from a pharmacy licensed by the ALBOP. These products sold within a pharmacy must be sold by an individual licensed as a pharmacist, a pharmacy technician licensed by ALBOP, or by an employee of the pharmacy under the direct supervision and control of a licensed pharmacist. Code of AL 1976, §20-2-190(c)(1). No person shall deliver, sell, or purchase products sold over-the-counter that contain a combined total of more than 3.6

grams per calendar day or more than 7.5 grams per 30 days, of ephedrine base or pseudoephedrine base. Code of AL 1976, §20-2-190(4). Purchaser of the product or products to be at least 18 years of age, to provide a valid, unsuspended driver's license or nondriver identification card issued by this state, a valid, unsuspended driver's license or nondriver identification card issued by another state, a U.S. Uniformed Services Privilege and Identification Card, or a U. S. or foreign passport. Code of AL 1976, §20-2-190(5)a.

**Other information may be obtained from the following:**

**Controlled Substance Information Drug Enforcement Administration**  
Birmingham, Alabama 205/321-1300  
Mobile, Alabama 800/882-9539

**Foreign Pharmacy Graduate Equivalency Examination & Reciprocity Issues**  
**National Association of Boards of Pharmacy**  
1600 Feehanville Drive  
Mount Prospect, IL 60056  
847/391-4406  
<http://www.nabp.net>

**Association & Continuing Education Information**  
**Alabama Pharmacy Association**  
1211 Carmichael Way  
Montgomery, Alabama 36106  
334/271-4222  
Louise Jones, Executive Director  
<http://www.aparx.org> - [ljones@aparx.org](mailto:ljones@aparx.org)

**Alabama Society of Health-System Pharmacists**  
P.O. Box 36972  
Birmingham, Alabama 35236  
205/358-8538  
Bobby Mosca, Assisant Executive Dir  
<http://www.alshp.org> - [admin@alshp.org](mailto:admin@alshp.org)

**Medicaid Pharmacy Policy Information**  
**Alabama Medicaid**  
Box 5624  
Montgomery, AL 36103-5624  
Kelli Littlejohn, Pharmacy Program Administrator  
334/242-5000  
[kelli.littlejohn@medicaid.alabama.gov](mailto:kelli.littlejohn@medicaid.alabama.gov)