

Pharmacy	Standard Operating Procedure		
Title	Dispensing CIII - V Controlled Substances		
Document No.	5.07	Revision	0

Prepared by/Date: _____ Approved by/Date: _____

- I. **Purpose:** This procedure describes the requirements for dispensing Schedule III-V Controlled Substances at the Pharmacy.
- II. **Scope:** This procedure applies to all licensed pharmacists or interns working under the supervision of a licensed pharmacist who are responsible for prescription verification, billing, and dispensing CIII-V controlled substance medications.
- III. **Definitions:**

Schedule III Controlled Substances: Substances in this schedule have a potential for abuse less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include:

- Combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®)
- Products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine)
- Buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction

Examples of schedule III non-narcotics include:

- Benzphetamine (Dimelex®)
- Phendimetrazine
- Ketamine
- Anabolic steroids, such as oxandrolone (Oxandrin®)

Schedule IV Controlled Substances: Substances in this schedule have a low potential for abuse relative to substances in Schedule III. Schedule IV substances include:

- Propoxyphene (Darvon® and Avocet-N 100®)
- Barazolam (Lorazax®)
- Clonazepam (Klonopin®)
- Clorazepate (Crixene®)
- Diazepam (Valium®)
- Estazolam (Provan®)
- Methazolam (Mezcal®)
- Temazepam (Restoril®)
- Zolpidem (Ambien®)

Schedule V Controlled Substances: Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes. Examples include:

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- Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®)

IV. Safety Requirements: N/A

V. Procedure

General Requirements

1.0 Before dispensing a controlled substance, the pharmacist must verify that the prescription is valid and the prescriber meets the legal requirements of the State Board of Pharmacy to prescribe for a controlled substance.

2.0 A prescription failing to meet the requirements outlined in the federal Controlled Substances Act and the state Controlled Substances Act for the state where the Pharmacy is located will not be dispensed by the pharmacist.

3.0 Prescription Verification:

To be considered valid, a prescription for a controlled drug in any form must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional judgment. Each prescription must be written with indelible pencil or typewriter, dated on the date issued, must be manually signed by the practitioner, and contain ALL of the following:

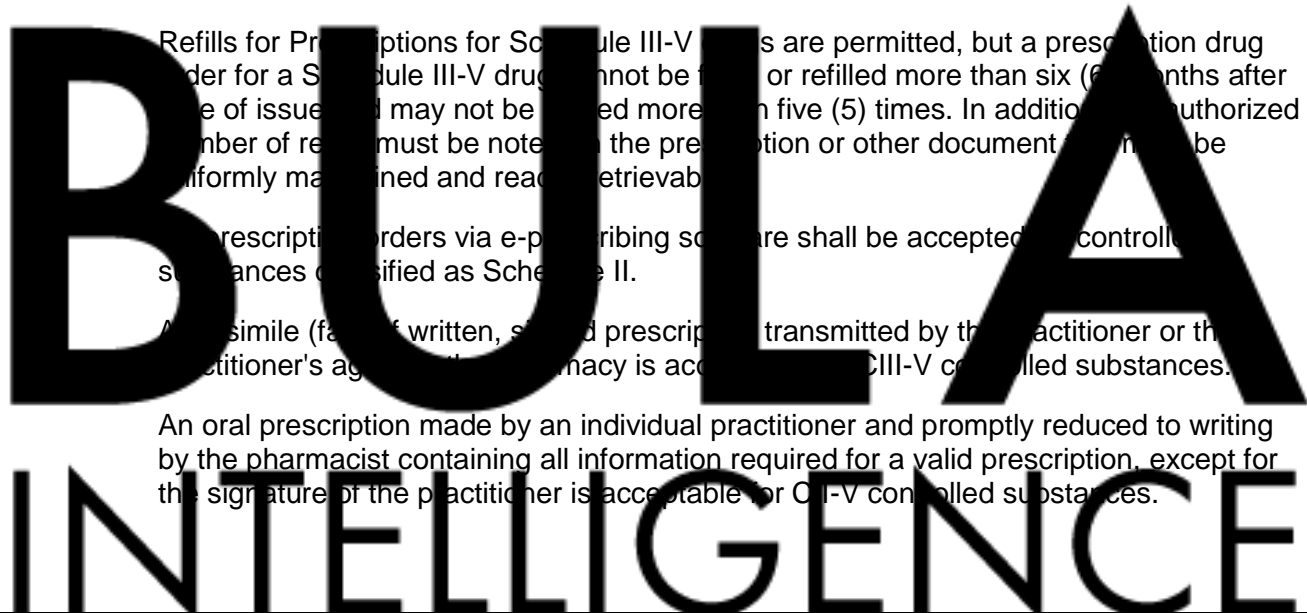
- The full name and address
- The drug name, strength, dosage form, quantity prescribed, and directions for use
- The name, address, and DEA registration number of the practitioner

Refills for Prescriptions for Schedule III-V drugs are permitted, but a prescription drug order for a Schedule III-V drug cannot be filled or refilled more than six (6) months after the date of issuance and may not be refilled more than five (5) times. In addition, the number of refills must be noted on the prescription or other document and must be uniformly maintained and readily retrievable.

Prescription orders via e-prescribing software shall be accepted for controlled substances classified as Schedule II.

A facsimile (fax) of written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy is acceptable for CIII-V controlled substances.

An oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription, except for the signature of the practitioner is acceptable for CIII-V controlled substances.



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Electronic prescriptions for Schedule III-V must meet DEA requirements for such prescriptions (reference "Electronic Prescriptions for Controlled Substances." The rule is available online at: http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf)

4.0 Changes to a Controlled Substance Schedule III-V Prescription

A 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 instructions only after consultation with an agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted by the pharmacist on the prescription. Pharmacists and practitioners must comply with any state legal laws, regulations, or policies prohibiting any of these changes to controlled substance prescriptions.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

5.0 Registration Verification:

Registrants and registration numbers shall be verified at the point of service, utilizing (but not limited to) the following:

- <http://www.deadiversion.usdoj.gov/>
- Home state medical board of prescribers

6.0 Monitoring:

The pharmacist MUST monitor the patient's Controlled Substance Activity using the state's SCPMP (reference SOP-4.03 Control Substance Prescription Monitoring Program) on each controlled substance prescription received prior to dispensing.

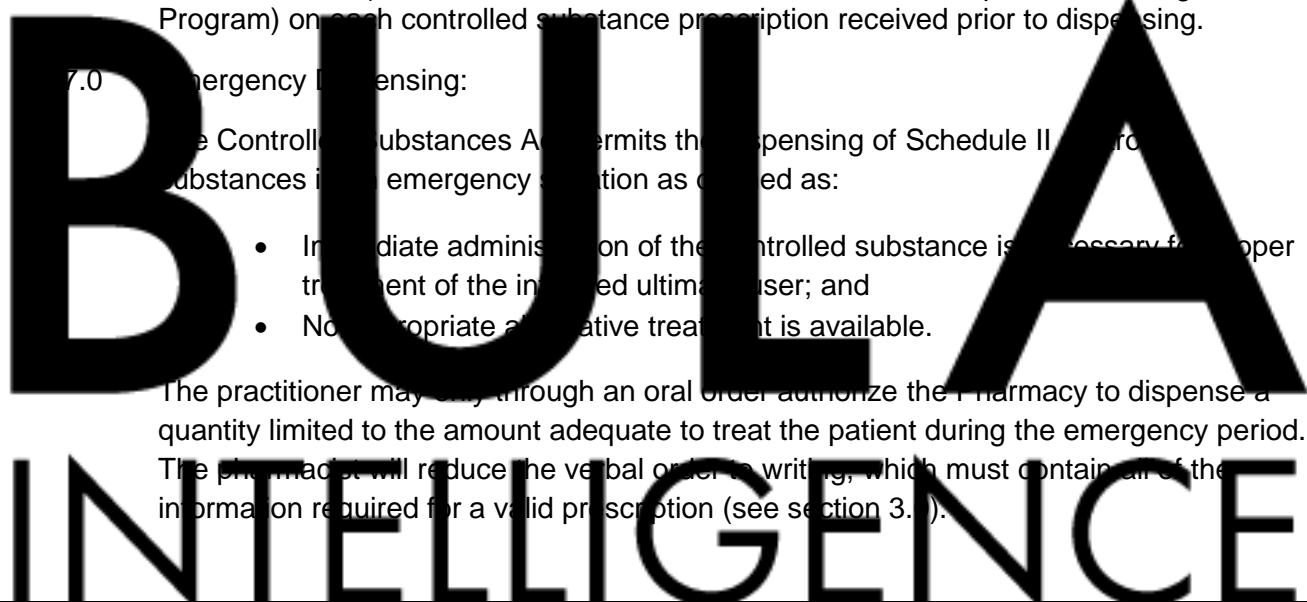
7.0 Emergency Dispensing:

The Controlled Substances Act permits the dispensing of Schedule II controlled substances in an emergency situation as defined as:

- Immediate administration of the controlled substance is necessary for proper treatment of the involved ultimate user; and
- No appropriate alternative treatment is available.

The practitioner may only through an oral order authorize the Pharmacy to dispense a quantity limited to the amount adequate to treat the patient during the emergency period.

The pharmacist will reduce the verbal order to writing, which must contain all of the information required for a valid prescription (see section 3.1).



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The pharmacist shall make all reasonable attempts to determine that the oral authorization came from a registered individual practitioner.

The practitioner must deliver to the Pharmacy a valid written prescription within 7 days of the emergency dispensing. The valid prescription must contain the words "Authorization for Emergency Dispensing."

Note: In the event that the practitioner fails to provide the Pharmacy with a valid prescription, the pharmacist is required to report this to the local DEA office. Failure to report this voids the authority to fill an emergency oral order (the pharmacist is liable for violating the Controlled Substances Act).

8.0 Transfer of a prescription order for a controlled substance classified as Schedule III, IV, or V is permitted for the purposes of refill dispensing between pharmacies on a one-time basis only.

Transfer of such prescription(s) in or out shall be conducted by a licensed pharmacist. Licensed interns or technicians are not permitted to conduct such a transfer.

Transfer information shall be recorded on the prescription via electronic means in the Pharmacy management system, including:

- Name of pharmacy transferring or receiving Rx
- Address
- Telephone number
- Transfer date
- Transferring pharmacist
- Receiving pharmacist
- DEA number of pharmacy

Or as required by federal or state regulatory requirements for Transfer of Prescriptions

9.0 Partial Fills: The Pharmacy will not partial fill a prescription order for a controlled substance classified as Schedule III; if the Pharmacy does not have sufficient product on hand, it may dispense the amount on hand and then dispense the remaining balance within 72 hours. If the remaining balance is not received by the Pharmacy within 72 hours, it will not be dispensed.

10.0 The pharmacy will not fill prescription order for "Office Use" for controlled substance classified as Schedule III.

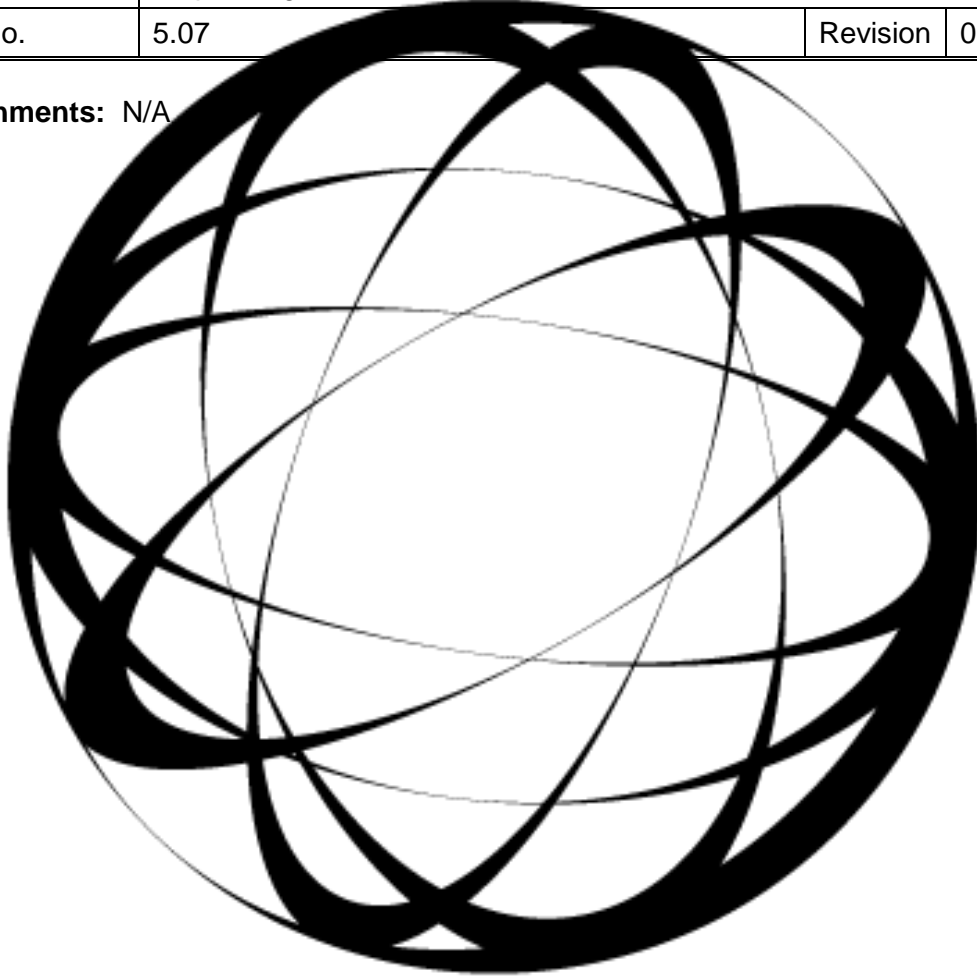
VI. References:

- 21 CFR 1306.05(a)
- DEA General Prescribing and Dispensing of Controlled Substances FAQ available at: www.dea.gov

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VII. Attachments: N/A



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