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**Practitioner's Manual**

**SECTION V – VALID PRESCRIPTION REQUIREMENTS**

**Prescription Requirements**

A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (for example, an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include:

1. drug name
2. strength
3. dosage form
4. quantity prescribed
5. directions for use
6. number of refills (if any) authorized

A prescription for a controlled substance must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature.

The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.

**Who May Issue**

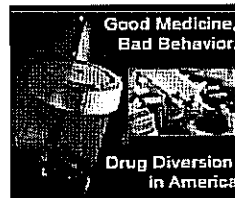
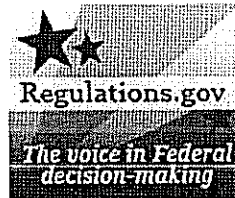
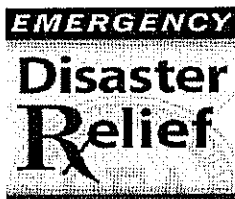
A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice
2. Registered with DEA or exempted from registration (that is, Public Health Service, Federal Bureau of Prisons, or military practitioners)
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements as set forth in the CFR are met.

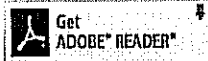
**Purpose of Issue**

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. In addition, a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription within the meaning and intent of the Controlled Substances Act and the person knowingly

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filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

### Schedule II Substances

Schedule II controlled substances require a written prescription which must be signed by the practitioner. There is no federal time limit within which a Schedule II prescription must be filled after being signed by the practitioner.

While some states and many insurance carriers limit the quantity of controlled substance dispensed to a 30-day supply, there are no specific federal limits to quantities of drugs dispensed via a prescription. For Schedule II controlled substances, an oral order is only permitted in an emergency situation.

### Refills

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited (Title 21 U.S. Code § 829(a)).

### Issuance of Multiple Prescriptions for Schedule II Substances

DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
2. The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
3. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
4. The issuance of multiple prescriptions is permissible under applicable state laws.
5. The individual practitioner complies fully with all other applicable requirements under the Controlled Substances Act and Code of Federal Regulations, as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

### Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a Schedule II prescription to the pharmacy by facsimile. The original Schedule II prescription must be presented to the pharmacist for review prior to the actual dispensing of the controlled substance.

In an emergency, a practitioner may call-in a prescription for a Schedule II controlled substance by telephone to the pharmacy, and the pharmacist may dispense the prescription provided that the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period. The prescribing practitioner must provide a written and signed prescription to the pharmacist within seven days. Further, the pharmacist must notify DEA if the prescription is not received.

### Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for Schedule II controlled substances. The facsimile of a Schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing Schedule II narcotic controlled substances to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further prescription verification is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing Schedule II controlled substances for residents of Long Term Care Facilities (LTCF) may transmit a prescription by facsimile to the dispensing

pharmacy. The practitioner's agent may also transmit the prescription to the pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy.

3. A practitioner prescribing a Schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent may transmit the prescription to the pharmacy. The practitioner or agent will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription.

### Schedule III-V Substances

A prescription for controlled substances in Schedules III, IV, and V issued by a practitioner, may be communicated either orally, in writing, or by facsimile to the pharmacist, and may be refilled if so authorized on the prescription or by call-in.

### Refills

Schedule III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date on which the prescription was issued. After five refills or after six months, whichever occurs first, a new prescription is required.

### Facsimile Prescriptions for Schedule III-V Substances

Prescriptions for Schedules III-V controlled substances may be transmitted by facsimile from the practitioner or an employee or agent of the individual practitioner to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription.

### Telephone Authorization for Schedule III-V Prescriptions

A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V pursuant to 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.

### Delivery of a Controlled Substance to Persons Outside the U.S.

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in another country. Any such delivery or shipment is a prohibited export under the CSA.

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