



Schedule II Prescriptions



Reminders of Federal Laws

March 19, 2010

Citations of Laws: The federal regulation of the DEA regarding what is required on a prescription is 21 CFR 1306.05(a), originally written in 1971. The Missouri statute regarding what is required on a prescription is Section 195.060.1, RSMo, also enacted in 1971.

What information is required to be documented on a written prescription? *(All of these are essential parts)*

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| Date written | Drug name |
| Patient’s full name | Drug strength |
| Patient’s full address <i>(not a P.O. Box)</i> | Drug form |
| Doctor’s address | Drug quantity |
| Doctor’s DEA number | Directions for use/administration |
| Doctor’s manual signature <i>(stamps, scanning, digital not allowed)</i> | |

Electronic or digital signatures are not allowed:

When a prescription arrives at a pharmacy on paper, the prescription must have been physically and manually signed by the practitioner. A signature cannot be electronic, or added by stamp, computer, copying or adding a digital signature. This is the current federal law. Patients presenting original prescriptions must have original ink signatures. Schedule II prescriptions authorized to be faxed for hospice or long-term care must be manually and physically signed by the doctor and then it may be faxed.

The physician has the primary responsibility:

DEA Regulation 21 CFR 1306.05(a) states that the prescriber has the primary responsibility to insure that prescriptions meet all legal requirements and conform to the mandatory standards. Pharmacies have a secondary and corresponding responsibility.

Pharmacies cannot make any changes to Schedule II prescriptions

In December 2007, the DEA published in the *Federal Register* that “no changes could be made to the essential parts of Schedule II prescriptions, such as drug names, strengths, and quantities. The Missouri BNDD subsequently copied this same information on the BNDD website. Since that time practitioners have been making inquiries over what is considered “essential” and if items such as patients’ addresses or DEA numbers could be amended.

The BNDD called both the DEA Diversion Program Management for the Midwest and also the DEA Liaison and Policy Section at DEA headquarters. When asking about defining the “essential” parts of the prescription, or if any changes could be made, the DEA provided consistent answers.

In the *Federal Register*, when it said “no changes to essential parts” it listed examples such as drug names, strengths and quantities just as an example of some of the essential parts. These items were examples. The DEA said that no changes can be made to any of the essential parts of a Schedule II prescription. A listing of what is considered “essential” is in the federal regulation 21 CFR 1306.05(a). The DEA stated that everything listed is required and essential so pharmacies cannot make any changes at all to the requirements listed in the federal regulation. A list of what is mandatory and essential pursuant to the federal regulation is provided above. According to the DEA the pharmacy cannot make any changes.

21 CFR 1306.05(a) states:

Manner of issuance of prescriptions.

a) All prescriptions 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. In addition, a prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must include the identification number issued by the Administrator under [§1301.28\(d\)](#) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of [§1301.28\(e\)](#). Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g. , J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations. (*April 24, 1971*)

Missouri Statue—195.060.1, RSMo:

Except as provided in subsection 3 of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

These requirements for prescribing and dispensing are set by federal law. The DEA stated that the regulations will remain in effect until a new rule is promulgated or amended.

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