

16 DEPARTMENT OF PUBLIC SAFETY

230 MAINE DRUG ENFORCEMENT AGENCY

Chapter 1: REQUIREMENTS FOR WRITTEN PRESCRIPTIONS OF SCHEDULE II DRUGS

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SUMMARY: The following are rules governing security requirements for all written prescriptions for drugs classified as schedule II drugs under the federal Controlled Substances Act and the Code of Federal Regulations.

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1. Definitions

- A. **Security Prescription Blank.** “Security prescription blank” means a prescription blank that complies with the requirements of section 3 of this rule.
- B. **Schedule II Drug.** “Schedule II drug” has the same meaning as in the federal Controlled Substances Act of 1970, 21 United States Code, Section 812, as amended through the effective date of this Chapter. The United States Code is available at the State Law and Legislative Library, Maine State House, State Street, Augusta, Maine.

2. Requirement of a Security Prescription Blank for Schedule II Drugs

- A. Beginning January 1, 2003, all written prescriptions for schedule II drugs issued by health care providers must be written on a security prescription blank, unless the health care provider has been granted a waiver pursuant to Section 5.
- B. No prescription shall be filled that is not in conformity with these rules.

3. Requirements of a Security Prescription Blank

A prescription for a schedule II drug shall contain the following security features:

- A. A latent “void” pattern shall be printed across the entire width of the front of the prescription blank, such that if a prescription is photocopied the word “void” will appear in a pattern across the entire front of the prescription.
- B. A repetitive watermark shall be printed on the backside of the prescription blank so that it shall only be seen at a forty-five (45) degree angle. The watermark shall

bear the name of the company manufacturing the prescription blank or the word "security."

- C. The prescription blank shall contain a word or symbol printed with ink that disappears if rubbed or scratched briskly.
- D. The prescription blank shall contain a feature that shows obvious tampering if the blank is exposed to erasure or attempted erasure, either through the use of abrasion or chemicals.
- E. The prescription blank shall be four and one-quarter (4 ¼) inches high and five and one-half (5 ½) inches wide.
- F. The prescription shall bear the preprinted, stamped, typed, or manually printed name, address and telephone number of the prescribing health care provider.
- G. The prescription blank shall provide space for the patient's name and address, the health care provider's signature and the health care provider's Drug Enforcement Administration (DEA) registration number.

#### **4. Requirements for completion of written prescriptions for schedule II drugs**

All written prescriptions for schedule II drugs are subject to the following requirements:

- A. In cases of prescriptions where the name of more than one health care provider is pre-printed, the prescription must clearly indicate which health care provider issued the prescription;
- B. The health care provider shall indicate the desired quantity and strength of the drug on the prescription form by both writing out the quantity and by indicating or writing the quantity in numerical form;
- C. Prescriptions may be dispensed upon oral prescription of a health care provider only in emergency circumstances, and shall be promptly reduced to writing and filed by the pharmacy, but need not be written on a security prescription blank. The prescription shall also be reduced to a written prescription on a security prescription blank by the health care provider, and sent to the pharmacy within seven (7) days.
- D. Only one (1) prescription shall be written per prescription blank.

**5. Waiver of requirements for security prescription blank**

- A. A health care provider, pharmacy, printer, reproducer, or distributor of prescription blanks may apply in writing to the Department of Public Safety for a waiver from the requirements for security prescription blanks. A request for waiver shall include:
  - (1) A detailed statement of the security features provided by the system proposed by the applicant for the prevention of forgery or alteration of an original prescription; or
  - (2) A sample of the alternative prescription blank.
- B. The system or prescription blank proposed by the applicant shall provide a level of security substantially equivalent to a security prescription blank.
- C. The Department of Public Safety shall grant or deny the application in writing within 60 (sixty) days after the request is received.
- D. When a waiver has been granted, the Department of Public Safety may suspend or revoke the waiver if the alternative system or alternative prescription blank does not provide security substantially equivalent to a security prescription blank.
- E. The Department of Public Safety shall inform the Board of Pharmacy in writing upon granting or denying such a request for a waiver.

**6. Printers, Reproducers or Distributors of Security Prescription Blanks**

- A. A printer, reproducer or distributor of security prescription blanks shall require a written purchase order or request for security prescription blanks. A written purchase order or request shall remain on file for two (2) years.
- B. A purchase order or request shall be signed by:
  - (1) A health care provider whose name is to be printed on the security prescription blanks; or
  - (2) The chief medical officer of a health care facility, if the security prescription blanks are requested on behalf of a health care provider who stamps, types or manually prints his or her name, address, telephone number and Drug Enforcement Administration (DEA) number on the security prescription blank.

- C. The provisions of this section shall not apply to distributions between printers, reproducers, or distributors.

STATUTORY AUTHORITY: 32 M.R.S.A. §13786-A

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