

To: VSDS Members
From: Peter Taylor

Re: Tamper-Resistant Prescription Drug Pads

We have received a number of requests regarding the Federal Medicaid Law regarding Tamper-Resistant Prescription Drug Pads – Effective April 1, 2008

<http://ovha.vermont.gov/for-providers/tamper-resistant-drug-pads>

While this federal law relates only to Medicaid at this time we anticipate that the Vermont Board of Pharmacy will implement proposed rules in the near future that will also require Tamper Resistant Prescription Forms and that this rule will include pads compliant with the Federal Medicaid regulations <http://vtprofessionals.org/opr1/pharmacists/forms/RXdrafrulesannotated022409.pdf>

VSDS Members are encouraged to review the proposed pharmacy Board rules and prepare for the transition.

Draft 38

Administrative Rules

**February 24, 2009 Vermont Board of Pharmacy
printed February 24, 2009 effective (October 1, 2009)
cite as BOP Rule x.x.**

9.5 Tamper Resistant Prescription Forms

(a) Prescriptions shall be written so as to:

- (1) prevent unauthorized copying of a completed or blank prescription form,
- 2) prevent erasure or modification of information written on the prescription by the prescriber; and
- 3) prevent the use of counterfeit prescription forms.

(b) Handwritten prescriptions must be written on a tamper resistant pad.

(c) Computer generated printed prescriptions must be printed on tamper resistant paper or other tamper proof methods as defined by the Centers for Medicaid and Medicare Services, including micro-printing and/or printing a "void" pantograph accompanied by a reverse "Rx," which causes a word such as "Void," "Illegal," or "Copy" to appear when the prescription is photocopied.

- (d) Prescriptions written which comply with Medicaid rules will satisfy this rule.
- (e) Prescription form features which will satisfy this rule could, for example, include the following properties:
 - (1) a colored background with a watermark;
 - (2) when photocopied read “void” in the background;
 - (3) have printed on the form the name of the prescriber or hospital identification and batch numbering with serially numbered pages for prescriptions;

9.6 Loss of Prescription Pads or Forms Loss of any prescription pads or forms should be immediately reported to local law enforcement officials and the Board of Pharmacy.

19.3.1.2

9.7 Prescriptions Not Hand Written If communicated orally or by way of electronic transmission, the prescription drug order shall be immediately reduced to a form by the pharmacist that may be maintained for the time required by laws or rules.

19.3.1.4

9.8 Schedule II Prescriptions

(a) A prescription drug order for a Schedule II controlled substance may be communicated orally or by way of electronic transmission as permitted by federal law only in the following situations and with the following restrictions. Otherwise, a prescription drug order for a Schedule II controlled substance must be communicated in written form.

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(a) Except as provided below, a prescription drug order for a Schedule II controlled substance must be communicated in written form.

(b) A prescription drug order for a Schedule II controlled substance may be communicated by the practitioner or the practitioner’s agent by way of electronic transmission if permitted by federal law, provided the original written, signed prescription drug order is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in sub-sections (B) or (c) (c), (d) or (e) below in this section. The original, written prescription drug order shall be maintained in accordance with the section below on patient records.

1. (c) A prescription drug order for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be communicated by the practitioner or the practitioner’s agent to the a home infusion pharmacy by way of electronic transmission if permitted by federal law. The A printed hard copy of such electronic transmission serves as the original, written prescription drug order for purposes of this sub-section, and it shall be maintained in accordance with the section below on patient records.

(c) (d) A prescription drug order for a Schedule II controlled substance for a resident of a long term care facility may be communicated by the practitioner or the practitioner’s agent by way of electronic transmission if permitted by federal law. The hard copy of such electronic transmission serves as the original, written prescription drug order for purposes of this subsection, and it shall be maintained in accordance with the section below on patient records.

(e) A prescription drug order for a Schedule II narcotic substance for a resident under hospice care, no matter where provided, may be communicated by the practitioner or the practitioner’s agent by way of electronic transmission as provided by federal law.

- (1) The practitioner or the practitioner's agent must note on the prescription that the patient is a hospice patient.
- (2) The hard copy of such electronic transmission serves as the original, written prescription drug order for purposes of this sub-section, and it shall be maintained in accordance with the section below on patient records.

(D)

(f) In the case of an emergency situation, a prescription drug order for a Schedule II controlled substance may be communicated by the practitioner orally or by way of electronic transmission, provided that:

- (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription drug order signed by the prescribing practitioner);
- (2) The orally communicated prescription drug order shall be immediately reduced to writing by the pharmacist, or, if necessary, the prescription drug order communicated by way of electronic transmission shall be immediately reduced to a hard copy, and either Rules Draft 38 Feb.24, 2009 Page 42 of 84 shall contain the information required above in the sub-section Rule 9.1 above on prescription drug orders;
- (3) If the prescribing practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered legal practitioner, which may include a callback to the practitioner using the practitioner's phone number as listed in the telephone directory or other good faith efforts to insure his the practitioner's identity; and
- (4) Within 72 hours 7 days after authorizing an emergency oral prescription drug order, the prescribing practitioner shall cause a written prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of the sub-section above on prescription drug orders, the prescription drug order shall have written on its face "Authorization for Emergency Dispensing," and the date of the orally or electronically transmitted prescription drug order. The written prescription drug order may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 72-hour 7 day period. Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the emergency oral prescription drug order which had earlier been reduced to writing or to the hard copy of the electronically transmitted prescription drug order. The pharmacist shall notify the nearest office of the U.S. Drug Enforcement Administration if the prescribing practitioner fails to deliver a written prescription drug order.

19.3.1.5 9.9 Electronic Transmission

All prescription drug orders communicated by way of electronic transmission shall:

- (A)** (a) Be transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having access to the prescription drug order. This does not apply to the computer transition systems and persons necessary for the electronic transmission intermediary of prescriptions;
- (B)** (b) Identify Provide the transmitter's phone number for verbal confirmation, the time and date of transmission, and the identity of the pharmacy intended to receive the transmission, as well as any other information required by federal or state law;

(c) (c) Be transmitted by an authorized practitioner or his or her designated agent; and
(D) (d) Be deemed the original prescription drug order, provided it meets the requirements of this sub-section Rule 9.1 herein.

19.3.1.6

9.10 Authorized Agents for Oral Transmission The prescribing practitioner may authorize his agent to communicate a prescription drug order orally or by way of electronic transmission to a pharmacist in a licensed pharmacy, provided that the identity of the transmitting agent is included in the order. The prescribing practitioner may authorize his agent to communicate a prescription drug order

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orally, provided that the identity of the transmitting agent is included in the order.

9.11 Electronic Digital Signatures Required An electronic prescription transmission to a pharmacist in a licensed pharmacy requires the electronic digital signature of the prescriber.

19.3.4 9.12 No Carbon or Duplicate Prescriptions Carbon or duplicate written prescriptions are not valid prescriptions. A written prescription must bear the original signature of the prescriber, not a copy or photo copy or stamp of the signature of the prescriber.

19.3.1.7 9.13 Use of Independent Professional Judgment The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order communicated

by way of electronic transmission consistent with existing federal or state laws and rules.

19.3.1.8 9.14 Security of Electronic Equipment All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained in the pharmacy area so as to ensure against unauthorized access or observation.

19.3.1.9 9.15 Unauthorized Access Persons other than pharmacists, pharmacy technicians, pharmacy interns and others specifically authorized by law those bound by a confidentiality agreement pursuant to Section 5.300 above shall not have access shall have no access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients.

19.3.2 9.16 No prescription for a Schedule II controlled drug shall be filled more than 10 days after issuance of the prescription. **Filling Time Limits, Future Fill Dates**

(a) No prescription for a Schedule II controlled substance written without a future fill date may be filled more than 30 days after the date the prescription was issued.

(b) 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. Each prescription must contain both the original date of issue and the future fill date. For guidance, refer to regulations implementing the federal Controlled Substances Act.

(c) No prescription for a Schedule II controlled substance written to be filled at a future date may be filled more than 90 days after the date the prescription was issued.

19.3.3 9.17 One Year Limit No prescription for a non-controlled drug