



State of Vermont
Office of Vermont Health Access (OVHA)
Pharmacy Benefit Management Program

**Phase II: Federal Medicaid Law Regarding Tamper-Resistant
Prescription Drug Pads – October 1, 2008**

Dear Pharmacy Manager:

This letter contains critically important information regarding compliance with the Medicaid Tamper Resistant Requirements.

- As of October 1, 2008, all handwritten and/or computer-generated printed prescriptions for Medicaid patients must be fully compliant with federal guidance for prescription tamper resistance.

While the first phase of tamper resistance guidance required prescribers to use at least one feature from one category of tamper resistance, this second phase requires that handwritten or computer-generated printed Medicaid prescriptions contain **at least one** industry recognized feature **from each of the three** categories of tamper resistance. Prescriptions for Medicaid patients that are telephoned, faxed or ePrescribed are exempt from these tamper resistance requirements.

- Prior guidance for computer-generated printed prescriptions stated that special copy-resistant paper would likely be required to be in compliance as of October 1, 2008. CMS has clarified this statement and is now stating that while special paper **may** be used to achieve copy resistance, it is **not** necessary. Computer-generated printed prescriptions **may be printed on plain paper** and be fully compliant with all three categories of tamper resistance – provided they contain at least one feature from each of the three categories detailed below.

Review of CMS Requirements for October 1, 2008

By October 1, 2008, a handwritten or computer-generated and printed prescription must contain at least one feature in **all three** categories. No feature may be used twice:

- 1) **Copy Resistance:** One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription.
- 2) **Erasure/Modification Resistance:** One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.
- 3) **Counterfeit Resistance:** One or more industry-recognized features designed to prevent the use of counterfeit prescriptions.

The following best practices have been recommended to prescribers to meet the tamper-resistant requirements (See Appendix I for examples):

Recommended Best Practices for Tamper Resistant Printed Prescriptions

<u>Category 1:</u>	<u>Feature</u>	<u>Description</u>
Copy Resistance	<p>A) Void/Illegal/Copy Pantograph with or without Reverse Rx</p> <p>B) Micro-print signature line for computer-generated printed prescriptions if they cannot produce Void/Illegal/Copy Pantograph with or without Reverse Rx</p>	<p>A) <i>The word “Void,” “Illegal,” or “Copy” appears when the prescription is photocopied.</i></p> <p>B) <i>Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.</i></p>
 <u>Category 2:</u> Erasure / Modification Resistance	<p>A) An Erasure revealing background (resists erasures and alterations) for written prescriptions or printed on “toner-lock” paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions</p> <p> </p> <p>B) Quantity check off boxes, refill indicator (circle number of refills or “NR”), or border characteristics (dispense and refill # bordered by asterisks and optionally spelled out) for computer-generated printed prescriptions</p>	<p><i>Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form.</i></p> <p><i>Toner-lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from inkjet printers is absorbed into normal “bond” paper.</i></p> <p><i>In addition to the written quantity on the prescription, quantities are indicated in ranges.</i></p> <p><i>Quantities and refill # are surrounded by special characters such as an asterisks to prevent modification, e.g. QTY **50**.</i></p>
 <u>Category 3:</u> Counterfeit Resistance	<p>Security features and descriptions listed on the prescription</p>	<p><i>A complete list of the security features on the prescription paper aids pharmacists in identification of features and determining compliance.</i></p>

Appendix 1

Best Practices for Tamper Resistant Printed Prescriptions (Handwritten)

- Category 1** A) Photocopied “COPY”, “ILLEGAL”, or “VOID” Pantograph
- Category 2** A) An Erasure revealing background (resists erasures and alterations)
 B) Quantity check off boxes
 C) Refill indicator (circle number of refills or “NR”)
- Category 3** A) Security features and descriptions listed on the prescription

Appendix 1 (continued)

Front

Void or Copy Pantograph: displays "VOID" or "ILLEGAL" on a color copy of an Rx. It will appear on a wide range of copier settings. (Cat. 1)

SPRINGHAVEN MEDICAL PRACTICE
1234 HEALTH CENTER DRIVE
DAYTON, OH 45408
PHONE 1-937-221-1234 • FAX 1-937-434-5678

JOHN R. SMITH, M.D.
Lic: 123456 • DEA: XX1234567
NPI: 222222222

HELEN C. DOE, M.D.
Lic: 123456 • DEA: XX1234567
NPI: 222222222

PATIENT'S FULL NAME	SEX	DATE OF BIRTH
ADDRESS	DATE	

Rx 00000001

Preprinted Text Fields: Quantity check boxes, refill indicators, and preprinted limitations or guidelines make the Rx harder to modify. (Cat.2)

Heat-sensitive Image: An Rx, logo, or other symbol printed with Thermochromic ink, so the image changes color or disappears when it is rubbed briskly or exposed to warm breath. (Cat. 1 and 3)

TEST AREA Refills 1 2 3 4 _____ DEA #: _____
No Refills Void After _____ **VALID FOR CONTROLLED SUBSTANCES**

PRESCRIBER'S SIGNATURE _____

Back

Chemically-Protected Paper: Invisible coating causes "VOID" or a stain to appear on a handwritten Rx when altered by a wide range of chemicals. Toner receptor coating protects laser-printed Rx data from being removed or altered. (Cat. 2) Recommended for use with Preprinted Text Fields

Security Features List: a prominent display of the prescriptions features, sometimes part of a "Warning Band" or box. (CMS 3)

Heat-sensitive Image: An Rx, logo, or other symbol printed with Thermochromic ink, so the image changes color or disappears when it is rubbed briskly or exposed to warm breath. (CMS 1 and 3)

Pharmacology Aid or Copy Pantograph: displays "VOID" or "ILLEGAL" on a color copy of an Rx. It will appear on a wide range of copier settings. (CMS 1)

Chemically-Protected Paper Coating: causes "VOID" or a stain to appear on a handwritten Rx when altered by a wide range of chemicals. Toner receptor coating protects laser-printed Rx data from being removed or altered. (CMS 2)

Preprinted Text Fields: Quantity check boxes, refill indicators and preprinted limitations or guidelines make the Rx harder to modify. (CMS 2)

Example of a Color Copied Prescription

SPRINGHAVEN MEDICAL PRACTICE
1234 HEALTH CENTER DRIVE
DAYTON, OH 45408
PHONE 1-937-221-1234 • FAX 1-937-434-5678

JOHN R. SMITH, M.D.
Lic: 123456 • DEA: XX1234567
NPI: 222222222

HELEN C. DOE, M.D.
Lic: 123456 • DEA: XX1234567
NPI: 222222222

PATIENT'S FULL NAME	SEX	DATE OF BIRTH
ADDRESS	DATE	

Rx 00000001

1-24
 25-49
 50-74
 75-100
 101-150
 151 and over

TEST AREA Refills 1 2 3 4 _____ DEA #: _____
No Refills Void After _____ **VALID FOR CONTROLLED SUBSTANCES**

PRESCRIBER'S SIGNATURE _____

Hollow Pantograph: VOID or ILLEGAL is designed to not obscure or block vital information. Often showing strongest intensity at the "top" or the document. These pantographs generally do not "pop" on a black and white fax

Appendix I (continued)

Best Practices for Tamper-Resistant, Computer-Generated Printed Prescriptions

Category 1

A) Copy Resistance: Microprint signature line*

Category 2

A) Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)

B) Modification / Erasure Resistance: Printed on “toner-lock” paper for laser printed prescriptions and on plain bond paper for inkjet printed prescriptions

Category 3

A) Counterfeit Resistance: Listing of security features

*Microprint Line viewed at 5x magnification

THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION

Example A

Washington Medical Group
555 Pennsylvania Ave, Washington DC 20001
202-222-2222 (Fax) 202-222-1111

Name Jane Q Public	Date 06/29/2008
Addr 123 Main Street	DOB 07/04/1960
City Washington, DC 20001	Ph: 202-555-5555

HYDROCHLOROTHIAZIDE 12.5 MG CAPS One (1) tab by mouth each morning
Generic: HYDROCHLOROTHIAZIDE

Disp ***30*** THIRTY (2)
Refill ***3*** THREE

Security features: (*) bordered & spelled quantities, microprint signature line visible at 5x or > magnification that must show 'THIS IS AN ORIGINAL PRESCRIPTION' & the description of features (3)

(1) John Smith, MD
NPI# 1111111111

Category #1 – Copy Resistance: Microprint signature line*

Category #2 – Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)

Category #2 – Modification / Erasure Resistance: Printed on “toner-lock” paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions

Category #3 – Counterfeit Resistance: Listing of security features

*Microprint Line viewed at 5x magnification

THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION-THIS IS AN ORIGINAL PRESCRIPTION

Appendix I (continued)

Example B

Washington Medical Group
555 Pennsylvania Ave, Washington DC 20001
202-222-2222 (Fax) 202-222-1111

(1) Rx

Name Jane Q. Public **Date** 06/29/2008
Addr 123 Main Street **DOB** 07/04/1960
City Washington, DC 20001 **Ph:** 202-555-5555

HYDROCHLOROTHIAZIDE 12.5 MG CAPS One (1) tab by mouth each morning
Generic: HYDROCHLOROTHIAZIDE
Disp ***30*** THIRTY (2)
Refill ***3*** THREE

Security features include: (*) bordered and spelled quantities, a void pantograph and reverse Rx (when copied - the prescription will say "COPY" and the "Rx" in the upper right corner will NOT be visible), and this description of features. (3)

John Smith, MD
NPI# 1111111111

Category #1 – Void/Illegal/Copy Pantograph with or without Reverse Rx

Category #2 – Modification / Erasure Resistance: Border characteristics (dispense and refill # bordered by asterisks AND spelled out)

Category #2 – Modification / Erasure Resistance: Printed on “toner-lock” paper for laser printed prescriptions, and on plain bond paper for inkjet printed prescriptions

Category #3 – Counterfeit Resistance: Listing of security features

Appendix II

Summary of features that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines

Category 1 – Copy Resistance: One or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription form.	
Feature	Description
“Void,” “Illegal,” or “Copy” pantograph <u>with or without</u> Reverse “Rx”	<p>The word “Void,” “Illegal,” or “Copy” appears when the prescription is photocopied. Except where state law mandates the word “Void” or “Illegal” – it is recommended that the pantograph show the word “Copy” if the prescription is copied. The pantograph should be configured so as not to obscure the security feature description contained on the prescription, the patient and prescriber demographics, or the medication and directions.</p> <p>Some pantographs can be problematic because when the prescription is copied, the resulting “void” or other wording that appears makes the underlying prescription difficult to read. This type of pantograph should be avoided. We suggest that you ask your pad vendor about hollow “VOID” pantograph lettering which is less likely to obscure the prescription information.</p> <p>The Reverse Rx disappears when copied at a light setting – thus making the pantograph more effective in copy resistance. The pantograph may be used with a reverse Rx, but Reverse Rx is not effective as a feature by itself.</p>
Micro printing – To be effective, this feature must be printed in 0.5 font or less making it illegible to the pharmacist when copied	Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.
Thermochromic ink	Ink changes color with temperature change.
Coin-reactive ink	Ink changes color when rubbed by a coin.
<u>Watermarking</u> Security back print (artificial watermark)	Printed on the back of prescription form. The most popular wording for the security back print is “Security Prescription” or the security back print can include the state’s name. Can only be seen when viewed at an angle.
Digital watermarks	Weak digital watermarks cannot be read if copied and strong digital watermarks provide digital rights management/“proof” of origin when copied.
Watermarking on special paper	Special paper contains a watermark that can be seen when backlit.

Appendix II (continued)

Category 2 – Erasure / Modification Resistance: One or more industry-recognized features designed to prevent the erasure or modification of information written / printed on the prescription by the prescriber.

Features to Prevent Erasure	Description
An erasure revealing background (erasure resistance)	Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase, the consistent background color will look altered and show the color of the underlying paper.
Toner Receptor Coating / Toner Lock or Color Lock paper (erasure resistance for computer generated prescriptions <u>printed with a laser printer</u>) OR Chemically reactive paper (erasure resistance for hand written prescriptions)	Special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. Note – this is NOT necessary for inkjet printers – as the ink from inkjet printers is absorbed into normal “bond” paper. If exposed to chemical solvents, oxidants, acids, or alkalis that can be used to alter the prescription, the chemically reactive paper will react and leave a mark visible to the pharmacist.
Features to Prevent Modification	Description
Quantity check off boxes and refill indicator (circle or check number of refills or “NR)	In addition to the written quantity on the prescription, quantities are indicated in ranges. It is recommended that ranges be 25’s with the highest being “151 and over”. The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. The refill indicator indicates the number of refills on the prescription. Refill numbers must be used to be a valid prescription.
Pre-printed language on prescription paper Example: “Rx is void if more than XXX Rx’s on paper”	Reduces ability to add medications to the prescription. Line must be completed for this feature to be valid. Computer printer paper can accommodate this feature by printing, “This space intentionally left blank” in an empty space or quadrant.
Quantity and Refill Border and Fill (this is the recommended for computer generated prescriptions)	Quantities and refill # are surrounded by special characters such as an asterisks to prevent modification, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional).

Please note that while ONLY one feature from this Category 2 is required, it has been strongly recommended that one feature of erasure resistance and one feature of modification resistance be used. Inkjet printed prescriptions are de-facto erasure resistant based on the characteristics of inkjet ink.

Appendix II (continued)

Category 3 – Counterfeit Resistance: One or more industry-recognized feature designed to prevent the use of counterfeit prescription forms.	
Feature	Description
Security features and descriptions listed on prescriptions – this feature is <u>strongly</u> recommended on all prescriptions	Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.
Thermochromic ink	Ink changes color with temperature change.
State Approved Vendor ID	This feature is only effective in states with an approved vendor listing. Not applicable in Vermont.
Serial number	Number issued by printer of prescription or uniquely assigned by electronic medical record (EMR) or ePrescribing software; may or may not be sequential. Only valid if reported and tied to the pharmacy claim adjudication process. NY is the only state that has this system currently in place. Not applicable in Vermont.
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code. Not applicable in Vermont.
Security Thread	Metal or plastic security threads embedded in paper as used in currency.

Appendix III

FREQUENTLY ASKED QUESTIONS CONCERNING THE TAMPER-RESISTANT PRESCRIPTION LAW

Retroactive Eligibility:

Sometimes a person becomes eligible for Medicaid benefits after he or she has submitted a written prescription to a pharmacy and has had the pharmacy fill the prescription. In these retroactive eligibility situations, the recipient often will return to the pharmacy and present evidence of eligibility in order to get reimbursed by the pharmacy for whatever money the recipient previously paid the pharmacy to fill the prescription. Many have asked whether in order to submit a claim to Medicaid the pharmacy must obtain a compliant prescription.

Q: When it is determined that a Medicaid recipient is retroactively eligible for Medicaid and the recipient's original written prescription was filled during a period when the recipient is now deemed to have been Medicaid eligible, must the pharmacy, prior to submitting a claim to Medicaid, obtain a tamper-resistant written prescription, a verbal order, a faxed prescription, or an e-prescription prior to submitting a claim to Medicaid?

- A: When a Medicaid recipient is retroactively eligible for Medicaid after a pharmacy has already filled the recipient's prescription, CMS will presume that the prescription was compliant with section 7002(b), unless there is evidence that the prescription was non-compliant. This presumption applies to the filling of the prescription that occurred *before* the recipient became retroactively eligible for Medicaid. This presumption does *not* extend to any refills that occurred *after* the date on which the recipient is determined to be eligible for Medicaid. Such refills require that the pharmacy obtain a new, tamper-resistant prescription in compliance with section 7002(b). Alternatively, the pharmacy may obtain verbal confirmation of the prescription from the prescriber or may obtain the prescription from the prescriber by facsimile or e-prescription.

Emergency Prescription Fills

- Q: May the pharmacy provide the full prescription to the patient in the emergency fill situation, or must the pharmacy only provide a 72-hour supply?
- A: The pharmacy may provide the full prescription to the patient in the emergency fill situation, so long as the pharmacy obtains a compliant prescription in writing, or by telephone, fax, or e-prescription, within 72 hours.

Drug Orders in Certain Institutional Settings

CMS has received many questions about drugs prescribed in institutional settings that are ordered by way of drug orders written in patient charts or in other written formats, where these orders are not written on prescription pads.

- Q: Must a written order provided in an institutional setting described in section 1927(k)(3), and separately reimbursed by Medicaid, that is written into the medical record and conveyed by medical staff to a pharmacy be executed on a tamper-resistant prescription pad?
- A: CMS has concluded that a written order prepared in an institutional setting where the doctor or medical assistant writes the order into the medical record and then the order is given by medical staff directly to the pharmacy is considered "tamper resistant," so long as the patient never has the opportunity to handle that written order.

Prescriptions for Controlled Substances

- Q: Federal law and many State laws require that all prescriptions for Schedule II controlled substances be written. If a non-tamper-resistant, controlled-substance prescription that complies with Federal and State law is presented to a pharmacy, may the pharmacy obtain verbal confirmation from the prescriber in order to satisfy the tamper-resistant requirement?
- A: Yes. As long as the Schedule II requirements are satisfied, tamper resistance can be satisfied through any of the following methods: through a prescription that is transmitted verbally, sent by facsimile, or sent through an e-prescription, or is written on compliant, tamper-resistant prescription pad.

Physician-Provided Drugs

In many cases physicians provide prescription drugs directly to patients (e.g., via samples).

- Q: If the prescriber provides a drug directly to a Medicaid recipient, is a tamper-resistant prescription required?

A: No.

Communication between Physician/Prescriber and Pharmacy

The requirement for tamper resistance does not apply to non-written prescriptions, that is, it does not apply to: e-prescriptions; prescriptions transmitted to the pharmacy by facsimile; and prescriptions communicated to the pharmacy by telephone.

Q: Does the physician/prescriber have to be the individual who transmits a non-written prescription to a pharmacy?

A: No. A nurse or administrative staff person who is authorized to act on the prescriber's behalf may phone the pharmacy the order, send the order by facsimile, or electronically transmit the order to the pharmacy.

Q: Will the action of a pharmacist calling back a physician/prescriber and making appropriate documentation on the original, non-compliant written prescription make the prescription compliant for purposes of a subsequent Medicaid audit?

A: Yes. Documentation by the pharmacy of verbal confirmation of a non-compliant written prescription satisfies the requirements of the law.

Prescription Transfers between Pharmacies

Q: When Pharmacy # 1 transfers a tamper-resistant prescription to Pharmacy # 2 to be filled, will a facsimile or telephone call from Pharmacy # 1 to Pharmacy # 2 satisfy section 7002(b), or must Pharmacy # 2 obtain direct confirmation from the physician/prescriber?

A: Pharmacy # 2 need only obtain a phone call or a facsimile from Pharmacy # 1 in order to confirm the authenticity of the tamper-resistant prescription that was previously delivered to Pharmacy # 1. There is no need for Pharmacy # 2 to obtain direct confirmation of the original prescription from the physician/prescriber.

Ink Pens for the Erasure or Modification of Information on a Prescription

Q: Does the requirement of the use of an ink pen satisfy the second characteristic set forth on page two of the SMD Letter (i.e., a feature that "prevent[s] the erasure or modification" of information on a prescription)?

A: No, it does not. Ink can be erased and modified, and in part for those reasons, the use of an ink pen is not an industry recognized standard.

When a Prescriber Continues to use Non Tamper-Resistant Prescription Pads

Q. What should pharmacy staff do when a prescriber continues to use non tamper-resistant prescription pads/paper repeatedly after October 1, 2008?

A. Pharmacy staff may request that OVHA provide educational assistance to prescribers by filling out the request form on the following page and faxing it to OVHA.

Tamper-Resistant Prescriptions Provider Compliance Referral Form

Section 7002(b) of the Social Security Act states that payment shall not be made for “--- amounts expended for medical assistant for covered outpatient drugs (as defined in section 1972(k)(2) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad.” This provision becomes effective on April 1, 2008 and applies to all outpatient drugs including over-the-counter drugs. The law is applicable regardless of whether Medicaid is the primary or secondary payor of the prescription filled.

Upon Request, the Office of Vermont Health Access will provide educational interventions for those providers continuing to use non tamper-resistant prescription pads. To request educational assistance, complete this form and fax it to OVHA at the number listed below. Specific questions about this form should be directed to the OVHA Pharmacy Unit at 1-802-879-5900.

Please fax completed form to 1-802-879-5919.

Submitting pharmacy should provide the following information for non-compliant prescribers
(* denotes required information)

Prescriber Name * _____

NPI Number * _____ Phone (____) _____

Address _____

Prescriber Name * _____

NPI Number * _____ Phone (____) _____

Address _____

Prescriber Name * _____

NPI Number * _____ Phone (____) _____

Address _____

Prescriber Name * _____

NPI Number * _____ Phone (____) _____

Address _____

Prescriber Name * _____

NPI Number * _____ Phone (____) _____

Address _____

Submitting Pharmacy * _____ **Date** _____

NPI # * _____ **Phone** (____) _____