



July 17, 2008

Dear Medicaid Director:

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

- **As of October 1, 2008, all fee-for-service Medicaid prescriptions that are either handwritten or printed from an EMR / ePrescribing application must contain at least one feature from each of the three categories of tamper resistance (see below for details). Note – the tables below contain updated guidance from the NCPDP and CMS – so your previously issued guidance may need to be updated.**
- **CMS' prior guidance for printed prescriptions generated from EMRs or ePrescribing applications stated that special copy resistant paper would likely be required for printed prescriptions 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. EMR or ePrescribing generated 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.**

As of October 1, 2008, the second phase of the CMS tamper-resistant prescription law takes effect, and will require that all handwritten and/or computer generated (by an EMR or ePrescribing applications) printed prescriptions for fee-for-service Medicaid patients be fully compliant with federal and/or state 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 these handwritten or computer 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 remain exempt from these tamper resistance requirements.

On June 26, 2008, the National Council for Prescription Drug Programs (NCPDP) held an industry forum in an effort to review the implementation of the 2nd phase of the CMS tamper-resistant regulations and to discuss next steps necessary to ensure a smooth transition into the second phase of implementation on October 1. All segments of industry impacted by the Federal legislation were invited and participated including State Medicaid pharmacy administrators, National Association of State Medicaid Directors (NASMD), pharmacy associations, medical associations, CMS, printers of tamper resistant pads/paper, and the Physicians' EHR Coalition and the EHR Vendors' Association.

As a result of this meeting, industry standards for copy, erasure/modification, and counterfeit resistance have been clarified. If you issued specific guidance for your state based on the prior guidelines – please verify that your previously issued guidelines do not require further revision.

Also, CMS had previously stated that prescriptions printed from EMRs or ePrescribing applications would likely need special copy resistant paper to be in compliance as of October 1, 2008. CMS is now clarifying that guidance, based on its awareness of improved printing capabilities, and is now stating that while special paper may be used to achieve copy resistance, it is not a requirement. EMR or ePrescribing generated prescriptions may be printed on plain paper and be fully compliant with all three categories of the tamper-resistant regulations provided they contain at least one feature from each of the three categories detailed below.

Review of CMS Requirements

Currently, a handwritten or computer generated prescription must contain a feature in at least one of the following three characteristic categories to be compliant. By October 1, 2008 handwritten or printed prescriptions must contain a feature within **all three** categories. While the law specifies the term “prescription pad”, CMS stated that these requirements also apply to computer-generated prescriptions that are printed using paper inserted into the printer. No one feature may be counted twice.

- 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form
- 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber
- 3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms

For more information about the tamper resistant requirements, visit www.cms.hhs.gov/deficitreductionact/20_govinfo.asp

As determined by the industry forum, the following best practices are strongly suggested for adoption to meet the tamper-resistant requirements (See Appendix I for examples):

Best Practices for Tamper Resistant Printed Prescriptions

Category 1:	Feature	Description
Copy Resistance	<p>A) Void/Illegal/Copy Pantograph with or without Reverse Rx</p> <p>B) Micro print signature line for prescriptions generated by an EMR if they cannot produce Void/Illegal/Copy Pantograph with or without Reverse Rx</p>	<p><i>The word “Void,” “Illegal,” or “Copy” appears when the prescription is photocopied.</i></p> <p><i>Very small font which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied.</i></p>
Category 2:		
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>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 prescriptions generated by an EMR</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>
Category 3:		
Counterfeit Resistance	A) Security features and descriptions listed on the prescription	<i>A Complete list of the security features on the prescription paper aids pharmacists in identification of features and determine compliance.</i>

We strongly suggest that guidance be released no later than **August 15, 2008** in order to ensure that physicians and pharmacies have ample time to prepare for the October 1 implementation date. CMS has determined that states listed below, with the exception of Idaho, which had tamper-resistant prescription programs in place prior to the passage of the law are all in compliance with the October 1 deadline. Nevertheless, we are encouraging those states to revisit their guidance, as it may be incorrect or irrelevant for printed prescriptions from EMRs or ePrescribing applications. For your reference, a copy of the standards for each of the following states is attached as Appendix II.

California	Maine
Florida	New Jersey
Idaho ¹	New York
Indiana	Texas
Kentucky	Wyoming

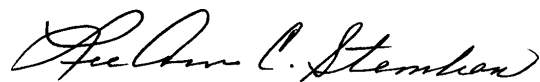
Appendix III summarizes features that could be used on a tamper-resistant prescription in compliance with the CMS guidelines to meet the requirements for October 1. They are categorized according to the three types of tamper-proof features described by CMS. **We would like to draw your attention to the first feature that falls into the third CMS Category of Counterfeit Resistance above.** The pharmacy community, as represented by the APhA, NACDS and NCPA strongly believe that while any feature in this category would satisfy CMS requirements for counterfeit resistance, that this listing of security features on every prescription should be required because it ALSO greatly assists pharmacists in identifying tamper resistant prescriptions, and thus should be a common feature for all prescriptions that require tamper resistance.

NCPDP and the other members of the industry forum encourage those states that have not issued guidance for the October 1 implementation date to publish your requirements no later than **August 15, 2008** so that providers have sufficient time to order fully compliant prescription pads, and that EMR and ePrescribing vendors have sufficient time to modify their prescription templates or prescription printing processes – such that they are also fully compliant with the October 1 deadline.

In addition to this guidance, we have created a template letter for you to use when communicating this information to your prescriber community. You are encouraged to modify this letter with your state specific requirements.

If you have any additional questions or concerns, please contact Michele Vilaret at mvilaret@nacds.org or Peter Basch at Peter.Basch@Medstar.net.

Respectfully,



Lee Ann Stember
President, NCPDP

cc:
American College of Physicians
American Pharmacists Association
Centers for Medicare & Medicaid Services
Computer Sciences Corporation
JenKare, LLC
HP Labs
LexMark International

¹ Because it only requires a feature to prevent copying, Idaho's current program complies only with the first stage of the implementation process.

Medical Group Management Association
MedStar Health
NASMD/APHSA
National Association of Chain Drug Stores
National Community Pharmacists Association
National Council for Prescription Drug Programs
NextGen Healthcare/EHRVA
North Carolina Medicaid
Promex Group- Medi Scripts Services
Rite Aid Corporation
Standard Register
SXC Health Solutions
Walmart Health & Wellness
Wyoming Department of Health

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 I (continued)
Best Practices for Tamper Resistant Printed Prescriptions (Handwritten)

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)

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

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: 2222222222

HELEN C. DOE, M.D.
 Lic: 123456 • DEA: XX1234567
 NPI: 2222222222

PATIENT'S FULL NAME	SEX	DATE OF BIR
ADDRESS	DATE	

Rx 00

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

PRESCRIBER'S SIGNATURE _____

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

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)

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. (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: 2222222222

HELEN C. DOE, M.D.
 Lic: 123456 • DEA: XX1234567
 NPI: 2222222222

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

PRESCRIBER'S SIGNATURE _____

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

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 Printed Prescriptions (Generated by an EMR)

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: (1) 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

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

Name Jane Q. Public
Addr 123 Main Street
City Washington, DC 20001

Date 06/29/2008
DOB 07/04/1960
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

Category #3 – Counterfeit Resistance: Listing of security features

Appendix II

Tamper-Resistant Prescription Pad Security Features Required by States Prior to April 1, 2008

State	Security Features
California	Prescription pads must be printed from approved vendors only. ¹ “Void” pantograph, security prescription watermark, chemical void protection, area of opaque writing, quantity check boxes with units, printed on security paper, security back printing, listing of security features, thermo chromatic ink, batch numbering, separate vendor ID, sequential numbering starting at 0001 at each new order. ¹
Florida	Prescription pads must be printed from approved vendors only. “Void” or “Illegal” pantograph (green or blue), erasure safe paper, background ink that resists reproduction, watermarked paper, security feature listing (face or back), batch number which includes vendor ID, physicians license verification required by vendor.
Idaho²	Non-copyable paper ONLY ¹
Indiana	“Void” pantograph (blue), Security Back print, quantity check boxes, refill quantity and “void after” wording, one prescription per form, dispense as written/may substitute wording. ¹
Kentucky	“Void” pantograph (green), Security Back print, quantity check boxes, refill quantity and “void after” wording, one prescription per form, dispense as written/may substitute wording. ¹
Maine	“Void” pantograph, repetitive watermark on backside, thermo chromatic ink, list of security features. ¹
New Jersey	Prescription pads must be printed from approved vendors only. State seal on face and back for pantograph, “Rx” graphic on face, blue face with black imprint, green back, batch number which includes vendor ID, 8 standard formats, pre-printed batch number, physicians license verification required by vendor, shipment log by vendor, prescription blanks for each prescriber or health care facility must be numbered consecutively.
New York	“Void” pantograph, thermo chromatic ink, diagonal lines, micro fine printing, serial number and bar code.
Texas	“Void” pantograph, thermo chromatic ink, erasure safety paper, security features listed, control number.
West Virginia	“Void” pantograph (green), Security Back print, quantity check boxes, refill quantity and “void after” wording, one prescription per form, dispense as written/may substitute wording. ¹
Wyoming	Prescription pads must be printed from approved vendors only. ¹ “Void” Pantograph, erasure protection on a colored background, security features listed, physician license verification by vendor. ¹

¹ For controlled substances only.

² Because it only requires features to prevent copying, Idaho’s current program complies only with the first stage of the implementation process.

Appendix III

Summary 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 with or without 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 paired 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) Digital watermarks Special paper watermarking	<p>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 states name. Can only be seen when viewed at an angle.</p> <p>Weak digital watermarks cannot be read if copied and strong digital watermarks provide digital rights management/“proof” of origin when copied.</p> <p>Uses special paper containing a watermark that can be seen when backlit.</p>

Appendix III (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 is 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 III (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.
Serial number	Number issued by printer of prescription or uniquely assigned by 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.
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.
Security thread	Metal or plastic security threads embedded in paper as used in currency.