February 1, 2008

Dear Medicaid Director:

This letter is a follow up to a previous letter sent to State Medicaid Directors on January 2, 2008, by 90 state and national pharmacy and medical associations.

On January 16, 2008, the National Council for Prescription Drug Programs (NCPDP) held an industry forum in an effort to bring conformity to State-issued guidelines regarding Federal legislation on Tamper-Resistant Prescription Pads. The CMS guidelines are broad enough to allow states considerable flexibility but it leaves states with the challenge of deciding how exactly they wish to meet the Federal guidelines. Conformity among states is important to insure broad compliance and to facilitate the processing of prescriptions across State lines.

All segments of industry impacted by the Federal legislation were invited and participated including State Medicaid pharmacy administrators, NASMD, pharmacy associations, medical associations, CMS, and printers of tamper resistant pads.

As you know, a requirement that Medicaid prescriptions be written on tamper-resistant pads/paper will be phased in, beginning on April 1, 2008, with prescriptions required to have, at a minimum, a single tamper-resistant feature. On October 1, 2008, prescriptions will be required to have a minimum of one feature from all three CMS categories of tamper resistant features. Like you, we want to ensure that Medicaid recipients will obtain needed medication after April 1, 2008 and ensure that the transition to these new prescription requirements is as smooth as possible for recipients, pharmacists and physicians.

CMS reported that they have recently provided clarification to several state Medicaid programs about certain specific tamper-resistant prescription features and whether those features will comply with the statue and CMS guidance. States have had specific questions about whether a provider can add a feature to a prescription to make it compliant with the requirements. States have proposed various features including particular kinds of ink to write the prescription (gel or indelible); writing out the drug quantities rather than just the number (i.e. thirty vs. 30); and embossed logos. The statute states that all written prescriptions must be "executed on a tamper-resistant pad." As a result CMS has determined that features added to the prescription after they are printed do not meet the requirement of the statute. Features that would make the prescription tamper-resistant include certain types of paper as well as certain items that can be pre-printed on the paper.

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CMS further clarified that computer generated prescriptions printed by a provider on plain paper, including Electronic Medical Record (EMR) computer generated prescriptions, may meet CMS guidance by containing one or more industry-recognized features designed either to prevent the erasure or modification of information contained on the prescription, or to prevent the use of counterfeit prescription forms. However, based on CMS' understanding of current prescription security technology, they do not believe that computer generated prescriptions printed by a prescriber on plain paper will be able to meet the requirement that prescriptions contain one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form. Therefore, beginning October 1, computer generated prescriptions must be printed on paper that meets that requirement. Examples of features designed to prevent unauthorized copying of a completed or blank prescription form can be found under the first category of features included in this document.

States are in the process of establishing requirements that physicians should employ to comply with the statute. To that end, we are writing to provide a summary of the features that the focus group agreed were successful in states with existing tamper-resistant requirements, least costly and most implementable within the timeframes required. Please note that CMS has reviewed and says that states which had tamper-resistant prescription pad programs in place prior to the passage of the law are all in compliance. However, states may need to further clarify requirements for computer-generated prescriptions printed from a physician practice management system or electronic medical record (EMR).

Review of CMS Requirements

By April 1, 2008 a prescription pad/paper must contain a feature within **at least one** of the following three characteristic 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.

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

By October 1, 2008, a prescription pad/paper must contain at least one feature in each of the **three** categories above. However, the focus group would like to recommend that states encourage physicians to be cognizant of all three categories by April 1, 2008, to eliminate the potential of wasted prescription pads/paper.

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

In developing our recommendations, we reviewed the requirements of the following states, which have already been deemed acceptable. 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	Wyoming
Kentucky	

The remainder of this letter summarizes features that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines within the timeframe required. They are categorized according to the three types of tamper-proof features as described by CMS. Features in **bold** tend to be less costly and easier for physicians to implement than the other features. The American Pharmacist Association (APhA), National Association of Chain Drug Stores (NACDS) and National Community Pharmacist Association (NCPA) believe that the features in *italics* are difficult for pharmacies to verify and would likely not be effective as state requirements.

Category 1 - One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form**.**	
Feature	**Description**
"Void" or "Illegal" pantograph	**The word "Void" appears when the prescription is photocopied. Due to the word "Void" on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.**
Reverse "RX" or White Area on prescription	"Rx" symbol or white area disappears when photocopied at light setting. This feature is normally paired with the "Void" pantograph to prohibit copying on a light setting.
Coin-reactive ink	Ink that changes color when rubbed by a coin – Can be expensive and is not recommended.
Security Back print	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.
Watermarking (forderiner)	Special paper containing "watermarking".
Diagonal lines (patented "Void")	Diagonal lines with the word "void" or "copy". Can be distracting or expensive.
Micro printing	Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

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

Category 2 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.	
Feature	**Description**
Uniform non-white background color	**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 or copy, the consistent background color will look altered and show the color of the underlying paper.**
Quantity check off boxes	**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. See illustration in Appendix 1.**
Refill Indicator (circle or check number of refills or "NR")	**Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.**
Pre-print "Rx is void if more than___ Rxs on paper" on prescription paper	**Reduces the ability to add medications to the prescription. - Line must be completed for this feature to be valid. Reduces the ability to add medications to the prescription. Computer printer paper can accommodate this feature by printing "This space intentionally left blank" in an empty space or quadrant.**
Quantity Border and Fill (for computer generated prescriptions on paper only)	**Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional)**
Refill Border and Fill (for computer generated prescriptions on paper only)	**Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional)**
Chemically reactive paper	**If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.**
Paper toner fuser	Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.
Safety or security paper with colored pattern	White (or some other color) mark appears when erased. This is expensive paper.

Category 3 - One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.	
Feature	**Description**
Security features and descriptions listed on 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.**
Form Batch Numbers	Each batch of prescriptions has a unique identifier. This feature is only effective in states with an approved vendor listing.
Serial number	Number issued by printer of prescription, may or may not be sequential. To be valid, this should be reported to the state. New York after several years now is tracking numbers electronically.
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.
Logos	Sometimes used as part of the background color or pantograph.
Metal stripe security	Metal stripe on paper, difficult to counterfeit.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.
Invisible fluorescent fibers/ink	*Visible only under black light.*
Thermo chromic ink	*Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.*
Holograms that interfere with photocopying	*May interfere with photocopying or scanning.*

We would like to draw your attention to the first feature that falls into the third CMS Category above. **The pharmacy community, as represented by the APhA, NACDS and NCPA strongly believe that it would be helpful if each state included, as a required feature, a listing of the security features of the prescription. This feature helps the pharmacist identify that this is a tamper-resistant prescription.**

NCPDP and the other members of the industry forum encourage those states that have not issued guidance to publish your requirements as soon as possible so that providers have time to order paper. We also respectfully request states implement features from those listed in bold above.

If your have any additional questions or concerns, please contact Michele Vilaret at mvilaret@nacds.org or Cathy Graeff at cgraeff@ncpdp.org.

Respectfully,

Lee Ann Stember
President, NCPDP

cc:
American Medical Association
American Pharmacists Association
Centers for Medicare & Medicaid Services
Computer Science Corporation
EDS-Government Solutions
HIMSS EHR Vendors Association
Medco
Medical Group Management Association
MedStar Health
NASMD/APHSA
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Community Pharmacists Association
National Council for Prescription Drug Program
NCSL
National Governors Association
North Carolina Division of Medical Assistance
State of Mississippi Division of Medicaid
Printco Incorporated
TennCare Pharmacy Program
Virginia Medicaid
West Virginia Bureau for Medical Services
Wyeth Pharmaceuticals
Wyoming Department of Health

<u>Appendix 1</u>
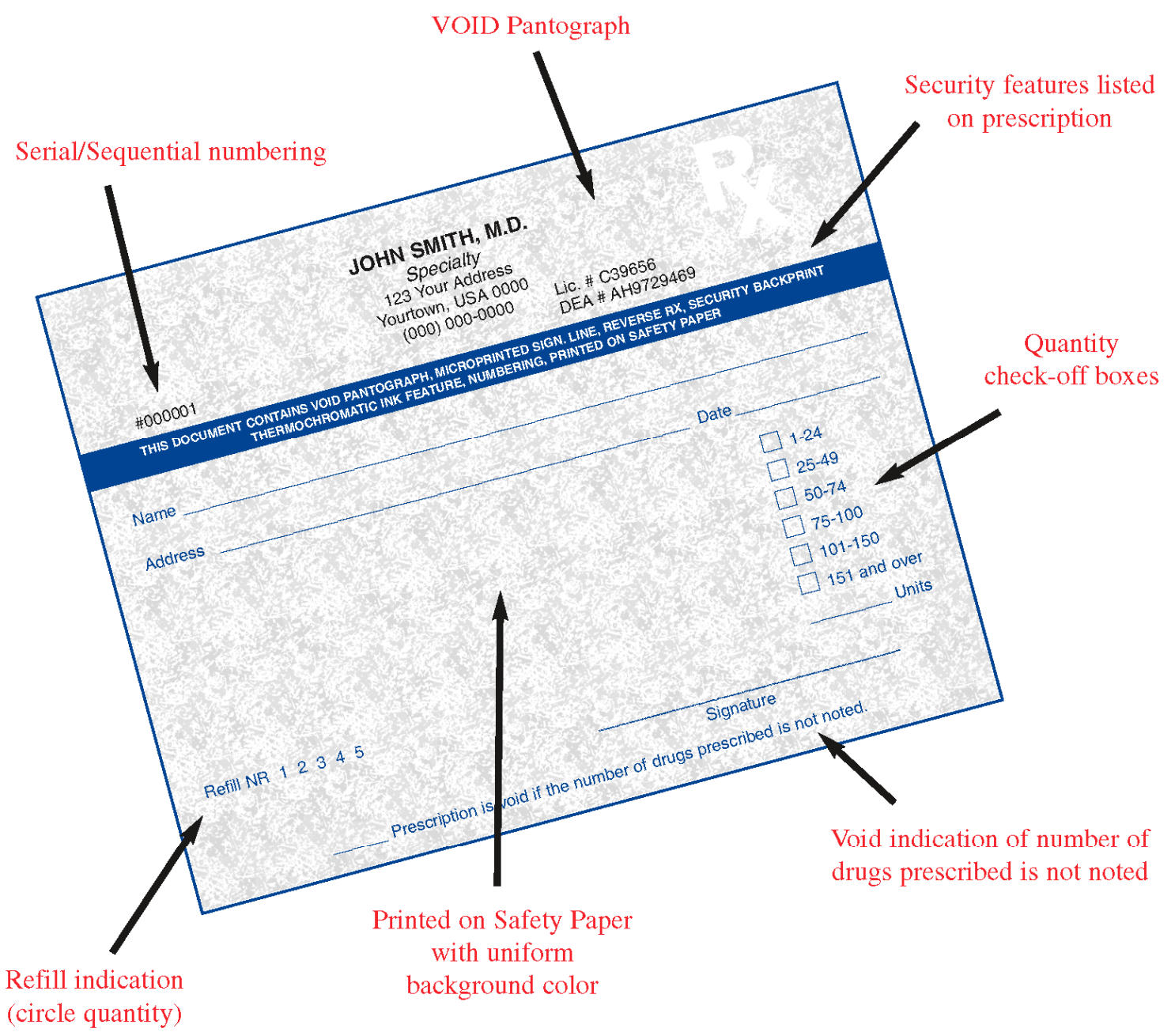**<u>Sample Tamper-Resistant Prescription Pad</u>**

The attached Appendix 1 Prescription Pad has the following recommended security features:

- "Void" Pantograph
- Numbering (serial number)
- Printed on Safety Paper with uniform background color
- Quantity check-off boxes
- Security features listed on prescription
- Refill indication (circle quantity)
- Void indication of number of drugs prescribed is not noted

Appendix 1
Sample Tamper-Resistant Prescription Pad
With Recommended Features

VOID Pantograph

Security features listed on prescription

Serial/Sequential numbering

Quantity check-off boxes

JOHN SMITH, M.D.
Specialty
123 Your Address
Yourtown, USA 0000
(000) 000-0000

Lic. # C39656
DEA # AH9729469

THIS DOCUMENT CONTAINS VOID PANTOGRAPH, MICROPRINTED SIGN. LINE, REVERSE RX, SECURITY BACKPRINT
THERMOCHROMATIC INK FEATURE, NUMBERING, PRINTED ON SAFETY PAPER

#000001

Date _____

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

Units _____

Name _____

Address _____

Signature _____

Refill NR 1 2 3 4 5

Prescription is void if the number of drugs prescribed is not noted.

Void indication of number of drugs prescribed is not noted

Refill indication
(circle quantity)

Printed on Safety Paper
with uniform
background color

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. "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.
Florida	Prescription pads must be printed from approved vendors only. "Void" pantograph (green or blue), erasure safe paper, background ink that resists reproduction, security feature listing (face or back), batch number which includes vendor ID, physicians license verification required by vendor.
Idaho[2]	Non-copyable paper ONLY
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.
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.
Maine	"Void" pantograph, repetitive watermark on backside, thermo chromatic ink, list of security features.
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, may be serialized at the prescriber's request.
New York	"Void" pantograph, thermo chromatic ink, diagonal lines, micro fine printing, serial number and bar code.
Wyoming	Prescription pads must be printed from approved vendors only. "Void" Pantograph, erasure protection on a colored background, security features listed, physician license verification by vendor.

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