PURPOSE:

The purpose of this bulletin is to remind providers enrolled in the Medical Assistance (MA) Program that on and after October 1, 2008, prescriptions for outpatient drugs for MA recipients must be on tamper resistant prescription pads/paper that have at least one feature from each of the three Federally defined categories of tamper resistance. No one feature may be counted twice.

SCOPE:

This bulletin applies to all prescribers and pharmacies enrolled in the MA Program who write and receive written outpatient drug prescriptions for MA recipients in the Fee-for-Service delivery system, including ACCESS Plus.

BACKGROUND/DISCUSSION:

Section 7702(b) of the U.S. Troop Readiness, Veteran’s Health Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (P.L. 110-28), amended Section 1903(i) of the Social Security Act (the Act), 42 U.S.C. § 1396b(i), by adding new subparagraph (23). The amendment requires that prescriptions for covered outpatient drugs be written on a tamper resistant prescription pad/paper in order to be eligible for MA payment. The requirement applies to written prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs, including over-the-counter drugs, presented for payment in the Fee-for-Service delivery system, including ACCESS Plus. It does not apply to written prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs presented for payment in the managed care delivery system.

On September 29, 2007, President George W. Bush signed the “Transitional Medical Assistance, Abstinence Education and QI Programs Extension Act of 2007”, Public Law 110-90, which postponed the October 1, 2007 implementation date for requiring that written...
prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs be on tamper resistant prescription pads/paper. Under the new law, effective with dates of service on or after April 1, 2008, all written outpatient prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs, including prescriptions for over-the-counter drugs, for MA recipients in the Fee-for-Service delivery system, including ACCESS Plus, were to be on tamper resistant prescription pads/paper that had at least one feature from one of the three Federally defined categories of tamper resistance.

This requirement applies to written prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs for all MA recipients in the Fee-for-Service delivery system, including:

- Medicare recipients (“dual-eligibles”) for those drugs covered by the MA Program and not covered by Medicare Parts B or D;
- MA recipients in HealthChoices Behavioral Health managed care organizations, if the prescription is paid by the Fee-for-Service delivery system;
- MA recipients with primary private insurance, whose outpatient prescription drugs are paid by the Fee-for-Service delivery system;
- MA recipients being discharged from a nursing facility when the MA Program pays for the prescribed drugs on an outpatient payment basis in the Fee-for-Service delivery system; and
- MA recipients receiving outpatient hospital clinic or independent medical clinic, outpatient psychiatric clinic, outpatient drug and alcohol clinic, or psychiatric partial hospitalizations services when the MA Program pays for the prescribed drugs on an outpatient payment basis in the Fee-for-Service delivery system.

The Federal requirement applies to all prescriptions for MA recipients, regardless of whether or not the prescriber is enrolled in the MA Program, if the MA Fee-for-Service Program will pay for the prescription. However, it does not change the scope of the drug benefit coverage available under the MA Program.

This requirement does not apply to:

- verbal, facsimile or electronically transmitted prescriptions. This includes prescriptions that are sent directly to the pharmacy even if the pharmacist prints out a hard copy for documentation in the files, as the prescription is never given directly to the recipient.
- refills of existing prescriptions when the original written prescription was presented to the pharmacy on or before March 31, 2008;
- written prescriptions for MA recipients presented for payment in the managed care delivery system;
- original written prescriptions for recipients who are determined retroactively eligible for MA;
- prescriptions written for MA recipients who live in nursing facilities, intermediate care facilities, and other similar institutional and clinical settings when the prescriber or
medical staff write the order into the medical record and the order is transmitted by telephone, facsimile or electronically by medical staff directly to the pharmacy; and

- drugs dispensed by dispensing providers.

According to the guidance issued by the Centers for Medicare and Medicaid Services (CMS), effective with dates of service on and after October 1, 2008, written prescriptions or prescriptions printed from an EMR/ePrescribing application for outpatient drugs for MA recipients must be written on tamper resistant prescription pads/paper that have at least one feature from each of the three Federal categories of tamper resistance as defined below:

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 erasure or modification of information written on the prescription by the provider;
3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

The National Council for Prescription Drug Programs (NCPDP) held an industry forum in June 2008, to review the implementation of the second phase of the CMS tamper resistant regulations and all segments of industry impacted by the Federal legislation participated. This industry forum recommended best practices for adoption in order to meet the Federal tamper resistant prescription pad requirements. These recommended best practices have been included under the Procedure Section.

The intent of the Federal requirements are to ensure that compliant tamper resistant prescription pads/paper will prevent erasure or modification of the prescription information, unauthorized copying of the prescription, and the use of counterfeit prescription pads/paper.

Additionally, CMS’ prior guidance for printed prescriptions generated from EMRs or ePrescribing applications provided that special copy resistant paper would likely be required for printed prescriptions in order to be compliant on October 1, 2008. CMS has further clarified their previous guidance, and is now providing 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 bond paper, and will be considered fully compliant with all three categories of tamper resistance, provided the prescription contains at least one feature from each of the three categories detailed above. Providers are advised that in order to meet the compliance requirements of a feature from all three categories, EMR/ePrescribing software enhancements may be necessary if plain bond paper is used.

PROCEDURE:

Effective with dates of service on and after October 1, 2008, prescriptions either handwritten or printed from an EMR/ePrescribing application for outpatient drugs for MA
recipients in the Fee-for-Service delivery system, including ACCESS Plus, must be written on tamper resistant prescription pads/paper that have at least one feature from each of the three Federally defined categories of tamper resistance. No one feature may be counted twice.

Examples that meet the required characteristics are as follows:

1) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form include but are not limited to the following:
   • a void/illegal/copy pantograph with or without a reverse “Rx” where the word “void”, “illegal”, or “copy” appears when the prescription is photocopied (NCPDP best practice). 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.
   • a microprint signature line for prescriptions generated by an EMR, if they cannot produce the void/illegal/copy pantograph with or without a reverse Rx, that is so small that it can be read only when viewed at 5x magnification or greater on the original but cannot be read from a copy (NCPDP best practice). To be effective, this feature must be printed in 0.5 font or less, making it illegible to the pharmacist when copied.
   • a watermark such as a security back print (artificial watermark), digital watermark, or special paper watermarking. A security back print is printed on the back of prescription form. The most popular wording for the security back print is “Security Prescription” and it can only be seen when viewed at an angle. Weak digital watermarks cannot be read if copied and strong digital watermarks provide digital rights management/“proof” of origin when copied. Special paper watermarking uses special paper containing a watermark that can be seen when backlit.
   • thermochromic ink that changes color with temperature change.
   • coin-reactive ink that changes color when rubbed by a coin.

2) one or more industry-recognized features designed to prevent erasure or modification of information written or printed on the prescription by the prescriber include but are not limited to the following:

Features to Prevent Erasure

• an erasure revealing background (resists erasures and alterations) for written prescriptions. The background consists of a solid color or consistent pattern that has been printed onto the paper (NCPDP best practice). This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase it, the consistent background color will look altered and show the color of the underlying paper.
• Toner Receptor Coating/Toner Lock or Color Lock paper for laser printed prescriptions. Toner-Lock paper is special printer paper that establishes a strong bond between laser-printed text and paper, making erasure obvious. This is not necessary for inkjet printed prescriptions because the ink is absorbed into the normal “bond” paper.
• chemically reactive paper that will react if exposed to chemical products used to alter the prescription and leave a mark visible to the pharmacist.

Features to Prevent Modification

• quantity check off boxes, refill indicator (circle number of refills or “NR” for no refills permitted), or border characteristics (dispense and refill number bordered by asterisks and optionally spelled out) for prescriptions generated by an EMR (NCPDP best practice). In addition to the written quantity on the prescription, quantities are indicated in ranges and the range box is checked off. Quantities and refill number are surrounded by special characters such as asterisks to prevent modification, e.g. QTY **50**.
• preprinted language that limits the number of prescriptions that can be contained on one prescription in order to reduce the ability to add medications to the prescription.

NOTES:

• 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.
• CMS has clarified that indelible ink or any other feature added to the prescription pad/paper after it has been printed, including the writing of drug quantities or the use of embossed logos, will not meet this Federal tamper resistant prescription pad/paper requirement.

3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms include but are not limited to the following:

• warning bands on the top and bottom of the form with security features.
• security thread such as metal or plastic threads embedded in paper as used in currency.
• thermochromic ink that changes color when exposed to heat.
• a thermal reactive patch that lightens or disappears when touched, rubbed or breathed on that will re-darken when cooled.
• bar codes on prescriptions, in which a serial or batch number is encoded in the bar code.
NOTE: The NCPDP recommended as a best practice that a complete list of the security features on the prescription paper and their descriptions be listed on the back of the prescription. This list would aid pharmacists in the identification of the tamper resistant features of the prescription and thereby assist in the determination of compliance with the Federal requirements.

Effective with dates of service on and after April 1, 2008, the Department of Public Welfare (the Department) required pharmacy providers to populate the National Council for Prescription Drug Programs (NCPDP) Version 5.1, field 419-DJ – Prescription Origin Code, using the following codes, to identify how the pharmacy received the prescription:

1 – written prescription;
2 – telephone prescription;
3 – electronic prescription;
4 – facsimile prescription.

NOTE: By populating the NCPDP Version 5.1, field 419-DJ – Prescription Origin Code with a one (1), the pharmacist is confirming to the MA Program that the written prescription is on tamper resistant prescription pad/paper that is compliant with the Federal requirements.

Pharmacists may fill a written outpatient drug prescription that is not on a tamper resistant pad/paper on an emergency basis, as long as the prescriber provides a verbal, faxed or electronic prescription or written or printed prescription from an EMR/ePrescribing application using a tamper resistant prescription pad/paper, to the pharmacist within 72 hours after the prescription is filled. If the pharmacist does not receive a compliant tamper resistant prescription within 72 hours of dispensing the drug, the pharmacist/pharmacy may not bill the MA Program for the dispensed prescription drug.

When a pharmacist determines that a prescriber is routinely writing prescriptions for MA recipients who have their pharmacy benefits paid under the Fee-for-Service delivery system on noncompliant prescription pads/paper, the pharmacist should notify the prescriber that the prescription does not meet the Federal tamper resistant prescription pad/paper requirements. This is to ensure that the prescriber did not inadvertently write the MA recipient’s prescription on the wrong prescription pad/paper and that the prescriber will provide the pharmacist with either a verbal, faxed or electronic prescription or a written or printed prescription from an EMR/ePrescribing application on a tamper resistant prescription pad/paper that is compliant with the Federal requirements.

Further, if on a routine basis, the pharmacist determines that a specific prescriber’s written prescriptions, for outpatient drugs for MA recipients whose drug benefits are paid under the Fee-for-Service delivery system, are not compliant with the Federal tamper resistant prescription pad/paper requirements, then the pharmacist may report the prescriber to the Office of Medical Assistance Programs’ Bureau of Program Integrity at 1-866-DPW-TIPS (1-866-379-8477) or write to the Department at:
Department of Public Welfare
Office of Medical Assistance Programs
Bureau of Program Integrity
P.O. Box 2675
Harrisburg, PA  17105-2675

More specific information about this new Federal requirement may be found in the Frequently Asked Questions and Answers that are posted on the Department’s website at the following website address:
http://www.dpw.state.pa.us/PartnersProviders/MedicalAssistance/DoingBusiness/MAPharmProg/003677488.htm

A list of approved Tamper Resistant Prescription Pad Suppliers may be accessed at the following website address:
http://www.dpw.state.pa.us/Resources/Documents/Pdf/ApprvdTamperResistantPrscrptnPadSuppliers.pdf.

NOTE: Other companies that are not on the Approved Tamper Resistant Prescription Pad Suppliers list may be used as long as the Federal requirements are met in regards to tamper resistant prescription pads/paper.