

Tamper-Resistant Prescription Pads

Updated: August 28, 2007

Background

Beginning October 1, 2007, hand-written, prescriptions for Medicaid outpatient drugs will only be reimbursable if written on a tamper-resistant prescription pad. The mandate was enacted as a fraud reducing measure in the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (Public Law 110-28). On August 17, 2007, CMS issued guidance to State Medicaid Agencies regarding the use of tamper-resistant prescription pads. Information on APhA's advocacy efforts related to this matter is posted on www.aphanet.org.

CMS Guidance to State Medicaid Agencies

- *Beginning* October 1, 2007, applied to hand-written outpatient Medicaid prescriptions, including over-the-counter medications in States that pay for them.
- Does not apply to drugs that are currently excluded in the Social Security Acts "covered outpatient drug" definition (Section 1927(k)(3)); therefore, the provision does not apply to drugs provided as part of the following:
 - Inpatient hospital services
 - Hospice services
 - Dental services (except when a State plan authorizes direct reimbursement to the dispensing dentist)
 - Physician services
 - Outpatient hospital services
 - Nursing facility services and intermediate care facility services for the mentally retarded
 - Other laboratory and x-ray services
 - Renal dialysis
- Does not apply:
 - To refills of written prescriptions presented at a pharmacy before October 1, 2007
 - To electronic prescriptions
 - To prescriptions faxed to the pharmacy
 - To prescriptions called in by the prescriber
 - When a Medicaid managed care entity pays for the prescription
- Applies regardless of whether Medicaid is the primary or secondary payer of the prescription being filled.
- Does not effect Drug Enforcement Administration (DEA) regulations regarding controlled substance medications that may require a written prescription.
- Does not restrict providing an emergency fill of any amount (up to the full prescription amount) of non-controlled or controlled dangerous substances for which a prescriber provides the pharmacy with a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.¹

¹ Seeking additional clarification from CMS; see Question #1 of this document.

- Beginning October 1, 2007, a tamper-resistant prescription pad must contain at least one of the following three characteristics:²
 - One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; and
 - One or more industry-recognized features designed to prevent the use of counterfeit prescription forms
- Beginning October 1, 2008, a tamper-resistant prescription pad must contain all of the above three characteristics.
- States may exceed the baseline standard as to what constitutes a tamper-resistant prescription pad.
- CMS deems that the tamper-resistant prescription pad characteristics required by States' laws and regulations meet or exceed the baseline standard. (See chart on page 6 of this document for a list of the States that have already implemented (or repealed) tamper-resistant prescription pad requirements.)
- States must make their own determination whether to allow pharmacists to accept an out-of-state prescription from another state.
- The law does not impose additional requirements on States' regarding retention of hardcopy prescriptions. States may follow current State and Federal laws and regulations regarding record retention.
- If a State elects to purchase compliant prescription pads and provide them to prescribers at no or reduced costs, the costs of the prescription pads is reimbursable as an administrative cost.
- Each State Medicaid Agency must establish its own enforcement plan for implementing the guidance in their State.
- State Medicaid Agencies are not required to file a State plan amendment with CMS in connection with action taken to comply with this guidance (Medicaid plan amendments are generally required for Medicaid program changes such as reimbursement, co-pays, eligibility, etc.)
- Failure of a State to enforce the tamper-resistant prescription pad requirement may result in the loss of federal funds.

What Does This Mean to You? – Frequently Asked Questions

Q: Does the prescription pad need all three tamper-resistant prescription pad characteristics?

A: Beginning October 1, 2007 the prescription pads only need one of the three tamper-resistant characteristics, then by October 1, 2008 the prescription pads will need all three tamper-resistant characteristics.

Q: What should I do if a Medicaid patient brings in a prescription from a non-compliant prescription pad?

A: CMS allows pharmacists to dispense emergency fills of non-controlled or controlled dangerous substances for which a prescriber submits a compliant prescription within 72 hours after the date on which the prescription was filled. Emergency fills can be of any amount up to the full prescription amount. Pharmacists are at financial risk for the amount of the emergency supply if the prescriber doesn't respond within the 72 hour time frame and there is no mandate for them to do so.

² Seeking additional clarification from CMS; see Question #2 of this document.

Q: What is tamper resistant prescription paper?

A: Most prescription pad vendors define tamper-resistant papers as prescription papers which provide some kind of security feature to lessen the occurrence of unauthorized duplication or alteration of a prescription. Examples of security features include: a security color background, paper resistant to erasures and alterations, copy secure paper that show “VOID” when photocopied, thermochromic ink that reveals “SAFE” when rubbed, and holograms or watermarks. The CMS guidance does not specify which of these or other features meet the required “industry-recognized” features.

Q: Will a pharmacy be held financially liable for filling legitimate yet non-compliant prescriptions?

A: A pharmacy will be held liable for the full prescription dispensed from a non-compliant prescription pad and the amount of any emergency fill if the prescriber does not provide a compliant prescription within the required 72 hour time-frame.

Q: Are any types of prescriptions exempt?

A: Yes. CMS has clarified that this requirement does not apply to drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other specified institutional and clinical settings (listed above). In addition, CMS exempted prescriptions transmitted electronically, via fax, and over the telephone by a prescriber.³ Finally, the requirement neither applies to refills of written prescriptions presented at a pharmacy before October 1, 2007, nor when a Medicaid managed care entity pays for the prescription.

Q: Are prescribers mandated to use these tamper-resistant prescription pads?

A: No. The new Federal law states that pharmacies will only receive reimbursement for hand-written Medicaid prescriptions if they are written on tamper-resistant prescription pads. However, the challenge is nothing in the Federal law or regulation requires prescribers to use tamper-resistant prescription pads for hand-written outpatient Medicaid medications. State Medicaid programs may use their flexibility in implementing this provision to require that prescribers use tamper-resistant pads for certain prescriptions.

Q: How will I know if a prescription is written from an approved tamper-resistant prescription pad?

A: Beginning October 1, 2007, a tamper-resistant prescription pad must contain one or more industry-recognized features to prevent: unauthorized copying of a completed or blank prescription form, the erasure or modification of information written on the prescription by the prescriber, or the use of counterfeit prescription forms. Beginning October 1, 2008, tamper-resistant prescription pads must contain all three features. States may add additional prescription pad requirements. APhA recognizes the challenge this presents to pharmacists in trying to identify a compliant tamper-resistant prescription and is seeking additional clarification from CMS (see Question #3 of this document.)

Q: Who will pay for the printing and distribution of tamper-resistant prescription pads?

A: Neither the Federal law nor the regulation addresses the costs associated with tamper-resistant prescription pads. However, for States that elect to purchase and provide compliant prescription pads to prescribers at no cost or a discounted rate, this cost may be reimbursable as administrative costs. Medicaid administrative costs refer to the Federal share of the States' expenditures for administration of the Medicaid program and are the costs of operating CMS, such as salaries and expenses, facilities, equipment, rent and utilities, etc.

³ Seeking additional clarification from CMS; see Question #1 of this document.

Q: What guidance has CMS provided my State Medicaid Director?

A: In addition to CMS' general guidance, the Agency provided a list of questions for State Health Policy makers to consider as they work to implement this requirement by October 1, 2007. The questions can be found at: <http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf>

Q: How will the tamper-resistant prescription pad requirement be enforced?

A: Each State Medicaid Agency is responsible for implementing this new requirement. Given the flexibility provided in the guidance, there may be variations in how each State Medicaid program chooses to implement and enforce the tamper-resistant prescription pad requirement.

Q: Where can I find tamper resistant prescription pads?

A: There are numerous companies that provide tamper resistant prescription pads for medical facilities. A partial list of prescription vendors is provided below:

www.medi-scripts-services.com

www.highsecuritypaper.com

www.nationalrxsecurity.com

www.scriptshield.com

www.kwiktickets.com/prescriptionPad.html

www.rxsecurity.com

www.chicagowatermark.com/Rx_pres_prices.html

These are just examples. It is not clear from CMS' guidance which if any of these vendors provide compliant tamper-resistant prescription pads.

Q: What should clinics or 340B covered entities do to prepare prescribers and pharmacists for the new tamper resistant requirements?

A: Proactively informing all prescribers about the new law requiring all Medicaid prescriptions to be written on tamper-resistant prescriptions pads would help with implementation of this new law.

These facilities could also follow the steps below:

- Establish procedures that will clearly identify a Medicaid patient (i.e. place a special notation on the encounter form);
- New procedures could formally be presented to all prescribers;
- Secure an adequate supply of tamper resistant prescription pads for all prescribers;
- Evaluate the feasibility of using tamper resistant prescription pads for all patients to ease the burden of identifying Medicaid patients;
- Inform the staff to expect an increase in inquiries from pharmacies to obtain oral or electronic prescriptions to accommodate Medicaid patients who do not have prescriptions on tamper resistant papers;
- Establish procedures or appoint appropriate staff to handle increased inquiries from pharmacies.

Remaining Questions for which APhA is Seeking Clarification:

Note: This Issue Brief will be updated as we receive feedback from CMS.

1. Will the action of a pharmacist calling back a prescriber and making appropriate documentation on the original non-compliant prescription count as a compliant prescription during a Medicaid audit? If not, will the pharmacist be allowed to write a new verbal prescription and have it be considered compliant? The guidance does not specify who initiates a verbal prescription order – will a call back count?

2. What are the industry standards that CMS recognizes for preventing copying, erasure or counterfeiting?
3. With so many variables, what resources will be available to pharmacists to identify industry standards and therefore enable them to identify tamper-resistant prescriptions?
4. Do States have the flexibility to delay implementation or enforcement?
5. Will States have the authority to implement a hold harmless provision for pharmacists who document their calls, faxes or other efforts to receive a compliant prescription from a prescriber but do not receive a response from the prescriber within the 72 hour timeframe?
6. Will there be resources to help pharmacists identify Medicaid as the secondary payer to help limit the number of prescriptions that may need to be reprocessed if the prescription was non-compliant?
7. The guidance provides 72 hours to receive a compliant prescription if the pharmacist fills the full prescription or an emergency supply. After a pharmacist provides an emergency supply, does this provision pre-empt State laws and regulations that may allow more days to receive a written prescription?
8. Does CMS' reference to "controlled dangerous substances" include State schedules of controlled substances?
9. How does this provision apply to discharge prescriptions for a Medicaid patient when they leave an inpatient setting with prescriptions to be filled at an outpatient pharmacy?
10. Is there any restriction on who supplies prescribers with compliant tamper-resistant prescription pads?
11. How does this provision apply to computer-generated prescriptions that print on plain paper and are then signed by the prescriber for the patient to take to the pharmacy? Is there an industry-standard to address computer printer paper?

Useful Links

CMS Guidance to State Medicaid Agencies:

<http://www.cms.hhs.gov/SMDL/downloads/SMD081707.pdf>

CMS State Health Policymakers Backgrounder:

<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf>
<<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf>>

APhA Press Statement on CMS' Final Guidance for Tamper-Resistant Prescriptions:

<http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=8372>

APhA Press Statement on New Medicaid Tamper-Resistant Prescription Pads:

http://www.aphanet.org/AM/Template.cfm?Section=Legislative_Action_Center&CONTENTID=8199&TEMPLATE=/CM/HTMLDisplay.cfm

APhA Comments to CMS on Tamper-Resistant Prescription Pads:

<http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=8196&TEMPLATE=/CM/ContentDisplay.cfm>

Congressional Press Statement on Tamper-Resistant Prescription Pads:

<http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=8204&TEMPLATE=/CM/ContentDisplay.cfm>

Congressional Letter to CMS on Tamper-Resistant Prescription Pads:

<http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=8200&TEMPLATE=/CM/ContentDisplay.cfm>

APhA Government Affairs Web site:

<http://www.aphaent.gov/GovAff>

States Activity Related to Tamper-Resistant Prescription Pads

States with tamper-resistant prescription pad requirements that have been implemented (10)	
California	Controlled Substances
Florida	Medicaid Prescriptions
Idaho	Controlled Substances
Indiana	Controlled Substances
Kentucky	Controlled Substances
Maine	Schedule II Controlled Substances
New Jersey	All Prescriptions
New York	All Prescriptions
Texas	Schedule II Controlled Substances
Wyoming	Controlled Substances
States with tamper-resistant prescription pad requirement that have not been implemented as of August 2007 (1)	
Vermont	Defers to State Board of Pharmacy
States with limited tamper-resistant prescription pas requirements that do not meet the requirements within the CMS guidance (1)	
Georgia	Limited to prescriptions that are generated electronically, with an electronic image of the prescribers signature, that are printed so the patient presents a hardcopy to the pharmacy
States that have repealed tamper-resistant prescription pad requirements prior to implementation (3)	
Michigan	Schedule II Controlled Substances
Mississippi	Controlled Substances
West Virginia	Schedule II Controlled Substances