

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850



Center for Medicaid and State Operations

August 17, 2007

SMDL #07-012

Dear State Medicaid Director:

The purpose of this letter is to offer guidance to State Medicaid agencies on section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, regarding use of tamper-resistant prescription pads, which was signed into law on May 25, 2007.

Section 7002(b), which amends section 1903(i) of the Social Security Act (the Act) (42 U.S.C. section 1936b(i)) by adding new paragraph (23), states that payment shall not be made for ". . . amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(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 October 1, 2007. The tamper resistant pad requirement of section 7002(b) applies to all outpatient drugs, including over-the-counter drugs in States that reimburse for prescriptions for such items. Section 1927(k)(3) of the Act provides exceptions to section 1927(k)(2) for drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other specified institutional and clinical settings. Such drugs in these settings (to the extent that they are not separately reimbursed) are exceptions to section 1927(k)(2), and, therefore, are not subject to the tamper-resistant pad requirement of section 7002(b). Section 7002(b) is applicable regardless of whether Medicaid is the primary or secondary payor of the prescription being filled.

The tamper-resistant pad requirement does not apply to refills of written prescriptions presented at a pharmacy before October 1, 2007. In addition, the payment limitation does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. The Centers for Medicare & Medicaid Services (CMS) particularly encourages the use of e-prescriptions as an effective and efficient method of communicating prescriptions to pharmacists. Please note, however, that Drug Enforcement Administration regulations regarding controlled substances may require a written prescription.

Paragraph (23) of section 1903(i) is not included among the payment limitations in the last paragraph of the section that are applicable "to items or services furnished and amounts expended by or through a managed care entity." Therefore, the requirement for the use of a tamper-resistant prescription pad does not apply when a managed care entity pays for the prescription.

To the extent permissible under State and Federal law and regulation, our guidance does not restrict emergency fills 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.

To be considered tamper resistant on October 1, 2007, a prescription pad must contain at least one of the following three characteristics:

- 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.

No later than October 1, 2008, to be considered tamper resistant, a prescription pad must contain all of the foregoing three characteristics. Failure of a State to enforce the tamper-resistant pad requirement of section 7002(b) may result in the loss of Federal financial participation.

States are free to exceed the above baseline standard as to what constitutes a tamper-resistant prescription pad. States should make their own determination whether to allow pharmacists to accept an out-of-State prescription that meets the tamper-resistant requirements of another State. Several States have laws and regulations concerning mandatory, tamper-resistant prescription pad programs, which were in effect prior to the passage of section 7002(b). CMS deems that the tamper-resistant prescription pad characteristics required by these States' laws and regulations meet or exceed the baseline standard, as set forth above.

The payment limitation set forth in section 1903(i)(23) of the Act does not impose additional requirements on States regarding retention of hard copy prescriptions. States may follow current State and Federal laws and regulations for record retention.

The CMS strongly supports State program integrity measures and wants States to be aware that both e-prescribing and use of tamper-resistant prescription pads may reduce instances of unauthorized, improperly altered, and counterfeit prescriptions. If a State elects to purchase compliant prescription pads for Medicaid prescriptions and provide them to prescribers at no cost or at a discounted rate, the cost of the prescription pads is reimbursable as an administrative expense.

States are not required to file a State plan amendment in connection with actions taken to comply with section 1903(i)(23). It is up to each State to establish its own enforcement plan for ensuring compliance with the payment restrictions contained in section 1903(i)(23).

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If you have any questions regarding this guidance, please contact Mr. David Frank, Director, Medicaid Integrity Group, at 410-786-8874.

Sincerely,

/s/

Dennis G. Smith
Director

cc:

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****REVISED****

**Georgia Medicaid FFS Tamper Resistant Prescription Pad (TRPP)
Requirement FAQs**

Q: What is the origin of this requirement?

A: This requirement is a federal requirement, but the states are required to implement it. The requirement originated from the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (H.R. 2206), section 7002(b).

Q: What is a TRPP?

A: In their final guidance, the federal government requires that by April 1, 2008 that tamper-resistant prescriptions include one or more industry-recognized features designed to:

- Prevent unauthorized copying of a completed or blank prescription form
- Prevent erasure or modification of information written on the prescription by the prescriber
- Prevent the use of counterfeit prescription forms

Q: What are industry-recognized features?

A: While the federal government has not identified the industry-recognized features, examples include but are not limited to the following:

Required tamper-resistant characteristics include one or more industry-recognized features designed to:		Examples include but are not limited to:
1	Prevent unauthorized copying of a completed or blank prescription form	<ul style="list-style-type: none">• Pantograph such that copied or faxed prescriptions show the word "Copy," "Illegal," or "Void."• High security watermark on the face or reverse side of the prescription blank• Coin-reactive ink that changes color when rubbed by a coin
2	Prevent erasure or modification of information written on the prescription by the prescriber	<ul style="list-style-type: none">• Tamper-resistant background ink shows erasures or attempts to change written information• Quantity check-off boxes• Pre-printed measures that reduce the ability to add prescriptions to the prescription pad. Ex. pre-printed indication of the number of prescriptions on the prescription pad.
3	Prevent the use of counterfeit prescription forms	<ul style="list-style-type: none">• Heat sensing imprints that disappear when touched.• Thermochromic ink technology that changes color

		<p>with temperature change.</p> <ul style="list-style-type: none"> • Heat sensing imprints that disappear when touched. • Invisible fluorescent fibers/ink that are visible only under black light. • Holograms that interfere with photocopying or scanning.
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Q: Doesn't the law have more stringent requirements by October 1, 2008?

A: Yes. By October 1, 2008, TRPPs will have to meet all three of the above requirements.

Q: Do the April 1st effective dates refer to the date the prescription was filled or written?

A: The April 1st effective dates refer to any prescription filled on or after those dates.

Q: What if I am dispensing a refill on or after the effective date, but the original prescription was filled before the effective date?

A: Refills for prescriptions that were originally filled prior to the effective date are exempt from the requirement.

Q: Can a provider add features to the prescription to make it compliant with the requirement such as:

- writing out the drug quantities rather than just the number (i.e. "thirty" vs. "30")
- using indelible or gel inks when writing the prescription
- using embossed logos

A: No. The statute states that all written prescriptions must be "executed on a tamper resistant pad." As a result, features added to the prescription after they are printed do not meet the requirement of the statute.

Q: Will prescriptions printed from a computer meet the tamper resistant prescriptions requirements?

A: Between April 1st and September 31, 2008, computer generated prescriptions containing one or more industry-recognized features designed either to prevent the erasure or modification of information contained on the prescription can meet the CMS requirements. Beginning October 1, 2008, prescriptions printed on plain paper will not be able to meet all three baseline characteristics outlined by CMS. Beginning October 1, 2008, computer generated prescriptions must be printed on paper that meets all three requirements.

Q: Does this requirement apply to the Georgia Medicaid members enrolled in one of the Care Management Organizations (Amerigroup, PeachState, or WellCare)?

A: No. This requirement only applies to Georgia Medicaid members enrolled in traditional fee-for-service Medicaid.

Q: Will the State endorse, credential or otherwise certify print vendors who meet the federal requirements?

A: Not at this time.

Q: What is considered to be a "prescription" under this requirement?

A: Any drug order that is not e-prescribed, faxed to the pharmacy from the prescribers office, or telephoned to the pharmacy by the prescriber.

Q: Are prescriptions printed from a computer at the prescribers office included in this definition of a prescription?

A: Yes. The paper utilized to print such prescriptions must be compliant as well.

Q: Are there any exceptions to the TRPP requirement?

A: Yes. Exceptions include prescriptions:

- Paid by a Georgia Medicaid Care Management Organization (Amerigroup, WellCare, PeachState)
- Provided in nursing facilities or intermediate care facilities for the mentally retarded (ICF/MR) and the drug is reimbursed as part of a total service and is not reimbursed through the outpatient pharmacy program
- Provided in any other institutional or clinical settings for which the drug is reimbursed as part of a total service and is not reimbursed through the outpatient pharmacy program
- Written orders 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
- e-prescribed, faxed to the pharmacy from the prescribers office, or telephoned to the pharmacy by the prescriber
- Refills for which the original prescription was filled before April 1, 2008.

Q: Are nursing homes prescriptions required to comply with this requirement?

A: Written orders 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.

Q: If the Medicaid recipient has other insurance and Medicaid is not primary but the prescription is being billed to Medicaid as a coordination of benefits claim, is a TRPP still required?

A: Yes.

Q: If I fill a prescription written for a Medicaid fee-for-service patient from another state, are the rules the same as for Georgia Medicaid?

A: No. Each state may have different rules. Please check the rules and requirements of the other state in which you are an enrolled provider.

Q: What happens if a person is retroactively enrolled in fee-for-service Medicaid?

A: The federal government requires the pharmacy to obtain a compliant tamper resistant prescription. This requirement may be accomplished by verbal verification of the prescription. This requires the pharmacist or licensed pharmacy intern to handwrite on the face of the original prescription the name of the person contacted at the prescribers office, the date verified, the initials or name of the pharmacist or licensed pharmacy intern who verified the prescription, and the word "Verified."

Q: Can the State make exemptions from the requirement?

A: No. This is a requirement of federal law.

Q: Where can I learn more about this requirement?

A: The following are resources for your review.

U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (H.R. 2206), section 7002(b)

- Centers for Medicare & Medicaid Services (CMS) Letter to State Medicaid Director (SMDL #07-012, 8/17/2007)
- Banner messages at the GHP Portal (www.ghp.ga.gov)
- CMS FAQ Document published 9/13/2007 (<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/MIPTRPFAQs9122007.pdf>)

Q: If I receive a non-tamper resistant prescription and I cannot verify the prescription with the provider at that time, can I dispense the medication on an emergency basis?

A: Yes, the pharmacy can fill the prescription on an emergency basis as long as the prescription complies with all other Medicaid policies and state, and federal laws. However, the dispensing pharmacist must obtain a verbal, faxed, electronic, or otherwise compliant written prescription within 72 hours after the date on which the prescription was filled. The pharmacist must verify the prescription order with the prescriber's office by handwriting on the face of the original prescription the name of the person contacted at the prescribers' office, the date verified, the initials or name of the pharmacist or licensed pharmacy intern who verified the prescription, and the word "Verified".

Q: If I fill a prescription not written on a tamper-resistant prescription pad on an emergency basis, am I limited to giving the patient only a 72-hour supply?

A: If the prescription complies with all Medicaid policies and is a covered benefit with no restrictions for the member, then you may dispense greater than a 72-hour supply.

Q: If I make every reasonable attempt to contact the prescribers office and still am unable to verify the prescription, am I still accountable if audited?

A: Yes, based on the federal requirements the pharmacy is still accountable.

Q: **Will DCH enforce this requirement?**

A: DCH is bound to enforce all federal requirements.

Q. **Wasn't the original requirement that TRPPs must be used for all Medicaid FFS prescriptions by October 1, 2007?**

A. Yes. However, on September 29, 2007, President Bush signed the *Transitional Medical Assistance, Abstinence Education, and QI Programs Extension Act of 2007* which delayed the implementation date for the Medicaid FFS TRPPs. Under the new law, all such prescriptions must have at least one of the TRPP characteristics specified by CMS by April 1, 2008, with all three characteristics by October 1, 2008.

Q. **Has CMS issued any additional FAQs that I may find helpful?**

A. Yes. On 9/13/2007, CMS issued FAQs on the TRPP requirement. These FAQs can be found at:

<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/MIPTRPFAQs9122007.pdf>

Additional Resources

U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (H.R. 2206), section 7002(b)

Centers for Medicare & Medicaid Services (CMS) Letter to State Medicaid Director (SMDL #07-012, 8/17/2007)

Centers for Medicare & Medicaid Services (CMS) Frequently Asked Questions Document published 9/13/2007 (<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/MIPTRPFAQs9122007.pdf>)

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