



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

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