

Late Breaking News!

The requirement for the use of Medicaid tamper resistant prescriptions has been delayed to April 1, 2008.

On September 26, the House of Representatives approved H.R. 3668, a bill that included a six-month delay in implementing the requirement for the use of tamper resistant prescription pads in selected situations involving Medicaid patients. On September 27, the Senate passed a companion measure. President Bush subsequently signed the legislation into law.

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Washington State Medical Association

WSMA Membership Memo: August 24, 2007

Medicaid Tamper-Proof Prescription Requirement to Go Into Effect October 1

Thanks to a provision tucked into the Iraq Accountability Appropriations Act of 2007, handwritten prescriptions for Medicaid fee-for-service patients must be written on tamper-resistant pads as of October 1, 2007.

The Centers for Medicare and Medicaid Services has now released guidance to State Medicaid Directors on the Oct. 1 requirement for handwritten prescriptions to be written on tamper-resistant prescription pads in order to be covered by Medicaid (*either as primary or secondary payer*), which is available at the following links:

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

Please note the following key elements of the guidance:

Exemptions:

- Prescriptions paid for by a managed care entity (i.e., *Healthy Options*) are exempt
- Electronic, faxed and telephoned prescriptions are exempt
- Prescriptions provided in nursing facilities and certain other settings are exempt
- Refills of written prescriptions presented at a pharmacy before Oct. 1 are exempt

Requirements:

By Oct. 1, 2007, prescription pads must meet one of the following standards, and by Oct. 1, 2008 they must meet all three:

- Features to prevent unauthorized copying of a blank or completed prescription
- Features to prevent erasure or modification of information written on the prescription
- Features to prevent use of counterfeit prescription forms

State laws and requirements for tamper-resistant prescriptions must meet or may exceed the CMS standard.

Emergencies: The requirement does not restrict emergency refills if the prescriber provides the pharmacy with a verbal, faxed, electronic, or tamper-resistant written prescription within 72 hours after the date the prescription was filled.

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WSMA Membership Memo: September 7, 2007

Medicaid Requirement for Tamper Resistant Rx Pads

You may recall from the last issue of the *WSMA Membership Memo* that, thanks to a provision tucked into the Iraq Accountability Appropriations Act of 2007, handwritten prescriptions for Medicaid fee-for-service patients must be written on tamper-resistant pads as of October 1, 2007. The WSMA has learned that **Lancer Limited of Spokane** now offers Rx pads that satisfy all three of the new tamper resistant criteria. To order, email info@lancerltd.com (email preferred) or call 1.800.541.2232.

Medicaid: Tamper-Resistant Rx Pads

List of Vendors

September 11, 2007

List prepared by Washington Medicaid – Health and Recovery Services Administration

Check with your current vendors to determine if they can supply paper/pads that are compliant with one or more of the new tamper resistant criteria.

- **Beard Business Forms; Yakima**
 - Contact: Tom Beard
 - Ph: 1.509.575.6352
 - tombeard@beardbusinessform.com

- **Lancer Ltd.; Spokane**
 - Contact: Pam Marshall
 - Can currently supply compliant paper that satisfies *all three tamper resistant criteria*.
 - Ph: 1.800.541.2232 or 1.509.922.0260
 - pam@lancerltd.com

- **Rx Security; Port Chester, NY**
 - Contact: Margo Hayes
 - Ph: 1.800.667.9723
 - margot@rxsecurity.com
 - Provides compliant paper to California, Florida Texas, Wyoming and other states with state law requirements

- **Standard Register; Seattle**
 - Contact: Tom Chase
 - Standard Register Security Plus
 - Ph: 877.314.2906
 - Tom.Chase@standardregister.com
 - Reportedly the sole vendor for Idaho, and also provides compliant paper to California, Florida Texas, Wyoming and other states with state law requirements

- Vendors listed on the Maine Medicaid program's website (in addition to Security Plus and Rx Security):
 - <http://www.americancorporateservice.com>
 - <http://www.kwiktickets.com>
 - <http://www.rxpads.com>

2007 Fact Sheet:

Tamper-resistant prescription pads

THE BACKGROUND

Effective October 1, 2007, all written Medicaid prescriptions must be written on tamper-resistant prescription pads. The requirement is part of a federal law passed earlier in 2007. It means:

- 1) **All written Medicaid prescriptions for fee-for-service must be written on tamper-resistant paper after October 1, 2007.**
- 2) **This requirement does not apply to prescriptions paid for by Washington's Healthy Options program or other Medicaid managed care programs, as well as cases in which drugs are provided in designated institutional or clinical settings.**
- 3) **The law applies to all prescribed drugs, including over-the-counter medications.**
- 4) **The new law does not apply to telephone, fax or electronic prescriptions.**
- 5) **The tamper-resistant requirement does not apply to refill prescriptions if the original written prescriptions were presented at a pharmacy before October 1, 2007.**
- 6) **Pharmacists are expected to use their best professional judgment to determine whether the prescription is written on compliant paper. If a prescription appears to be written on plain paper or if the pharmacist has any doubts, the prescriber should be contacted.**
- 7) **Telephone, fax or electronic verification of any prescription complies with the law.**

EMERGENCY DISPENSING:

The requirements allow for emergencies. In those instances, the pharmacy may fill the prescription as long as the pharmacy verifies it and a faxed, electronic, or compliant written prescription from the prescriber is forwarded to the pharmacy within 72 hours after the prescription was filled.

DEFINITION OF TAMPER-RESISTANT

After October 1, 2007, CMS says the tamper-resistant prescription forms must meet at least one of the following characteristics:

- 1) **No copying:** Pads must prevent unauthorized copying of completed or blank prescription forms. For example: Pantographs that reveal the word "void" when copied.
- 2) **No alterations:** Pads must prevent erasure or modification of writing on the prescription form. For example, chemical stains or altered background reveal attempts at ink or toner removal.
- 3) **No counterfeiting:** Pads must be distinctive and can't be reproduced, such as a watermark.

After October 1, 2008, the pads must meet all three characteristics to be considered tamper-resistant.

Washington Medicaid pharmacists are encouraged to try to verify prescriptions on noncompliant pads by calling, faxing or e-mailing prescribers. **DSHS encourages prescribers and pharmacists to use these approved processes whenever possible to ensure continuity of care and access to necessary medications for Medicaid recipients.**

All providers are cautioned to be rigorous about the possibility of tampered prescriptions in the case of Schedule II drugs and to report any suspicious prescriptions to the prescribing provider as quickly as possible.

A list of Washington State suppliers who provide pads that meet the CMS requirements is published on the Medicaid Web site at <http://maa.dshs.wa.gov> Other suppliers can be easily located by searching the Internet. DSHS is not endorsing any specific suppliers.

**FREQUENTLY ASKED QUESTIONS CONCERNING
THE TAMPER-RESISTANT PRESCRIPTION PAD LAW
(SECTION 7002(b) OF THE U.S. TROOP READINESS,
VETERANS' CARE, KATRINA RECOVERY, AND IRAQ
ACCOUNTABILITY APPROPRIATIONS ACT OF 2007)**

Effective Date of the New Law (Section 7002(b))

Q: Will the Centers for Medicare & Medicaid Services (CMS) delay the October 1, 2007 effective date of section 7002(b)?

A: No. Section 7002(b) does not give CMS the authority to delay the October 1 effective date. Only Congress may delay the effective date through new legislation. Therefore, the States are responsible for the full implementation and enforcement of the new law as of October 1.

Retroactive Eligibility

Sometimes, a person becomes eligible for Medicaid benefits after he has submitted a written prescription to a pharmacy and has had the pharmacy fill the prescription. In these retroactive eligibility situations, the recipient often will return to the pharmacy and present evidence of his eligibility in order to get reimbursed by the pharmacy for whatever money the recipient previously paid the pharmacy to fill the prescription. Many have asked whether, in order to submit a claim to Medicaid, the pharmacy must obtain a compliant prescription.

Q: When it is determined that a Medicaid recipient is retroactively eligible for Medicaid and the recipient's original, written prescription was filled during a period when the recipient is now deemed to have been Medicaid eligible, must the pharmacy, prior to submitting a claim to Medicaid, obtain a tamper-resistant written prescription, a verbal order, a faxed prescription, or an e-prescription prior to submitting a claim to Medicaid?

A: When a Medicaid recipient is retroactively eligible for Medicaid after a pharmacy has already filled the recipient's prescription, CMS will presume that the prescription was compliant with section 7002(b), unless there is evidence that the prescription was non-compliant. This presumption applies to the filling of the prescription that occurred *before* the recipient became retroactively eligible for Medicaid. This presumption does *not* extend to any refills that occurred *after* the date on which the recipient is determined to be eligible for Medicaid. Such refills require that the pharmacy obtain a new, tamper-resistant prescription in compliance with section 7002(b). Alternatively, the pharmacy may obtain verbal confirmation of the prescription from the prescriber or may obtain the prescription from the prescriber by facsimile or e-prescription.

Emergency Prescription Fills

Q: Page two of CMS' August 17, 2007 State Medicaid Director letter (the "SMD Letter") allows a pharmacy to fill prescriptions on an emergency basis and, within 72 hours after the fill date, obtain a written prescription that complies with section 7002(b) or obtain the prescription by verbal communication from the prescribing doctor, by facsimile, or by e-prescription. Will CMS define "emergency fill," as discussed in the SMD Letter? Is the emergency fill provision limited to certain drugs or to instances when the individual has no supply left?

A: CMS will not further define the "emergency fill" provision of the SMD Letter. Each State should refer to its own statutes, rules, and regulations to define the term.

Q: May the pharmacy provide the full prescription to the patient in the emergency fill situation, or must the pharmacy only provide a 72-hour supply?

A: The pharmacy may provide the full prescription to the patient in the emergency fill situation, so long as the pharmacy obtains a compliant prescription in writing, or by telephone, fax, or e-prescription, within 72 hours.

Q: Do States have the authority to implement a "hold harmless" provision for pharmacies that document their pharmacists' calls, faxes, or other efforts to obtain a compliant prescription but that do not receive a response from the prescriber within the 72-hour period?

A: No. Section 7002(b) does not contain a "hold harmless" provision.

Drug Orders in Certain Institutional Settings

As noted on page one of the SMD Letter, section 1927(k)(3) of the Social Security Act describes certain institutional settings, including nursing facilities, where outpatient drugs are not subject to section 7002(b). CMS has received many questions about drugs prescribed in institutional settings referred to in section 1927(k)(3) that are ordered by way of drug orders written in patient charts or in other written formats, where these orders are not written on prescription pads.

Q: Must a written order provided in an institutional setting described in section 1927(k)(3), and separately reimbursed by Medicaid, that is written into the medical record and conveyed by medical staff to a pharmacy be executed on a tamper-resistant prescription pad?

A: CMS has concluded that a written order 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.

Prescriptions for Controlled Substances

Q: Federal law and many State laws require that all prescriptions for Schedule II controlled substances be written. If a non-tamper-resistant controlled substance prescription that complies with Federal and State law is presented to a pharmacy, may the pharmacy obtain verbal confirmation from the prescriber in order to satisfy the tamper-resistant requirement of section 7002(b)?

A: Yes. As long as the Schedule II requirements are satisfied, section 7002(b) can be satisfied through any of the methods set forth in the SMD letter, that is, through a prescription that is transmitted verbally, sent by facsimile, or sent through an e-prescription, or is written on compliant, tamper-resistant prescription pad.

Q: Does CMS’ reference to “controlled dangerous substances” include State schedules of controlled substances?

A: Yes.

Physician-Provided Drugs

In many cases physicians provide prescription drugs directly to patients (e.g., via samples).

Q: If the prescriber provides a drug directly to a Medicaid recipient, is a tamper-resistant prescription required?

A: No.

Communication between Physician/Prescriber and Pharmacy

As noted on page one of the SMD letter, section 7002(b) does not apply to non-written prescriptions, that is, it does not apply to: e-prescriptions; prescriptions transmitted to the pharmacy by facsimile; and prescriptions communicated to the pharmacy by telephone.

Q: Does the physician/prescriber have to be the individual who transmits a non-written prescription to a pharmacy?

- A: No. A nurse or administrative staff person who is authorized to act on the prescriber's behalf may phone the pharmacy the order, send the order by facsimile, or electronically transmit the order to the pharmacy.
- Q: Will the action of a pharmacist calling back a physician/prescriber and making appropriate documentation on the original, non-compliant written prescription make the prescription compliant for purposes of a subsequent Medicaid audit?
- A: Yes. Documentation by the pharmacy of verbal confirmation of a non-compliant written prescription satisfies the requirements of section 7002(b).

Prescription Transfers between Pharmacies

- Q: When Pharmacy # 1 transfers a tamper-resistant prescription to Pharmacy # 2 to be filled, will a facsimile or telephone call from Pharmacy # 1 to Pharmacy # 2 satisfy section 7002(b), or must Pharmacy # 2 obtain direct confirmation from the physician/prescriber?
- A: Pharmacy # 2 need only obtain a phone call or a facsimile from Pharmacy # 1 in order to confirm the authenticity of the tamper-resistant prescription that was previously delivered to Pharmacy # 1. There is no need for Pharmacy # 2 to obtain direct confirmation of the original prescription from the physician/prescriber.

Record Retention

Page two of the SMD letter states that section 7002(b) "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." Several States only require a pharmacy to retain a scanned copy of the original prescription.

- Q: If a pharmacy notes in writing on the original prescription that it is tamper resistant and then scans the prescription, will this comply with section 7002(b) for purposes of a later audit?
- A: It depends upon the law of the individual State. Each State will determine what, if any, changes the State will require to its record retention policies in light of section 7002(b).

Characteristics of tamper-resistant prescription pads

- Q: Will CMS provide examples of existing State practices that meet CMS requirements?
- A: The tamper-resistant prescription pad characteristics set forth by the several States that currently have tamper-resistant prescription laws and/or regulations in effect are all acceptable examples of all three of the characteristics set forth on page two of the SMD Letter. These States are California, Florida, Indiana, Kentucky, Maine, New Jersey, New York, Texas, and Wyoming. (Idaho's regulations currently require one tamper-resistant feature; therefore, Idaho's law is compliant with the guidance given in the SMD Letter through September 30, 2008, but not thereafter.)
- Q: What are the "industry-recognized features" that CMS recognizes for the prevention of copying, erasure, or counterfeiting?
- A: The tamper-resistant prescription pad characteristics set forth by each of the States that currently have tamper-resistant prescription laws and/or regulations in effect are all acceptable examples of existing State practices that meet the requirements set forth by the SMD Letter.
- Q: Does the requirement of the use of an ink pen satisfy the second characteristic set forth on page two of the SMD Letter (i.e., a feature that "prevent[s] the erasure or modification" of information on a prescription)?
- A: No, it does not. Ink can be erased and modified, and in part for those reasons, the use of an ink pen is not an industry recognized standard.
- Q: How do the characteristics set forth on page two of the SMD Letter apply to computer-generated prescriptions that are printed on plain paper and are then signed by the prescriber? Is there an industry-recognized feature to address computer printer paper?
- A: A computer-generated prescription that is given to the patient to take to the pharmacy must be printed on compliant, tamper-resistant paper. Such compliant paper is available in the marketplace.
- Q: Will CMS publish a list of approved vendors that print prescription pads on compliant, tamper-resistant paper?
- A: No. As long as the prescription pads meet the requirements of the guidance in the SMD Letter, providers are free to choose whatever vendor they wish.
- Q: Is there any restriction on who may supply prescribers with compliant tamper-resistant prescription pads?

A: Each State may determine the vendors from which a prescriber may obtain tamper-resistant prescription pads.

Compliance

Q: Who will be responsible for ensuring that there is compliance with the requirements of section 7002(b)?

A: Primary responsibility for auditing Medicaid providers rests with the States. However, there are some circumstances in which CMS, the Office of the Inspector General of the U.S. Department of Health & Human Services, or some other Federal agency may have occasion to audit a pharmacy provider. When that occurs, the Federal agency will have authority to determine compliance with section 7002(b).

Medicaid as Secondary Payor

Q: Will there be resources to help pharmacists identify Medicaid as the secondary payor to help limit the number of prescriptions that may need to be reprocessed if the prescription was non-compliant?

A: Pharmacist-providers should consult with their State Medicaid agency for assistance in this area.