

- To:
- Blood Banks
  - Dentists
  - Dispensing Physicians
  - Family Planning Clinics
  - Federally Qualified Health Centers
  - Inpatient Hospital Providers
  - Narcotic Treatment Service Providers
  - Nurse Practitioners
  - Nursing Homes
  - Optometrists
  - Outpatient Hospital Providers
  - Pharmacies
  - Physicians
  - Physician Assistants
  - Physician Clinics
  - Podiatrists
  - Rural Health Clinics
  - HMOs and Other Managed Care Programs

## Tamper-Resistant Prescription Pad Requirement

Effective October 1, 2007, federal law imposes a new requirement on prescriptions paid for by Medicaid, SeniorCare, or BadgerCare fee-for-service. The law requires that all written or computer-generated prescriptions that are given to a patient to take to a pharmacy must be written or printed on tamper-resistant prescription pads or tamper-resistant computer paper. This requirement applies to prescriptions for both controlled and noncontrolled substances. This *Wisconsin Medicaid and BadgerCare Update* provides information regarding implementation of this new federal requirement for prescribers and dispensing providers.

### Tamper-Resistant Prescription Pads Now Required

Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 includes a provision requiring that all written and computer-generated prescriptions that are given to a Medicaid recipient to take to a pharmacy must be written or printed on tamper-resistant prescription pads or

tamper resistant computer paper. Refer to Attachment 1 of this *Wisconsin Medicaid and BadgerCare Update* for a copy of the Centers for Medicare and Medicaid Services (CMS) guidance regarding this new requirement. Attachment 2 is a Frequently Asked Questions (FAQ) document provided by the CMS. This requirement is effective October 1, 2007. All other Medicaid policies and procedures regarding prescriptions continue to apply.

### Required Features for Tamper-Resistant Prescription Pads or Computer Paper

To be considered tamper-resistant as of October 1, 2007, prescription pads/paper must contain at least one of the following three characteristics:

- 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.
- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

As of October 1, **2008**, all three of the above-listed characteristics are required by federal law.

### **Exclusions to Tamper-Resistant Prescription Pad Requirement**

Following are exclusions to the tamper-resistant prescription pad requirement:

- Refills of prescriptions presented at a pharmacy before October 1, 2007.
- Prescriptions faxed directly from the prescriber to the pharmacy.
- Prescriptions electronically transmitted directly from the prescriber to the pharmacy.
- Prescriptions telephoned directly from the prescriber to the pharmacy.
- Prescriptions paid for by a Medicaid Managed Care Organization (MCO).
- Prescriptions provided to recipients in nursing facilities, intermediate care facilities for the mentally retarded, and other specified institutional and clinical settings to the extent that drugs are part of their overall rate. However, written prescriptions filled by a pharmacy outside the walls of the facility are subject to the tamper-resistant requirement.

### **72-Hour Grace Period**

Prescriptions presented by patients on non-tamper-resistant pads or paper may be dispensed and

considered compliant if the pharmacy receives a compliant prescription order within 72 hours.

### **Coordination of Benefits**

The federal law imposing these new requirements applies even when Wisconsin Medicaid is the secondary payer.

### **Retroactive Medicaid Eligibility**

If a patient becomes retroactively eligible for Wisconsin Medicaid, the federal law presumes that prescriptions retroactively dispensed were compliant. However, prospective refills will require a tamper-resistant prescription.

### **Penalty for Noncompliance**

Payment made to the pharmacy for a claim corresponding to a noncompliant order may be recouped, in full, by Wisconsin Medicaid.

### **Obtaining Tamper-Resistant Prescription Pads and Paper**

Prescribing providers should begin acquiring tamper-resistant prescription pads and/or computer paper in order to meet the October 1, 2007, compliance deadline. Wisconsin Medicaid is planning to provide a limited supply of pads and paper to Wisconsin Medicaid/SeniorCare prescribing providers. However, this supply may not be available prior to October 1, and prescribers are not encouraged to wait for a Medicaid supply. Providers are not required to use the state-supplied pads to be compliant. Providers should refer to the Wisconsin Medicaid Web site in late September 2007 for information about this assistance.

The *Wisconsin Medicaid and BadgerCare Update* is the first source of program policy and billing information for providers.

Although the *Update* refers to Medicaid recipients, all information applies to BadgerCare recipients and SeniorCare participants also.

Wisconsin Medicaid, BadgerCare, and SeniorCare are administered by the Division of Health Care Financing, Wisconsin Department of Health and Family Services, P.O. Box 309, Madison, WI 53701-0309.

For questions, call Provider Services at (800) 947-9627 or (608) 221-9883 or visit our Web site at [dhfs.wisconsin.gov/medicaid/](http://dhfs.wisconsin.gov/medicaid/).

PHC 1250

ATTACHMENT 1  
Centers for Medicare and Medicaid Services (CMS)  
Guidance Regarding Tamper-Resistant Prescription Pads  
Requirement

(A copy of the guidance is located on the following pages.)



## **Center for Medicaid and State Operations**

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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).

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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ATTACHMENT 2  
Centers for Medicare and Medicaid Services (CMS)  
“Frequently Asked Questions” Document

(A copy of the “Frequently Asked Questions” Document  
is located on the following pages.)



**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.