



STATE OF HAWAII
DEPARTMENT OF HUMAN SERVICES
Med-QUEST Division
Medical Standards Branch
P. O. Box 700190
Kapolei, Hawaii 96709-0190

September 24, 2007

MEMORANDUM

ACS M07-13A
Continuation of ACS M07-13

TO: Medicaid Physicians, Dentists, Physician Assistants, Advanced Practice Registered Nurses, Optometrists, Medicaid Participating Hospital Emergency Rooms, Other Providers with Prescribing Authority and Pharmacy Providers

FROM: Lois Lee, Acting Med-QUEST Division Administrator *ll*

SUBJECT: FEE-FOR-SERVICE (FFS) PROGRAM ONLY

PRESCRIBERS NEED TAMPER-RESISTANT PRESCRIPTION PAPER AND/OR PADS (TRPP) TO USE EFFECTIVE OCTOBER 1, 2007

Section 7002 (b) of the United States Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007 that was recently enacted states effective **October 1, 2007**, all written prescriptions will only be reimbursable if on a TRPP for Medicaid FFS outpatient drugs. Prescribers need to order TRPP from printers to use for any written prescriptions such as for CII medications. Pharmacists who receive non-TRPP prescriptions must confirm these with prescribers to be considered for Medicaid Fee-For-Service (FFS) reimbursement.

Please see the attached Frequently Asked Questions (FAQs) recently issued by the Centers for Medicare and Medicaid Services (CMS) regarding TRPP, as well as examples of tamper resistant prescriptions used in other states. The website www.himed-questffs.org has more information such as links to: TRPP Summary, Printers Approved by Medi-Cal (California Medicaid), Provider Memorandum M07-13 dated August 30, 2007, etc.

If you have questions regarding this memo or Medicaid drug claims processing, please contact Affiliated Computer Services Pharmacy Benefits Manager (ACS PBM) Call Center at 1 (877) 439-0803.

Attachments

**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 Payer

Q: 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?

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

SAMPLE

FLORIDA PRESCRIPTION FORMS

Must be used for all Medicaid prescriptions in Florida.

Batch Number (arrow pointing to PR1010725096114)

Reverse RX (arrow pointing to the back of the form)

Security Features Listed (arrow pointing to the security features section)

Void Pantograph (arrow pointing to the void pantograph area)

Microprint Signature line (arrow pointing to the signature line)

Form Content:

JOHN SMITH, M.D.
123 Your Address
YOURTOWN, USA 00000
0001 000-0000

PR1010725096114

VOID PANTOGRAPH (VOID PANTOGRAPH) (VOID PANTOGRAPH) (VOID PANTOGRAPH) (VOID PANTOGRAPH)

Name _____ Date _____

Address _____

Prescription is void if more than one (1) prescription is written per blank.

INSTITUTION STYLE SECURITY PRESCRIPTION FORM SAMPLE IN A MULTIPLE DRUG FORMAT

Institution forms can only be used by health care facilities licensed under Health & Safety Code section 1250. Generally, these are 24-hour acute care hospitals, skilled nursing facilities, etc. The forms are preprinted with the facility and the facility's "designated prescriber" information as indicated below. The actual prescriber information will be printed, handwritten, or stamped on the form when the prescription is written.

VOID APPEARS WHEN COPIED • REVERSE RX • MICROPRINT SIGNATURE LINE • CA WATERMARK	
Institution's State License Number Institution Name Address City, State Zip	
9999999-0001	
Designated Prescriber: Designated Prescriber Name, Category of Licensure, DEA Number, State License Number	
Prescriber Name & Category of Licensure	DEA Number
Name	DOB
Address	Sex: <input type="checkbox"/> M <input type="checkbox"/> F
Telephone Number	State License Number
1)	Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151-over Unit _____ Refills: 0-1-2-3-4-5 <input type="checkbox"/> Do Not Substitute Initials _____
2)	Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151-over Unit _____ Refills: 0-1-2-3-4-5 <input type="checkbox"/> Do Not Substitute Initials _____
3)	Quantity: <input type="checkbox"/> 1-24 <input type="checkbox"/> 25-49 <input type="checkbox"/> 50-74 <input type="checkbox"/> 75-100 <input type="checkbox"/> 101-150 <input type="checkbox"/> 151-over Unit _____ Refills: 0-1-2-3-4-5 <input type="checkbox"/> Do Not Substitute Initials _____
X	Date _____
Prescription is void if the number of drugs is not noted: _____	
THERMOCHROMIC INK SYMBOL • QUANTITY CHECK BOXES • CHEMICAL VOID PROTECTION	

Batch/Lot Numbers – Unique batch and sequential lot numbers assigned by approved security printers. Numbers are not tracked by the State.

Actual Prescriber – the prescription is not valid without the actual prescriber information filled in.

Opaque Writing fades or disappears when photocopied repeatedly to lighten.

Six quantity check boxes allow quick confirmation that the quantity prescribed has not been altered.

Do Not Substitute – if desired, prescriber must check box and initial

Refills – CII drugs cannot be refilled, only CIII – V can be refilled.

Description of security features in warning bands on face or listed on back of prescription. (see sample of backside)

Statement allows multiple prescriptions on one form. Prescribers must note the number of drugs prescribed.

Thermochromic ink feature changes color or disappears temporarily with hot breath or when rubbed briskly. It slowly returns to normal as it cools.

Alternatively, institutions may order a form designed to write only one controlled substance. See the previous form sample using a single drug prescription format.