

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

ALBERT HAWKINS Executive Commissioner

** Important Medicaid Information **

Tamper-Resistant Prescriptions

Pursuant to federal law (H.R. 2206 / Public Law 110-28, U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act, 2007), effective April 1, 2008, prescribing practitioners will be required to use tamper-resistant prescription paper when writing a prescription for any drug for Medicaid recipients.

The Texas Health and Human Services Commission (HHSC) requested an exemption to this regulation for its Medicaid providers. However, the federal Centers for Medicare and Medicaid Services (CMS) determined that it does not have the statutory authority to grant an exemption to federal law.

This regulation applies to all *written* prescriptions submitted for payment through the Vendor Drug Program (VDP) for all Texas Medicaid beneficiaries. The regulation does not apply to prescription orders transmitted to a pharmacy via telephone, fax, or electronically. According to CMS, the purpose of tamper-resistant prescription pads is to reduce instances of unauthorized, improperly altered, and counterfeit prescriptions.

In order for a written prescription to be considered tamper resistant by CMS, the prescription paper must meet the following three characteristics:

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

The tamper-resistant requirement is only mandatory for prescriptions written for Medicaid clients. However, HHSC encourages prescribers to adopt the use of tamper-resistant paper for all their patients. It will reduce their over-all risk and will avoid the confusion of determining which pad to use for which patient.

Schedule II Controlled Substances

CMS has determined that the prescription forms for Schedule II controlled substances, issued by the Texas Department of Public Safety (DPS) under the Texas Prescription Program, meet the baseline standards set forth above. Providers should continue using these pads for all prescriptions for Schedule II controlled substances. These pads should not be used to write prescriptions for non-Schedule II drugs.

Effective April 1, 2008, federal law requires Medicaid agencies to limit reimbursement for written (and non-electronic) prescriptions to only those executed on tamper-resistant pads. Prescribing practitioners should take necessary steps to ensure that tamper-resistant paper is used for all written or printed prescriptions provided to Medicaid clients, or that compliant, non-written alternatives are used for transmitting prescriptions, such as by telephone, fax, or electronic submittal. Pharmacies are required to ensure that all written Medicaid prescriptions submitted for payment to the Vendor Drug Program are written on a compliant tamper-resistant pad.

Exceptions

Prescription orders transmitted to a pharmacy electronically, by telephone, or by fax are exempt from this requirement. Prescribing practitioners are encouraged to submit prescriptions through one of these approved processes whenever possible to ensure continuity of care and access to necessary medications for Medicaid recipients. The tamper-resistant requirement also does not apply to refills of a written prescription that was dispensed at a pharmacy before April 1, 2008. Please see the Questions and Answers (<u>Appendix A</u>) for additional exemptions and exceptions.

Access to Care

The tamper-resistant prescription pad requirement is intended to reduce forged and altered prescriptions and deter drug abuse. It is not intended to restrict recipient access to medically necessary pharmaceuticals. If a Medicaid recipient presents with a non-compliant prescription, the pharmacist can obtain telephone verification from the prescriber and dispense the prescription in full (as written). The pharmacist must note the verification on the original written prescription. The pharmacist may also fill the prescription and obtain a compliant prescription by facsimile, electronic prescription, or re-written on tamper-resistant paper within 72 hours after the date the prescription was filled.

Any time a patient presents a written prescription and the pharmacist is unsure whether the prescription is compliant, the prescribing practitioner should be contacted for verification. See <u>Appendix B</u> for a list of tamper-resistant features that are commonly available. To assist pharmacists in determining if a prescription is in compliance with the tamper-resistant requirements, prescribers are encouraged to purchase prescription paper that lists the security features.

Obtaining Prescription Pads

Prescribers may select their supplier of CMS-compliant prescription pads. Information on available vendors may be obtained online by using a keyword search of "secure prescription pads."

There are many compliant features available from security prescription vendors. The National Council for Prescription Drug Programs (NCPDP) has developed a guide to many of the available features. Prescribers should refer to the guide (<u>Appendix B</u>) before ordering tamper-resistant prescription pads or paper.

Pharmacists have voiced concerns about how to identify a tamper-resistant prescription. HHSC encourages pharmacists to call the prescriber every time they have a question. <u>HHSC strongly encourages all prescribers to order tamper-resistant prescription pads that clearly list the security features.</u> This will reduce the number of calls and cause the least workflow disruption for both pharmacists and prescribers.

The Texas Medical Association sent a message to physicians on February 1, 2008. The notice is available on their website (<u>www.texmed.org</u>) under the link "<u>Tamper-Resistant Rx Pads Required</u> <u>April 1</u>." The notice also includes a consolidated list of vendors of compliant pads.

In addition, some states such as California, Florida, Indiana, Kentucky, Maine, West Virginia, and Wyoming currently have tamper-resistant programs in place whereby they certify specific printers for tamper-resistant prescription pads. These printers meet the baseline requirements set by CMS. Links to printers approved by other states are provided below:

- California:
 - •• <u>www.ag.ca.gov/bne/security_printer_list.php</u>
- Florida:
 - <u>http://floridamedicaid.acs-inc.com</u> (From the choices on the left-hand side of the page select "Provider Support" followed by "Counterfeit-proof Prescriptions.")
- Maine:
 - •• www.mainecarepdl.org/index.pl/home/tamper-resistant-prescription-padsh

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).
 - •• www.cms.hhs.gov/SMDL/downloads/SMD081707.pdf
- Centers for Medicare & Medicaid Services (CMS) Frequently Asked Questions Document published 9/13/2007.
 - http://www.cms.hhs.gov/DeficitReductionAct/Downloads/MIPTRPFAQs9122007.pdf

If you have any questions:

- Vendor Drug Field Administration Pharmacists
 - ➢ Ft. Worth − Loretta Disney, R.Ph. (817) 321-8092
 - ▶ Ft. Worth Walter Reynolds, R.Ph. (817) 321-8090
 - San Antonio Sharon Gaskill, R.Ph. (210) 619-8167
 - McAllen Belinda Cordova, R.Ph. (956) 971-1281
- Vendor Drug Pharmacy Resolution Desk
 - ▶ (800) 435-4165
- Vendor Drug website
 - www.txvendordrug.com

Appendix A: Question and Answers

CMS provided guidance on the requirements and use of tamper-resistant prescription pads to states. Based on this guidance, the Texas Health and Human Services Commission (HHSC) has developed this Question and Answer document to assist practitioners and address frequently asked questions.

QUESTION	ANSWER
Where can providers obtain tamper-resistant prescription pads?	Prescribers are encouraged to check with their current suppliers of prescription pads. Providers may also obtain information on vendors of tamper-resistant prescription pads online by using a keyword search of "secure prescription pads." In addition, some states such as California, Florida, Indiana, Kentucky, Maine, West Virginia, and Wyoming currently have tamper-resistant programs in place whereby they certify specific printers for tamper-resistant prescription pads. The Texas Medical Association has published a list of vendors approved for other states at the link below. These printers meet the baseline requirements set by CMS. <u>www.texmed.org/Template.aspx?id=6495</u>
Is HHSC certifying approved printers/suppliers of tamper-resistant prescription pads?	No. At this time, HHSC is not certifying printers or suppliers.
What is the cost of tamper- resistant prescription pads?	HHSC does not have cost information on prescription pads. Prices are available from printers/suppliers.
Will the state reimburse medical providers for the cost of the tamper- resistant prescription pads?	No.
When will this rule become effective, and when are providers and pharmacies expected to comply with this change?	 Beginning April 1, 2008, Medicaid providers will be required to submit all written prescriptions on tamper-resistant paper meeting all three of the following characteristics: Prevents unauthorized copying of completed or blank prescription forms. Prevents erasure or modification of information written on the prescription form. Prevents the use of counterfeit prescription forms.
Is this requirement limited to Schedule II controlled substances?	CMS has determined that the prescription forms for Schedule II controlled substances, issued by the Texas Department of Public Safety (DPS) under the Texas Prescription Program, meet the baseline standards for a tamper-resistant prescription. Providers should continue using these pads for all prescriptions for Schedule II controlled substances. All other written prescriptions for Medicaid recipients must be executed on tamper resistant paper.

Does this apply to Medicaid recipients enrolled in managed care plans?	Yes, because all prescriptions for all Medicaid recipients in Texas are reimbursed through the Vendor Drug Program. Managed care entities do not reimburse for out-patient prescription drugs for Texas Medicaid recipients and therefore those prescriptions are not exempt from this requirement.
Are there any exceptions to having to use tamper- resistant written prescriptions?	Yes. Telephone, fax, and electronic prescriptions are exempt from this requirement. Providers are encouraged to use these methods when submitting prescriptions.
How can a pharmacist determine whether a written prescription is tamper resistant?	 A compliant, written prescription will have the following industry-recognized features: Prevents unauthorized copying of blank or completed forms. Prevents erasure or modification of completed forms. Prevents counterfeiting. There are many suppliers of tamper-resistant prescription pads, so there will be many variations in these features. HHSC strongly encourages providers to use compliant pads that list their security features. Pharmacists are expected to use their best professional judgment. If a prescription appears to be written on plain paper, or the pharmacist has any doubts, the prescriber should be contacted.
If a patient presents with a prescription that is not on a tamper-resistant pad and needs the medication right away, can the pharmacy fill the prescription?	Yes, the pharmacist may fill the prescription in full as it is written. CMS requires that a compliant prescription be obtained within 72 hours of filling the prescription. A compliant prescription is considered one that has been faxed, telephoned, submitted electronically, or written on a tamper-resistant prescription pad. Note: Prescriptions filled on an emergency basis due to not being written on tamper resistant paper are not limited to a 72-hour supply of medication.
What should providers do in the event that tamper- resistant prescription pads are not available to them by April 1, 2008?	Providers may submit prescriptions using an approved alternative method such as by fax, telephone, or electronic prescription submittal.
Does this policy apply in cases of retroactive eligibility? What if the patient was not eligible for Medicaid at the time of the visit?	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 <i>before</i> the recipient became retroactively eligible for Medicaid. This presumption does <i>not</i> extend to any refills that occurred <i>after</i> 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 by facsimile or electronic prescription.

Are all providers required to comply?	Yes. All providers writing prescriptions for Medicaid clients are required to comply, irrespective of specialty or the setting in which they practice. All written prescriptions are required to be submitted on tamper-resistant prescription pads.
Are tamper-resistant prescriptions required when Medicaid is the secondary payer?	Yes. Per federal law, tamper-resistant prescriptions are required for all written Medicaid prescriptions.
Are refills exempt from this rule?	Refills of written prescriptions are only exempt if the original written prescription was presented at a pharmacy before April 1, 2008.
Are tamper-resistant prescriptions required in facilities?	Only hand-written prescriptions provided directly to the patient are required to be executed on tamper-resistant prescription pads. Prescriptions for patients in nursing homes and other facilities, where the patient does not handle the prescription directly, are exempt from this requirement. However, if the facility provides a written prescription to be filled by the client directly, it must be written on a tamper-resistant prescription pad.
Are "drug orders" written for a resident of a nursing facility exempt from this rule?	Yes. Drug orders transmitted directly from a nursing facility to a pharmacy are exempt, as the patient does not directly handle the prescription.
Are prescriptions printed in a practitioner's office from a patient's medical record exempt from this requirement?	No. If the prescription order is presented to the pharmacy on paper, it must be on tamper-resistant paper. Faxed and other electronic "drug orders" are exempt. Tamper-resistant printer paper may also be available from suppliers of compliant prescription pads.
Does this requirement apply when a prescription is provided for an over- the-counter drug?	Yes. This applies to all prescribed outpatient drugs, including over-the-counter drugs.
Are prescriptions written prior to April 1, 2008, but filled after April 1, 2008, exempt from this rule?	No. Any <u>new</u> written prescription filled on or after April 1, 2008, must be executed on a tamper-resistant prescription pad, irrespective of the date the prescription was written.
Does this mean the 72- hour emergency supply can be used for a non- compliant prescription?	No. For non-compliant tamper-resistant prescription pad prescriptions, the pharmacy should fill the prescription <u>as written</u> . The pharmacy must obtain a verbal, faxed, electronic, or compliant written prescription from the prescribing provider within 72 hours after the date on which the prescription was filled.

Appendix B: NCPDP Guide to Features Available for Tamper-Resistant Pads and Paper

This section summarizes features that could be used on a tamper-resistant pad/paper in compliance with the CMS guidelines within the timeframe required. They are categorized according to the three types of tamper-proof features as described by CMS. Features in bold tend to be less costly and easier for physicians to implement than the other features. The American Pharmacist Association (APhA), National Association of Chain Drug Stores (NACDS), and National Community Pharmacist Association (NCPA) believe that the features in italics are difficult for pharmacies to verify and would likely not be effective as state requirements.

Feature	Description
"Void" or "Illegal" pantograph	The word "Void" appears when the prescription is photocopied. Due to the word "Void" on faxed prescriptions, this feature requires the pharmacy to document if the prescription was faxed.
Reverse "Rx" or white area on prescription	"Rx" symbol or white area disappears when photocopied at light setting. This feature is normally paired with the "Void" pantograph to prohibit copying on a light setting.
Coin-reactive ink	Ink that changes color when rubbed by a coin – can be expensive and is not recommended.
Security back print	Printed on the back of prescription form. The most popular wording for the security back print is "Security Prescription" or the security back print can include the state's name.
Watermarking (forderiner)	Special paper containing "watermarking."
Diagonal lines (patented "Void")	Diagonal lines with the word "void" or "copy." Can be distracting or expensive.
Micro printing	Very small font writing, perhaps acting as a signature line. This is difficult to photocopy and difficult to implement if using computer printer. It is also difficult for a pharmacist to see.

Category 1 - One or more industry-recognized features designed to prevent unauthorized copying of a

Category 2 - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description
Uniform non-white background color	Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered and show the color of the underlying paper.

Quantity check-off boxes	In addition to the written quantity on the prescription, quantities are indicated in ranges. It is recommended that ranges are 25s, with the highest being "151 and over." The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. See sample prescription on page B-3.
Refill Indicator (circle or check number of refills or "NR")	Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.
Pre-print "Rx is void if more than Rxs on paper" on prescription paper	Reduces the ability to add medications to the prescription. Line must be completed for this feature to be valid. Reduces the ability to add medications to the prescription. Computer printer paper can accommodate this feature by printing, "This space intentionally left blank" in an empty space or quadrant.
Quantity Border and Fill (for computer generated prescriptions on paper only)	Quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **50** Value may also be expressed as text, e.g. (FIFTY), (optional).
Refill Border and Fill (for computer generated prescriptions on paper only)	Refill quantities are surrounded by special characters such as an asterisk to prevent alteration, e.g. QTY **5** Value may also be expressed as text, e.g. (FIVE), (optional).
Chemically reactive paper	If exposed to chemical solvents, oxidants, acids, or alkalis to alter, the prescription paper will react and leave a mark visible to the pharmacist.
Paper toner fuser	Special printer toner that establishes strong bond to prescription paper and is difficult to tamper.
Safety or security paper with colored pattern	White (or some other color) mark appears when erased. This is expensive paper.

Category 3 - One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Feature	Description
Security features and descriptions listed on prescriptions	Complete list of the security features on the prescription paper for compliance purposes. This is strongly recommended to aid pharmacists in identification of features implemented on prescription.
Form Batch Number	Each batch of prescriptions has a unique identifier. This feature is only effective in states with an approved vendor listing.
Serial number	Number issued by printer of prescription, may or may not be sequential. To be valid, this should be reported to the state. New York, after several years, is now tracking numbers electronically.
Encoding techniques (bar codes)	Bar codes on prescription. Serial number or Batch number is encoded in a bar code.

Logos	Sometimes used as part of the background color or pantograph.
Metal stripe security	Metal stripe on paper, difficult to counterfeit.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.
Invisible fluorescent fibers/ink	Visible only under black light.
Thermo chromic ink	Ink changes color with temperature change. This is expensive paper and problematic for storage in areas not climate controlled.
Holograms that interfere with photocopying	May interfere with photocopying or scanning.

The sample Prescription Pad displays several of the recommended security features:

