



Reminder: Federal Medicaid "Tamper Proof" Prescription Requirement Becomes Effective on April 1, 2008 — TennCare Issues Guidance on Wednesday, March 5, 2008

Beginning April 1, 2008, all written prescriptions for Medicaid recipients must be on paper with at least one tamper-resistant feature as outlined by the Centers for Medicare and Medicaid Services (CMS) and defined by the State. Beginning October 1, 2008, these prescriptions must be on paper that meets all three baseline characteristics of tamper-resistant pads. CMS has outlined the three baseline characteristics as those that: (1) prevent unauthorized copying of a completed or blank prescription form; (2) prevent the erasure or modification of information written on the prescription by the prescriber; or (3) prevent the use of counterfeit prescription forms.

States are responsible for defining specific features that meet the baseline characteristics in order for a prescription to be considered tamper-resistant in that State. Therefore, CMS recommends reviewing your State's policy for guidance on acceptable tamper-resistant features. Please note that electronic prescriptions, faxed prescriptions and prescriptions sent over the telephone are exempt from this requirement. **Failure to comply could result in a withholding of Medicaid reimbursement.**

TPA reminds pharmacies that, effective April 1, 2008, according to TennCare policy, "Prescriptions reimbursed by TennCare written on non tamper-resistant forms are subject to recoupment." TPA notes this also applies to emergency supplies referenced below.

TENNCARE GUIDANCE – March 5, 2008

Effective April 1, 2008, ALL prescriptions for TennCare patients must be written using tamper-resistant pads/paper, with the limited exceptions outlined below:

- Refills of written prescriptions presented at a pharmacy before April 1, 2008
- Prescriptions sent to the pharmacy electronically (either by e-prescribe or by fax)
- Prescriptions communicated to the pharmacy by telephone
- Drugs administered in nursing facilities and ICFMR's

WHY? A federal law/mandate intended to reduce fraud and abuse was embedded in a law passed by Congress primarily dealing with funding for the Iraq War.

WHAT DO YOU NEED TO DO? If you receive a non tamper-resistant prescription, contact the prescriber and have the prescription re-issued in a tamper-resistant format (i.e., submitted as a fax, verbal, or electronic prescription or re-written on a compliant form) prior to dispensing the full amount. Prescriptions for CII items received on a non tamper-resistant form should be verified with the prescriber and that verification noted on the original order form.

If you are unsuccessful in obtaining a compliant or exempt prescription, provide the TennCare enrollee with a copy of the Non Tamper-Resistant Notice as required by the "Grier" Consent De-

claration. Also request that the enrollee contact their prescriber for assistance. The Non Tamper-Resistant Notice explains the requirement for tamper-resistant prescriptions and informs enrollees of their rights to an appeal. Copies of the Non Tamper-Resistant Denial notice are available for download at <https://tennessee.fhsc.com> under the "Providers Documents" tab, or directly from TennCare by contacting 888-816-1680. *[The notice has not yet been posted by FirstHealth; TPA members can download it in English and Spanish from the TennCare page of the TPA website, www.tnpharm.org.]*

WHAT IS A TAMPER RESISTANT PRESCRIPTION PAD?

According to the federal government, to be considered tamper resistant on **April 1, 2008, a prescription pad must have at least one feature from any category listed below.** And on October 1, 2008, prescriptions will be required to have a minimum of one feature from each of the three CMS categories listed below:

1. Industry-recognized feature(s) designed to prevent unauthorized copying
2. Industry-recognized feature(s) designed to prevent erasure or modification of information written by the prescriber
3. Industry-recognized features list designed to prevent use of counterfeit prescription forms *[additional information available soon]*

WHAT HAPPENS ON OR AFTER APRIL 1, 2008, IF A TENNCARE PATIENT PRESENTS TO A PHARMACY WITH A PRESCRIPTION THAT IS NOT TAMPER-RESISTANT?

In a non-emergency situation, the drug should not be provided unless the pharmacist is able to reach the prescriber and obtain a verbal, electronic, or compliant written prescription.

If you believe the patient has an urgent need for the drug and you are unsuccessful in obtaining a compliant or exempt prescription from the prescriber, dispense a 3-day supply of the medication using a Prior Authorization Code of 8 in NCPDP field 461-EU. The 3 day supply prescription will count towards prescription limits, but the balance can be filled once the tamper-resistant prescription is obtained.

The balance-fill prescription should be submitted with a Submission Clarification Code of 5 in NCPDP field 420-DK. If you dispense the full amount of the prescription because it is a un-breakage package, a tamper-resistant copy must be obtained within 72 hours of the time the prescription was filled. This process is identical to that used for non-PDL emergency fills, except that reimbursement is subject to recoupment if you do not obtain a compliant prescription within 72 hours. **Prescriptions reimbursed by TennCare written on non tamper-resistant forms are subject to recoupment.**

THE FEATURES TO BE CONSIDERED COMPLIANT FOR OCTOBER 1, 2008, ARE EXPLAINED ON THE NEXT PAGE.

It's easy to join TPA or pay 2008 membership dues! Visit <https://secure.xo.com/tnpharm.org/index.shtml> or call TPA, 615.256.3023.

Tennessee Pharmacists Association 615.256.3023 615.255.3528 Fax tpa@tnpharm.org www.tnpharm.org



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FEATURES TO BE CONSIDERED COMPLIANT FOR OCTOBER 1, 2008 (from the Bureau of TennCare, March 5, 2008)

Category 1 – Designed to prevent unauthorized copying of a completed or blank prescription form.

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.
Watermarking	Special paper containing “watermarking”.

Category 2 – Designed to prevent the erasure or modification of information written on the prescription by the prescriber.

Feature	Description
Quantity check off boxes with Refill Indicator (circle or check number of refills or “NR”)	In addition to the written quantity on the prescription, quantities are indicated in ranges. It is recommended that ranges be 25's with the highest being “151 and over”. The range box corresponding to the quantity prescribed MUST be checked for the prescription to be valid. Indicates the number of refills on the prescription. Refill number must be used to be a valid prescription.
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.

Category 3 – Designed to prevent the use of counterfeit prescription forms.

Feature	Description
Security features and descriptions listed on prescriptions (This feature is required on all TennCare tamper-resistant pads/paper after 10/1/2008)	Complete list of the security features on the prescription paper for compliance purposes.
Heat sensing imprint	By touching the imprint or design, the imprint will disappear.

FDA Advisory Committees: Nomination Opportunities

The Food and Drug Administration (FDA) utilizes advisory committees to provide FDA with independent advice from outside experts on issues related to human and veterinary drugs, biologics products, medical devices, and food. Generally, the advisory committees: are comprised of representatives for industry, patients and providers; serve up to a four year term; and meet one to four times a year in the Washington, DC area. Although the advisory committees provide advice to the Agency, final decisions are made by the FDA. Anyone interested in serving as a member of an FDA advisory committee is encouraged to self-nominate or nominate a colleague by submitting a cover letter and curriculum vitae or resume to FDA. Information can be emailed to cv@oc.fda.gov or mailed to: Food and Drug Administration, Advisory Committee Oversight and Management Staff (HF-4), 5600 Fishers Lane, Room 15A12, Rockville, Maryland 20857.

For a listing of current FDA advisory committee vacancies go to: www.fda.gov/oc/advisory/vacancies/acvacbycenter.html.

On February 27, 2008, FDA released a Federal Register notice announcing that the Pediatric Advisory Committee will have a vacancy for a non-voting industry representative whose term would begin June 30, 2008. The deadline for accepting nomination materials for prospective candidates is March 28, 2008. The Pediatric Advisory Committee advises and makes recommendations to FDA regarding: pediatric research; identification of research priorities related to pediatric therapeutics and treatment needs; ethics, design, and

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analysis of clinical trials; pediatric labeling; adverse event reports for drugs granted pediatric exclusivity; and any other matters involving pediatrics.

FDA is also requesting nominations for industry organizations to participate in the non-voting member selection process. A letter of interest must be sent to FDA by March 28, 2008. All letters of interest and nominations for the Pediatric Advisory Committee should be submitted via e-mail at Carlos.Peña@fda.hhs.gov or in writing to: Carlos Peña, Office of Science and Health Coordination (HF-33), Food and Drug Administration, 5600 Fishers Lane, Room 14B-08, Rockville, MD 20857.

For more information, go to the Federal Register notice at <http://a257.g.akamaitech.net/7/257/2422/01jan20081800/edocket.access.gpo.gov/2008/pdf/E8-3719.pdf>.