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Sequence Number: 12-23-09
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File Date (effective date): 12/21/2009
End Effective Date: 06/19/2010

Emergency Rule Filing Form

Emergency and Public Necessity rules are effective from date of filing for a period of up to 180 days.

Agency/Board/Commission:	Board of Osteopathic Examination
Division:	
Contact Person:	Alison G. Cleaves Deputy General Counsel
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Rule Type:
X Emergency Rule

Revision Type (check all that apply):
___ Amendment
X New
___ Repeal

Statement of Necessity:
Pursuant to T.C.A. §4-5-208, the Board of Osteopathic Examination is authorized to promulgate emergency rules in the event that the rules are required by an enactment of the General Assembly within a prescribed period of time that precludes utilization of rulemaking procedures described elsewhere in T.C.A. Title 4, Chapter 5, for the promulgation of permanent rules.

Chapter 1035 of the Public Acts of 2008 provides that certain authorized prescribers (medical doctors, podiatrists, dentists, advanced practice nurses, optometrists, osteopaths, and physician's assistants) are required to issue handwritten, typed, or computer-generated prescriptions on tamper-resistant prescription paper in accordance with the Centers for Medicare and Medicaid Services ("CMS") guidelines. The Act became effective on October 1, 2008 with respect to TennCare prescriptions and July 1, 2009 for all other prescriptions. Each board regulating the respective professions affected by the law have their own authority contained within the practice acts to promulgate rules affecting their licensees relative to tamper-resistant prescriptions.

Due to the length of time necessary to complete the rulemaking process, these emergency rules were required in order for the Board to begin implementation of this new prescription requirement in order to comply with the enactment of General Assembly. The Board conducted a rulemaking hearing on the 12th day of August, 2009 to consider comments on the adoption of these as permanent rules. The emergency rules became effective from June 25, 2009 to December 7, 2009. Although rulemaking hearing rules were sent to the Attorney General's Office on August 25, 2009, they are still under the Attorney General Office's review. If the emergency rules are allowed to lapse without any permanent rules established, then the licensees will not have any guidance in the form of rules relative to prescribing on tamper-resistant prescriptions. Tenn. Code Ann. §4-5-208(b) provides that an agency may adopt the same or substantially similar emergency rules within one (1) calendar year from its first adoption if the agency clearly establishes that it could not reasonably be foreseen during the period of time in which the public necessity rules were effective, that such emergency would continue or would likely recur during the next nine (9) months. The agency met all of the requirements provided in the law and made timely submissions of the emergency rules (then public necessity rules) as well as the rulemaking

hearing rules to the Attorney General's Office; however, the agency could not have reasonably foreseen that an Attorney General's opinion would be requested relative to the definition of "prescriber" contained in these rules as it relates to the Board of Osteopathic Examiners. Because the results of the Attorney General's opinion may impact the definition of prescriber relative to nursing that is contained in these rules (i.e., advanced practice nurse with a certificate of fitness to prescribe), this has delayed the review of the rulemaking hearing rules for the promulgation of permanent rules. The agency is now refiling the original public necessity rules as emergency rules to fill in the gap between the expiration of the public necessity rules and the effective date of the permanent rules to ensure continuity in the standard of care.

For a copy of these emergency rules contact: Rosemarie Otto, Executive Director, 227 French Landing, Suite 300, Heritage Place MetroCenter, Nashville, Tennessee 37243 at (615) 741-4540.

Rule(s) Revised (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/RuleTitle per row)

Chapter Number	**Chapter Title**
1050-02	General Rules and Regulations Governing the Practice of Osteopathy
Rule Number	**Rule Title**
1050-02-.22	Tamper-Resistant Prescriptions

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Department of Health
Board of Osteopathic Examiners
Division of Health Related Boards

New Rules

Chapter 1050-02
General Rules and Regulations Governing the Practice of Osteopathy

1050-02-.22 Tamper-Resistant Prescriptions

(1) Purpose.

This rule is designed to implement the law requiring that licensed osteopathic physicians have all written, typed, or computer-generated prescriptions issued on tamper-resistant prescription paper.

(2) Definitions.

The following definitions are applicable to this rule:

(a) "Drug" shall have the same meaning as set forth in T.C.A. § 63-10-204(16).

(b) "Prescriber" means an individual licensed in Tennessee as a medical doctor, podiatrist, advanced practice nurse with a certificate of fitness to prescribe, dentist, optometrist, osteopathic physician, or physician's assistant.

(c) "Prescription order" shall have the same meaning as set forth in T.C.A. § 63-10-204(38).

(d) "Tamper-resistant prescription" means a written prescription order with features that are designed to prevent unauthorized copying, erasure, modification, and use of counterfeit prescription forms.

(3) Tamper-Resistant Prescription Requirements.

(a) A prescriber shall ensure that all handwritten, typed, or computer-generated prescription orders are issued on tamper-resistant prescriptions. Tamper-resistant prescriptions shall contain the following features:

1. Either a void or illegal pantograph or a watermark designed to prevent copying;

2. Either quantity check-off boxes with refill indicators or a uniform, non-white background color designed to prevent erasure or modification; and

3. Security features and descriptions listed on the prescriptions designed to prevent use of counterfeit forms.

(4) Security Measures and Recordkeeping.

(a) Each prescriber shall undertake adequate safeguards and security measures to ensure against loss, improper destruction, theft, or unauthorized use of the tamper-resistant prescriptions in the prescriber's possession.

(5) Use of Tamper-Resistant Prescriptions.

(a) Facsimile Prescription Transmission.

1. Prescriptions sent by facsimile transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, quantity prescribed, and the method by which the prescription has been transmitted.

(b) Electronic Prescription Transmission.

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document that the prescription was transmitted electronically in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules.

Authority: Chapter 1035 of the Public Acts of 2008 and T.C.A. §§53-10-401 and 63-9-116. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].

* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Donald Polk, D.O.	X				
Paul G. Smith, D.O.	X				
Karen R. Shepherd, D.O..	X				
Janice Hinton	X				
Jill Robinson, D.O.				X	
Rafael M. Sanchex, D.O.				X	

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 12/4/09

Signature: Alison G. Cleaves

Name of Officer: Alison G. Cleaves

Title of Officer: Deputy General Counsel Department of Health

Subscribed and sworn to before me on: 12/4/09

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/2011

THEODORA P. WILKINS NOTARY PUBLIC AT LARGE DAVIDSON COUNTY, TENN.

All emergency rules provided for hereunder have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.
Attorney General and Reporter

12-16-09
Date

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Filed with the Department of State on: 12/21/2009

Effective for: 180 *days

Effective through: 06/19/2010

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

Tre Hargett
Secretary of State

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to TCA 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Rule 1050-02-.22(1) Purpose-establishes that the purpose of the new rule is to implement the law contained in Tenn. Code Ann.§§ 53-10-401 and 63-9-116 requiring individuals licensed to engage in the practice of osteopathic medicine to have all written, typed or computer-generated prescriptions issued on tamper-resistant prescription paper.

Paragraph (2) Definitions—establishes the definitions necessary to implement and enforce the substantive portions of the rule. Through the definition of "prescriber", the rule identifies those health care providers who are identified in the law as being required to have all written, typed or computer-generated prescriptions on tamper-resistant paper. The rule also establishes a definition of "tamper-resistant prescription" to mean a prescription order that is placed on tamper-resistant paper that is designed to ensure that the prescription order is not copied, modified, erased or used in producing counterfeit forms.

Paragraph (3) Tamper-Resistant Prescription Requirements—provides that tamper-resistant prescriptions shall contain features that have been recommended by the Centers for Medicare and Medicaid Services ("CMS"). The tamper-resistant prescription shall have either a "void" or "illegal pantograph" or a watermark designed to prevent copying; either quantity check-off boxes with refill indicators or a uniform, non-white background designed to prevent erasure or modification; and a list of security features and descriptions.

Paragraph (4) Security Measure and Recordkeeping—provides that the health care providers affected by the law shall ensure that adequate safeguards and security measures are taken to prevent against loss, improper destruction, theft and unauthorized use of the tamper-resistant prescriptions.

Paragraph (5) Use if Tamper-Resistant Prescriptions—provides that prescriptions that are received by a licensed pharmacy by facsimile or by electronic transmission do not have to be placed on tamper-resistant prescription paper. The details of the prescription should be noted in the patient record; however the method of transmission is not required to be recorded.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The new rule was promulgated to implement Public Chapter 1035 of the 2008 Public Acts codified in Tenn. Code Ann. §§ 53-10-401 and 63-9-116.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Relative to the Board of Osteopathic Examination, the persons affected by the rule are those individuals licensed to engage in the practice of osteopathic medicine.

(D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

I am unaware of any opinion of the Attorney General or any judicial ruling which directly relates to this rule.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The new rule will have neither a positive nor a negative fiscal impact.

(F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Rosemarie Otto, Program Administrator and I possess substantial knowledge and understanding of the new rule.

(G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Rosemarie Otto, Program Administrator and I will explain the new rule at a scheduled meeting of the Committee.

(H) Office address and telephone number of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

I may be reached at the Department of Health, Office of General Counsel, Plaza One, Suite 210, 220 Athens Way, Nashville, Tennessee 37243 ((615) 741-1611). Rosemarie Otto may be reached at the Department of Health, Health Related Boards, 227 French Landing, Suite 300, Nashville, Tennessee 37243 ((615) 741-4540).

(I) Any additional information relevant to the rule proposed for continuation that the committee requests.

I, as well as the Program Administrator, Rosemarie Otto will provide any additional information requested by the Committee relative to the new rule.