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Emergency or Public Necessity Rule(s) Filing Form

Emergency and Public Necessity rules are effective from date of filing for a period of up to 165 days.

Agency/Board/Commission: Department of Health
Division: Board of Optometry
Contact Person: Alison G. Cleaves
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Rule Type :
___ Emergency Rule
X Public Necessity Rule

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

Statement of Necessity:
Pursuant to T.C.A. §4-5-209, the Board of Optometry is authorized to promulgate public necessity 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 becomes effective on October 1, 2008 with respect to TennCare prescriptions and July 1, 2009 for all other prescriptions.

Due to the length of time necessary to complete the rulemaking process, these public necessity rules are required in order for the Board to begin implementation of this program to comply with the enactment of General Assembly. The Board is conducting a rulemaking hearing on the 12th day of August, 2009 to consider comments on the adoption of these as permanent rules.

For a copy of these public necessity rules contact: Barbara Maxwell, Executive Director, 227 French Landing, Suite 300, Heritage Place MetroCenter, Nashville, Tennessee 37243 at (615) 532-5127.

Richard Orgain, O.D.
Richard Orgain, O.D., Chairman
By Barbara B. Maxwell

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

Chapter Number	**Chapter Title**
1045-02	General Rules Governing the Practice of Optometry
Rule Number	**Rule Title**
1045-02-.16	Tamper-Resistant Prescriptions

1045-02-.16 Tamper-Resistant Prescriptions

1045-02-.16 Tamper-Resistant Prescriptions.

(1) Purpose.

This rule is designed to implement the law requiring that licensed optometrists 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, 63-8-112, and 63-8-126. [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)
Richard Orgain, O.D.	X				
Linda Tharp, O.D.	X				
David Talley, O.D.	X				
Kimberly Button				X	
Jeff Foster, O.D.	X				
Scott Spivey, O.D.	X				

I certify that this is an accurate and complete copy of emergency or public necessity rules, lawfully promulgated and adopted.

Date: 5/27/09

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: 5/27/09

Notary Public Signature: E Gless

My commission expires on: 1/23/10

All emergency or public necessity rules provided for herein 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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

6-10-09
Date

Department of State Use Only

Filed with the Department of State on: 6/25/09

Effective for: 165 *days

Effective through: 12/7/09

** Temporary rules may be effective for up to 165 days from the date of filing.*

Tre Hargett by Hope Pat, PA

Tre Hargett
Secretary of State

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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;

1045-02-.16 (1) Purpose- establishes that the purpose of the new rule is to implement the law contained in Tenn. Code Ann. §53-10-401 and §63-8-126 requiring individuals licensed to engage in the practice of optometry to have all written, typed, or computer-generated prescriptions issued on tamper-resistant prescription paper.

Paragraph (2) Definition – establishes definitions that are necessary for the implementation and enforcement of the substantive portion 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 prescription 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 as guidance from 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 Measures 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 of 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 method of transmission as well as the details of the prescription should be noted in the patient record.

(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 63-8-126.

(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 Optometry, the persons affected by the rule are those individuals licensed to engage in the practice of optometry.

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

I an 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;

Barbara Maxwell, Executive Director 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;

Barbara Maxwell, Executive Director 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). Barbara Maxwell may be reached at the Department of Health, Health Related Boards, 227 French Landing, Suite 300, Nashville, Tennessee 37243 ((615) 532-5127).

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

I, as well as the Executive Director, Barbara Maxwell will provide any additional information requested by the Committee relative to the new rule.