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Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Board of Medical Examiners
Division:	
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Revision Type (check all that apply):

___ Amendment
_X_ New
___ Repeal

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/RuleTitle per row)

Chapter Number	**Chapter Title**
0880-02	General Rules and Regulations Governing the Practice of Medicine
Rule Number	**Rule Title**
0880-02-.23	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)

Rulemaking Hearing Rules
Department of Health
Board of Medical Examiners
Division of Health Related Boards

New Rules

Chapter 0880-02
General Rules and Regulations Governing the Practice of Medicine

0880-02-.23 Tamper-Resistant Prescriptions.

(1) Purpose.

This rule is designed to implement the law requiring that licensed 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 assistant.

(c) "Prescription order" shall have the same meaning as set forth in T.C.A. §63-10-204(34).

(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, and quantity prescribed. The prescriber may, but is not required to, document the means by which the prescription was 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 the prescription 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. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

Authority: Chapter 1035 of the Public Acts of 2008 and T.C.A. §§53-10-401, 63-6-101, and 63-6-236. [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 rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Mitchell Mutter, M.D.	X				
Charles W. White, Sr., M.D.	X				
Subhi D. Ali, M.D.	X				
George L. Eckles, M.D.				X	
Monica Franklin	X				
Dennis Higdon, M.D.	X				
Barrett F. Rosen, M.D.	X				
Neal Beckford, M.D.	X				
Keith Lovelady, M.D.	X				
Regine Webster		X			
Irene Wells	X				
Michael D. Zanolli, M.D.	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Medical Examiners on July 21, 2009, and is in compliance with the provisions of TCA §4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *May 28, 2009*

Notice published in the Tennessee Administrative Register on: *June 15, 2009*

Rulemaking Hearing(s) Conducted on: (add more dates). *July 21, 2009*

Date: 8/7/09

Signature: Alison G. Cleaves

Name of Officer: Alison G. Cleaves

Title of Officer: Chief Deputy General Counsel
Tennessee Department of Health

Subscribed and sworn to before me on: 8/7/09

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 7/7/2011

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

All rulemaking hearing 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.

Robert E. Cooper, Jr.

Attorney General and Reporter

3-19-10

Date

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Filed with the Department of State on: 3/22/10

Effective on: 6/20/10

Tre Hargett

Secretary of State

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PUBLICATIONS

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. §4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

MINUTES

RULEMAKING HEARING

TENNESSEE BOARD OF MEDICAL EXAMINERS

JULY 21, 2009

The rulemaking hearing for the Tennessee Board of Medical Examiners was held on July 21, 2009 in the Department of Health Conference Center's Iris Room on the First Floor of the Heritage Place Building in MetroCenter, Nashville, Tennessee. The rulemaking hearing was scheduled to begin at 9:00AM; it commenced at approximately 9:20AM and ended at approximately 9:45AM.

Prior to the rulemaking hearing, Mr. Yarnell Beatty, Esq. submitted a written comment dated July 15, 2009 relative to the rulemaking before the Board of Medical Examiners about tamper-resistant prescriptions. Mr. Beatty also personally appeared at the July 21, 2009 rulemaking hearing before the Board to address the Board and reiterate his written comments. In his letter and personal presentation, Mr. Beatty indicated that he had two concerns outlined as follows: (1). The definition of "prescriber" which includes a reference to an "advanced practice nurse with a certificate of fitness to prescribe" when it should reference a "nurse practitioner with a certificate of fitness to prescribe". In response to his comments, the Board voted that it would keep the language contained in the rules, that is, the reference to an advanced practice nurse with a certificate of fitness to prescribe contained in its definition of prescriber; and (2). The language contained in Rule 0880-02-.23(5)(a) and (b) relative to the documentation of the method by which a prescription (facsimile or electronic) is transmitted in the patient's medical record should be removed from the subparagraphs of the rule. Mr. Beatty indicated that often, at the time a prescription is written, the physician may not have any indication how the prescription was transmitted to the pharmacy, making it difficult to enter this method of transmission in the patient's medical record. Mr. Beatty recommended that the language "and the method by which the prescription has been transmitted" be removed from Rule 0880-02-.23(5)(a)(2) and that the language "was transmitted electronically" be removed from Rule 0880-02-.23(5)(b)(2). Mr. Beatty also recommended that in both subparagraphs, language should be inserted indicating that the prescriber may, but is not required to document the means by which the prescription was transmitted. In response to this comment, the Board voted to accept Mr. Beatty's recommendations and change the language contained in the notice of rulemaking to reflect same.

Alison G. Cleaves, Esq.
Chief Deputy General Counsel
Department of Health

8/7/09
Date

Regulatory Flexibility Addendum
Pursuant to Public Chapter 464 of the 105th General Assembly, prior to initiating the rule making process as described in § 4-5-202(a)(3) and § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

Economic Impact Statement

Board of Medical Examiners, Tamper-Resistant Prescriptions.
Chapters 0880-02

(1) The type or types of small businesses and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

Public Chapter 1035 of the 2008 Public Acts (codified in Tenn. Code Ann. §§53-10-401 and 63-6-236) provides that certain authorized prescribers, including physicians, shall ensure that written or printed prescriptions shall be on tamper-resistant paper. To the extent that the individual health care practitioners identified in this bill may operate a small business in the course of practicing their profession, the small businesses that would be affected by this bill are medical offices or clinics; an estimate of the number of small businesses that would be affected is unknown.

(2) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule that would bear the cost of, or indirectly benefit from the proposed rule.

The new rules do not contain any reporting, recordkeeping or other administrative costs required for compliance.

(3) A statement of the probable effect on impacted small businesses and consumers.

The new rules will impact all affected health care practitioners, some of which may own small businesses in the course of practicing their respective professions.

(4) A description or any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the proposed rule that may exist, and to what extent the alternative means might be less burdensome to small business.

There is no less burdensome, less intrusive or less costly alternative methods of implementing the law.

(5) A comparison of the proposed rule with any federal or state counterparts.

The new rules are comparable, yet less stringent than other states' rules relative to tamper-resistant prescriptions while complying with the Centers for Medicare and Medicaid Services's ("CMS") guidelines.

(6) Analysis of the effect of the possible exemption of small businesses from all of any part of the requirements contained in the proposed rule.

Regardless of whether the health care practitioner operates a small or a large business, in order to comply with the mandates in the law, all health care practitioners affected by the law (medical doctors, podiatrists, dentists, advanced practice nurses, optometrists, osteopathic physicians, and physician assistants) must ensure that all written or printed prescriptions are on tamper-resistant paper.

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 0880-02-.23(1) Purpose- establishes that the purpose of the new rule is to implement the law contained in Tenn. Code Ann. §53-10-401 and §63-6-236 requiring individuals licensed to engage in the practice of medicine 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 63-6-236.

(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 Medical Examiners, the persons affected by the rule are those individuals licensed to engage in the practice of 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, 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;

Rosemarie Otto, 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). 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 Executive Director, Rosemarie Otto will provide any additional information requested by the Committee relative to the new rule.