

**Department of State  
Division of Publications**

312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower  
Nashville, TN 37243  
Phone: 615-741-2650  
Fax: 615-741-5133  
Email: [register.information@tn.gov](mailto:register.information@tn.gov)

**For Department of State Use Only**

Sequence Number: 05-05-10  
Rule ID(s): 4715  
File Date: 05/11/2010  
Effective Date: 10/29/2010

## Proposed Rule(s) Filing Form

*Proposed rules are submitted pursuant to T.C.A. §4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.*

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Maternal and Child Health/Women's Health and Genetics
<b>Contact Person:</b>	Margaret Major
<b>Address:</b>	Cordell Hull Building 425 Fifth Avenue Nashville, Tennessee
<b>Zip:</b>	37243
<b>Phone:</b>	(615) 741-7353
<b>Email:</b>	<a href="mailto:Margaret.Major@tn.gov">Margaret.Major@tn.gov</a>

**Revision Type (check all that apply):**

- Amendment  
 New  
 Repeal

**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/Rule Title per row)**

Chapter Number	Chapter Title
1200-14-01	Communicable and Environmental Diseases
Rule Number	Rule Title
1200-14-01-.28	The Treatment of the Eyes of Newborn Infants

Chapter 1200-14-01  
Communicable and Environmental Diseases

Repeals

Rule 1200-14-01-.28, The Treatment of the Eyes of Newborn Infants, is repealed.

Authority: T.C.A. § 68-1-103.

\* 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)
N/A					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Commissioner on 03/18/2010, and is in compliance with the provisions of TCA 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State.

Date: 3-23-10

Signature: Kassie Wiley

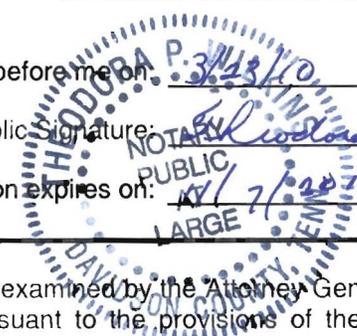
Name of Officer: Kassie Wiley

Title of Officer: Assistant General Counsel

Subscribed and sworn to before me on: 3/23/10

Notary Public Signature: Christina P. Wilkins

My commission expires on: 7/20/11



All proposed 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.

RE Cooper, Jr.

Robert E. Cooper, Jr.  
Attorney General and Reporter

5-5-10

Date

**Department of State Use Only**

Filed with the Department of State on: 5/11/10

Effective on: 10/29/10

Tre Hargett

Tre Hargett  
Secretary of State

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### **Regulatory Flexibility Addendum**

Pursuant to § T.C.A. 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

#### Regulatory Flexibility Analysis

- (1) The proposed rule does not overlap, duplicate, or conflict with other federal, state, or local government rules.
- (2) The proposed rule exhibits clarity, conciseness, and lack of ambiguity.
- (3) The proposed rule repeals a rule that is obsolete, and the repeal will allow small business to make medical decisions based on current standards of care. The proposed rule has no reporting requirements.
- (4) The proposed rule has no deadlines or schedules and has no reporting requirements.
- (5) The proposed rule has no reporting requirements or compliance requirements.
- (6) The proposed rule removes outdated medical directives from the rules and allows medical providers who may be small businesses to operate within the standards of medical practice for their profession.
- (7) There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation, nor are there any costs involved.

#### Economic Impact Statement

- (1) **Type of small businesses subject to the proposed rule.** Medical providers are subject to the proposed rule, but there is no practical method of determining the number of providers that are small businesses. There is no cost associated with this proposed rule. Medical providers will benefit from the proposed rule because it repeals a rule that limits their ability to practice the standard of care recommended by national organizations.
- (2) **Projected reporting, recordkeeping and other administrative costs required for compliance.** The proposed rule repeals a current rule that is outdated. There is no cost associated with the repeal.
- (3) **Impact of probable effect on impacted small businesses and consumers.** The proposed rule repeals an outdated rule which specifies the standard of care to be practiced by medical providers. Repeal of the rule will allow medical providers to provide their patients with the standard of care recommended by national organizations.
- (4) **Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed.** There are no less burdensome alternatives than repealing an outdated rule.
- (5) **Comparison of proposed rule with any federal or state counterparts.** Repeal of the current rule will allow medical providers to use the most current national medical standards of care for the treatment of newborns.
- (6) **Analysis of the effect of possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.** Because the proposed rule is a rule repeal, there are no requirements in the proposed rule from which to exempt small businesses. However, exempting small businesses from this rule repeal would result in inconsistencies in the standard of care among medical providers that are small businesses and those that are not. Additionally, exempting small businesses from the rule repeal would be contrary to the intent of the statutory authority for the medical treatment of newborns, found in Tenn. Code Ann. § 68-5-202; the 2008 amendment to § 68-5-202 and repeal of § 68-5-201 specifically abolished the Department of Health's responsibility to name and approve the prophylaxes used in the treatment of eye disease in newborns.

**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 1200-14-01-.28 specifies the prophylaxes, as approved by the Department of Health, to be used for the treatment of ophthalmia neonatorum in the eyes of newborns. The 2008 repeal of Tenn. Code Ann. § 68-5-201 abolished the Department of Health's responsibility to name and approve the prophylaxes for treating the eyes of newborns and to publish instructions for treatment. The 2008 amendment to § 68-5-202 also eliminated the Department's responsibility to approve the prophylaxes. The effect of these statutory changes allows medical providers to practice the standard of care recommended by national organizations. Rule 1200-14-01-.28 is contrary to the intent of these statutory changes and must be repealed. The repeal of this rule does not affect other regulations.**

- (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;

**T.C.A. § 68-1-103 authorizes the Commissioner of Health to adopt rules and regulations subject to the provisions of Title 68, Chapter 1.**

- (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;

**Medical providers will be directly affected by the repeal of Rule 1200-14-01-.28 and will most likely support the repeal.**

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

**We are unaware of any opinions of the attorney general and reporter or judicial rulings that relate to T.C.A. Title 68, Chapter 5, Part 2, or Rule 1200-14-01-.28.**

- (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;

**Promulgation of this rule will have no effect on state and local government revenues or expenditures.**

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

**Deana Vaughn, CNM, APN, MSN, Nursing Consultant, Women's Health, Tennessee Department of Health**

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

**Veronica Gunn, MD, MPH, FAAP, Chief Medical Officer, Tennessee Department of Health**

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

**Tennessee Department of Health, 425 5<sup>th</sup> Avenue North, 3<sup>rd</sup> Floor Cordell Hull Building, Nashville, TN 37243  
Phone: 615-741-3111  
Email: [Veronica.Gunn@tn.gov](mailto:Veronica.Gunn@tn.gov)**

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

N/A

1200-14-01-.28 THE TREATMENT OF THE EYES OF NEWBORN INFANTS.

- (1) ~~In accordance with the provisions of T.C.A. §§68-5-201 and 68-5-202, the Department hereby designates and approves any of the following agents as a standard prophylactic against ophthalmia neonatorum. When administered in accordance with the manufacturer's instructions:~~

~~Silver nitrate 1% (one percent) aqueous solution  
Erythromycin ophthalmic ointment  
Tetracycline ophthalmic ointment  
Tetracycline ophthalmic suspension~~

- (2) ~~The prophylactic shall be given using one of the appropriate agents designated in this rule as soon as practical after the birth of the infant but always within one hour. Silver nitrate is effective in preventing gonococcal infections but does not prevent chlamydial disease and frequently causes chemical conjunctivitis. Erythromycin and tetracycline are effective in preventing both gonococcal and chlamydial ophthalmia and do not cause chemical conjunctivitis. However, the topical use of these drugs does not prevent nasopharyngeal chlamydial infection or pneumonia. Silver nitrate 1% (one percent) is the product least likely to be adversely affected by extended storage and varying temperatures.~~

~~Authority: T.C.A. §§4-5-202, 68-1-103, 68-1-104, 68-1-201, and 68-5-104.  
Administrative History: Original rule certified June 7, 1974. Repeal and new rule filed March 31, 1977; effective May 2, 1977. Amendment filed April 20, 1987; effective June 4, 1987. Amendment filed March 30, 2004; effective July 29, 2004.~~