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Sequence Number: O

Rule ID(s): <u>5/3/6-5</u>

File Date: Of

Effective Date: Ole 150 [30];

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.

Agency/Board/Commission:	
Division:	Maternal and Child Health
Contact Person:	Margaret Major
Address:	Margaret Major Cordell Hull Building, 5 th Floor 425 Fifth Avenue Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-0377
Email:	Margaret.Major@tn.gov

Revision Type (check all that apply):

Amendment

X New

X 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
1200-15-03	Investigations of Sudden, Unexplained Infant and Child Deaths
Rule Number	Rule Title
1200-15-0301	Purpose
1200-15-0302	Definitions
1200-15-0303	Standards for Investigations
1200-15-0304	Reimbursement of County Governments

Chapter Number	Chapter Title
1200-21-01	Sudden Infant Death Syndrome
Rule Number	Rule Title
1200-21-0101	Purpose
1200-21-0102	Availability and Appropriateness of Services
1200-21-0103	Definitions
1200-21-0104	Description of Services

New Rules

Chapter 1200-15-03 Investigations of Sudden, Unexplained Infant and Child Deaths

1200-15-03-.01 Purpose.

1200-15-03-.02 Definitions.

1200-15-03-.03 Standards for Investigations.

1200-15-03-.04 Reimbursement of County Governments.

1200-15-03-.01 Purpose.

The purpose of this chapter is to establish minimum standards for conducting and completing an investigation, including an autopsy if deemed necessary, into sudden, unexplained infant and child deaths.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, and 68-1-1103.

1200-15-03-.02 Definitions.

For purposes of this chapter,

- (1) "Autopsy" means the post mortem examination of a deceased infant or child by a licensed pathologist to determine cause of death.
- "Child" means a person who is at least one year of age and has not reached his or her eighteenth birthday.
- (3) "Department" means the Tennessee Department of Health.
- (4) "Infant" means a baby who was born alive and has not reached his or her first birthday.
- (5) "Sudden, unexplained infant or child death" means the unexpected death of an infant or a child with no known or apparent cause.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, and 68-1-1103.

1200-15-03-.03 Standards for Investigations.

- (1) The standards for conducting and completing an investigation, including performance of an autopsy, into a sudden, unexplained infant death shall include the standards applicable to infants found in T.C.A. § 68-1-1102, and the standards authorized or required by Tennessee Code Annotated Title 38, Chapter 7. The same standards shall apply to sudden, unexplained child death.
- (2) In addition to the standards found in T.C.A. § 68-1-1102 and Title 38, Chapter 7, the standards for conducting and completing an investigation, including performance of an autopsy, into a sudden, unexplained infant or child death shall be those found in the most current version of the Centers for Disease Control and Prevention's publication, "Sudden, Unexplained Infant Death Investigation Reporting Form," for infants, and the Department's "Sudden, Unexplained Child Death Investigation Reporting Form," for children. The Department shall provide access to these publications upon request. The pathologist performing the autopsy shall complete the appropriate form.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, 68-1-1103, and 68-3-502.

1200-15-03-.04 Reimbursement of County Governments.

The Department shall reimburse county governments for the cost of each autopsy performed for an investigation into a sudden, unexplained infant or child death that is carried out in accordance with the investigation standards in this chapter. The Department shall reimburse up to the maximum allowable of \$1,250.00 per autopsy, including travel costs. The Tennessee Department of Finance and Administration's Comprehensive Travel Regulations shall govern the reimbursement rate for travel costs.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, and 68-1-1103.

Repeals

Rule 1200-21-01-.01 Purpose is repealed.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, 68-1-1103.

Rule 1200-21-01-.02 Availability and Appropriateness of Services is repealed.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, 68-1-1103.

Rule 1200-21-01-.03 Definitions is repealed.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, 68-1-1103.

Rule 1200-21-01-.04 Description of Services is repealed.

Authority: T.C.A. §§ 68-1-1101, 68-1-1102, 68-1-1103.

* 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 10/25/10, 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: 4/8/2011 Signature: Mandam

Name of Officer: Mary Kennedy

Deputy General Counsel
Title of Officer: Department of Health

Subscribed and sworn to before me on:

Notary Public Signature: Aug B. Hunt

My commission expires on:

July 8, 2013

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.

Robert E. Cooper, Jr. Attorney General and Reporter

Date

Department of State Use Only

Filed with the Department of State on: 01 falt

Effective on:

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.

These rules do not affect small businesses. The rules affect county governments and families or other members of the public impacted by sudden, unexplained infant or child death.

Impact on Local Governments

Pursuant to T.C.A. 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (http://state.tn.us/sos/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

It is anticipated this rule amendment will have a decrease in local government expenditures.

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;

The new rules establish minimum standards for conducting and completing an investigation, including an autopsy if deemed necessary, into the sudden, unexplained death of any infant or child. The Sudden Infant Death Syndrome (SIDS) rules found in chapter 1200-21-1, which were more limited in scope are repealed. The new rules address deaths attributed to SIDS as well as the sudden, unexplained deaths of children who are one (1) year of age through age seventeen (17).

(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. §68-1-1103(2) requires the promulgation of rules that establish minimum standards for conducting and completing an investigation, including an autopsy if deemed necessary, into the sudden, unexplained death of any infant or child from birth to age seventeen (17).

(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;

The county governments eligible for reimbursement under this rule will likely be supportive of these rules.

(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 that directly relate to Tennessee Code Annotated Title 68, Chapter 1, Part 11, Sudden, Unexplained Child Death. There are opinions that relate to Tennessee Code Annotated Title 38, Chapter 7, Post-Mortem Examinations, which is referenced in the rules. Chapter 7 has been amended since the issuance of these opinions, and the opinions may no longer be relevant. The opinions are as follows: No. 02-064 (addressing the duties of non-physician assistants), No. 01-032 (addressing the state medical examiner's facility), No. 96-034 (addressing payment for the cost of court-ordered autopsies), and No. 02-021 (addressing deputizing a non-physician investigator).

We are unaware of any judicial rulings that relate to the rules.

(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;

\$161,800 increase in state expenditures \$99,300 decrease in local expenditures

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

Margaret Major Director, Women's Health and Genetics 425 5th Avenue North Nashville, TN 37243-0860 Margaret.Major@tn.gov 615-741-0377 (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Margaret Major Director, Women's Health and Genetics 425 5th Avenue North Nashville, TN 37243-0860 Margaret.Major@tn.gov 615-741-0377

(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

Margaret Major
Director, Women's Health and Genetics
425 5th Avenue North
Nashville, TN 37243-0860
Margaret.Major@tn.gov
615-741-0377

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

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RULES OF

TENNESSEE DEPARTMENT OF HEALTH BUREAU OF HEALTH SERVICES ADMINISTRATION

CHAPTER 1200-21-1 SUDDEN INFANT DEATH SYNDROME

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1200-21-1-.01 PURPOSE

The purpose of these regulations is to provide services for parents and families victimized by Sudden Infant Death Syndrome (SIDS).

Authority: T.C.A. §68-1-1102. Administrative History: Original rule filed August 27, 1984; effective September 26, 1984.

1200-21-1-.02 AVAILABILITY AND APPROPRIATENESS OF SERVICES

- (1) Services provided for the SIDS programs will be available throughout the state in 95 counties, and will be provided in accordance with T.C.A. §68-1-1101.
- (2) Every parent or guardian of a SIDS incident will be offered an autopsy to validate the diagnosis.
- (3) Diagnosis of SIDS will be certified on the death certificate.

Authority: T.C.A. §68-1-1102. Administrative History: Original rule filed August 27, 1984; effective September 26, 1984.

1200-21-1-.03 DEFINITIONS

- (1) Sudden Infant Death Syndrome means the death of an ostensibly healthy child who is less than (3) years of age which occurs suddenly and unexpectedly with no known or apparent cause and which remains unexplained after the performance of an autopsy.
- (2) Autopsy as defined in this program means the post mortem examination of the deceased infant by a licensed pathologist to rule out all potential causes of infant death.
- (3) Physician means a person licensed to practice medicine or osteopathy in the State of Tennessee.
- (4) Medical Examiner means the physician designated as county medical examiner pursuant to T.C.A. §38-7-104.

Authority: T.C.A. §68-1-1102. Administrative History: Original rule filed August 27, 1984; effective September 26, 1984.

1200-21-1-.04 DESCRIPTION OF SERVICES

- (1) Provision of autopsy will be made available to all parents or legal guardians of suspected SIDS incidents.
 - (a) The parents or legal guardians shall authorize or refuse autopsy through completion of the following form. The local medical examiner shall assist the parents or legal guardians in completing the form.

PARENTAL AUTHORIZATION OR REFUSAL OF AUTOPSY FORM

DATE:		
COUNTY:		=
Total Control of Contr	N, that on this date, I,	=
do voluntarily	AND A STANDARD COMMUNICATION OF THE	_,
refuse	uutionzo	_,
The state of the s	ce of an autopsy on my child	
acting for the	Fennessee Department of Health and Environment.	
	Signed Witness	
	Date	
(b)	The refusal of the parents or legal guardians to authorize the autopsy shall in no winterfere with the duties of the District Attorney General, County Coroner, and/or County Medical Examiner as set forth in T.C.A. §38-7-106.	
(c)	Autopsies will be performed by pathologists licensed to practice in Tennessee.	
(d) —	The county medical examiner will assign a pathologist to perform the post morte examination. All transportation costs of the deceased infant to and from the patholog will be submitted to the county court. Transportation costs will not exceed the currestate rate.	gist
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