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Sequence Number: 08-27-09
Rule ID(s): 4325
File Date: 08/25/2009
Effective Date: 11/23/2009

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:	Department of Health Policy, Planning and Assessment
Division:	Tennessee Cancer Registry
Contact Person:	Martin Whiteside, D.C., Ph.D., M.S.P.H.
Address:	6th Floor, Cordell Hull Building, 425 5th Avenue North, Nashville TN
Zip:	37243
Phone:	615-532-7903
Email:	martin.whiteside@tn.gov

Revision Type (check all that apply):

X Amendment
___ 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/Rule Title per row)

Chapter Number	**Chapter Title**
1200-07-02	Cancer Reporting System
Rule Number	**Rule Title**
1200-07-02-.03	Definitions

(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)

Rule 1200-07-02-.03 Definitions, is amended by adding the following new paragraph 10 and re-numbering the subsequent paragraphs accordingly.

(10) "In situ cancer" means an abnormality of the development and organization of cells without the invasion of neighboring tissue. Examples of in situ cancers include, but are not limited to:

(a) Cervical Intraepitheleal Neoplasia (CIN) II lesions; and

(b) Cervical Intraepitheleal Neoplasia (CIN) III lesions.

Authority: T.C.A. §§ 68-1-1002, 68-1-1003(a) and 68-1-1004.

* 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)
NA					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Bureau of Administrative Services, Division of Informational Resources (board/commission/ other authority) on 1/15/2009 (mm/dd/yyyy), 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: 11/18/08

Rulemaking Hearing(s) Conducted on: (add more dates). 1/15/09

Date: 07/08/09

Signature: Mary Kennedy

Name of Officer: Mary Kennedy
Deputy General Counsel

Title of Officer: Tennessee Department of Health

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

Notary Public Signature: Theodora P. Wilkins

My commission expires on: 11/7/2011

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

All 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

8-20-09
Date

Department of State Use Only

Filed with the Department of State on: 8/25/09

Effective on: 11/23/09

Tre Hargett by Wm Lee, POA
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.

PUBLIC HEARING COMMENTS

RULEMAKING HEARING

BUREAU OF ADMINISTRATIVE SERVICES, DIVISION OF INFORMATIONAL RESOURCES

JANUARY 15, 2009

The rulemaking hearing for the Bureau of Administrative Services, Division of Informational Resources, Cancer Reporting System, was held on January 15, 2009 in the Department of Health Office of General Counsel's Conference Room, 220 Athens Way, Suite 210, Nashville, Tennessee 37243.

No members of the public attended the rulemaking hearing. No written or oral comments were received at the rulemaking hearing.

Mary Kennedy, Esq.
Deputy General Counsel
Department of Health

07/08/09
Date

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.

(If applicable, insert Regulatory Flexibility Addendum here)

Regulatory Flexibility Analysis

Bureau of Administrative Services, Division of Informational Resources, Cancer Reporting System

(1) The extent to which the rule or rule may over lap, duplicate, or conflict with other federal, state, and local governmental rules.

The new rules do not overlap, duplicate, or conflict with other federal, state, and local governmental rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

The new rules exhibit clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

The reporting requirements contained in the rules are the same for large or small businesses.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

The reporting requirements contained in the rules are the same for large or small businesses.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

The reporting requirements contained in the rules are the same for large or small businesses.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

The rules do not establish performance standards for the entities certified pursuant to the rules (hospitals, laboratories, facilities and health care practitioners).

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The rules do not create unnecessary barriers to stifle entrepreneurial activity, curb innovation, or increase costs.

Economic Impact Statement

1. **Name of Board, Committee or Council: Bureau of Administrative Services, Division of Informational Resources, Cancer Reporting System**

2. **Rulemaking hearing date:** January 15, 2009

3. **Types of small businesses that will be directly affected by the proposed rules:**

   All hospitals, laboratories, facilities and health care providers will be affected by these rules in that they are responsible for reporting data pursuant to T.C.A.§§ 68-1-1001 et. seq.

4. **Types of small businesses that will bear the cost of the proposed rules:**

   Please see the answer to question 3.

5. **Types of small businesses that will directly benefit from the proposed rules:**

   Please see the answer to question 3.

6. **Description of how small business will be adversely impacted by the proposed rules:**

   Please see the answer to question 3.

7. **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 to the new rules.

8. **Comparison of the proposed rule with federal or state counterparts:**

   Federal: The Office of Cancer Surveillance is not aware of any federal regulatory counterparts, however Public Law 102-515 specifically requires the reporting of certain types of data "for each form of in situ and invasive cancer."

   State: The Office of Cancer Surveillance has not identified other states that have promulgated rules defining in situ cancer.

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 regulation in place requires the reporting of "in situ cancer." This rule clarifies the current regulation by providing a definition of "in situ cancer" which includes, as examples, Cervical Intraepitheleal Neoplasia (CIN) II and Cervical Intraepitheleal Neoplasia (CIN) III lesions.

(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;

Public Law 102-515 specifically requires the reporting of certain types of data "for each form of in situ and invasive cancer." T.C.A. 68-1-1001 *et seq.* , the "Tennessee Cancer Reporting System Act of 1983" provides that the Commissioner promulgate such rules as will enable the Department to carry out its duties and responsibilities in requiring reporting of cancer and submission of such additional information as is necessary and appropriate to provide accurate and continuing data to the medical, scientific and academic communities into the causes, types and demography of cancer.

(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;

Hospitals, laboratories, facilities and health care practitioners are directly affected by this rule. Although given the opportunity to comment, the community of providers has neither urged adoption nor rejection of this rule.

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

There are no attorney general opinions nor are there judicial rulings that directly relate 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;

Fiscal impact will be minimal.

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

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243; Martin Whiteside, DC, PhD, MSPH, Director, Office of Cancer Surveillance, Tennessee Department of Health, 6th Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243

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

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243; Martin Whiteside, DC, PhD, MSPH, Director, Office of Cancer Surveillance, Tennessee Department of Health, 6th Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243

(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

Mary Kennedy, Deputy General Counsel, Tennessee Department of Health, 220 Athens Way, Suite 210, Nashville TN 37243 (615) 741-1611; Martin Whiteside, DC, PhD, MSPH, Director, Office of Cancer Surveillance, Tennessee Department of Health, 6th Floor, Cordell Hull Building, 425 5th Avenue, North, Nashville, TN 37243 (615) 532-7903

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

None.