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Sequence Number: 10-22-19
Rule ID(s): 9265
File Date: 10/25/19
Effective Date: 1/23/20

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Tennessee Department of Health
Division:	Population Health Assessment
Contact Person:	Gabriel Galletti, Assistant General Counsel
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Revision Type (check all that apply):

X Amendment
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. 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-.05	Cancer Case Reporting

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Rule Chapter 1200-07-02
Cancer Reporting System

Amendment

Rule 1200-07-02-.05 Cancer Case Reporting is amended by deleting subparagraph (5)(b) in its entirety and substituting instead the following language so that as amended the new subparagraph shall read:

(5) (b) If a hospital, laboratory, facility, or health care practitioner fails to provide the required data by the required deadline in the format specified by the department or if the data are of unacceptable quality, the Commissioner or the Commissioner's authorized representative may casefind and abstract the information by a direct examination of those patients' medical records. In these cases, the facility shall reimburse the department for the actual cost of casefinding, abstracting, coding, and editing, a maximum of which is seventy dollars ($70) per hour, plus, if necessary, reasonable ancillary and travel expenses. A hospital, laboratory, facility, or health care practitioner from whom reimbursement is sought may appeal the assessment of expenses under the Tennessee Uniform Administrative Procedures Act. The appeal shall be to the Commissioner in writing and within thirty (30) days of receipt of the assessment.

Authority: T.C.A. §§ 68-1-103, 68-1-1003

* 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)
N/A					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Health, Population Health Assessment (board/commission/ other authority) on 08/22/2019 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *06/20/19 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *08/22/19 (mm/dd/yy)*

Date: 9/9/19

Signature:

Name of Officer: Gabriel Galletti

Title of Officer: Assistant General Counsel
Department of Health

MARK INGRAM
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

Subscribed and sworn to before me on: 9/9/19

Notary Public Signature:

My commission expires on: March 7 2023

Agency/Board/Commission: Tennessee Department of Health, Population Health Assessment

Rule Chapter Number(s): 1200-07-02

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.

Herbert H. Slatery III
Attorney General and Reporter

10/21/2019
Date

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Filed with the Department of State on: 10/25/19

Effective on: 1/23/20

Tre Hargett
Secretary of State

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

A single public comment was received at the hearing from a representative from the Tennessee Hospital Association who commented that some smaller, rural hospitals were concerned that the proposed rule could disproportionately impact their operations. While the rule change will ensure timely reporting of cancer cases from all facilities, the main intent of the change is to enable the Department to capture the actual expenses and costs it may incur while performing the duties imposed by the Tennessee Cancer Reporting System Act of 1983 (Tenn. Code Ann. § 68-1-1001, et seq.). Currently the rules accompanying the statute only allow the Department to capture $50 per case for casefinding and abstracting cancer cases for a delinquent facility, a cost that is substantially below the market rate. Some facilities opted for this low rate by asking the Department to perform their casefinding and abstracting, a result that exceedingly burdened the Department. The rule change is not intended to increase the burden on any particular facility beyond the reasonable duties already imposed by Tennessee law.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

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

This new rule does not overlap, duplicate, or conflict with other federal, state, and local government rules.

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

This new rule is established with clarity, conciseness, and lack of ambiguity.

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

This new rule does not establish new compliance and/or reporting requirements for small businesses.

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

This new rule does not establish schedules or deadlines for compliance and/or reporting requirements for small businesses.

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

This new rule does not establish compliance or reporting requirements for small businesses.

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

This new rule does not establish performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

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

This new rule does not create unnecessary entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Department of Health, Division of Population Health Assessment

Rulemaking hearing date: 08/22/2019

1. **Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

   While most facilities that diagnose and treat cancer are large healthcare facilities, some smaller practices, such as clinics, would do this work, too.

2. **Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

   The proposed rule ensures that healthcare facilities pay the Department's reasonable expenses if the Department reports the facilities' own cancer cases. The rule would not add any reporting, recordkeeping, or other administrative costs that are not already required by statute. In practice, the proposed rule would shift reporting costs from the public to the private sector. Healthcare facilities would be more likely to report their own cancer cases, rather than having the government do it for them.

3. **Statement of the probable effect on impacted small businesses and consumers:**

   To the extent that small businesses have reportable cancer diagnoses, the proposed rule would have minimal effect. These small businesses are statutorily required to report their own cancer cases to the Department. In the event these businesses fail to do so, the proposed rule ensures that they pay the Department's actual costs. The proposed rule would have no effect on consumers.

4. **Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

   There is no less burdensome, less intrusive, or less costly alternative method of achieving the purposes and/or objectives of the proposed rule.

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

   Federal: The proposed rule has no federal counterpart.

   State: The proposed rule would bring Tennessee more in line with other states that regulate the reporting of cancer to a central registry. These states allow their registries to recoup their actual, reasonable expenses when they report for a facility. Research shows that only one other state limits what may be charged, a limit of $100. Several states even provide for the imposition of costly penalties when facilities fail to timely report cancer cases.

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

   This rule does not provide any exemptions for small businesses.

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://publications.tnsosfiles.com/acts/106/pub/pc1070.pdf) of the 2010 Session of the General Assembly)

The proposed rule will not have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 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 1200-07-02-.05(5)(b) provides that if a facility fails to timely report the required cancer information to the Department, it may obtain the information itself. Timely reporting is defined by the Tennessee Cancer Reporting System Act of 1983 as six months from the date of diagnosis of cancer in a patient. This reporting obligation is "mandatory"; it is not the Department's role. T.C.A. § 68-1-1003(g). Timely reporting is critical for the Department's efforts to address and combat cancer. The rule, however, is outdated and actually incentivizes facilities to delay their reporting. Under the statute, the Department charges its reasonable expenses for reporting a facility's cancer information. But the rule limits these expenses, that is, what the Department can charge, to a maximum of $50 per case. The Department, however, estimates that to report the average cancer case costs the Department over five times this amount. To allow the Department to recoup its actual costs, the proposed rule makes the following changes:

- Two changes are made to the rule's first sentence: (1) "[B]y the required deadline" is added as a condition when the Department can casefind and abstract a facility's cancer case information. This language is taken directly from the statute, which provides that when a facility does not timely report, the Department can obtain the report via a direct examination and charge the Department's reasonable expenses. T.C.A. § 68-1-1003(f). (2) In describing how the Department can casefind and abstract, the "enter the facility" language is stricken and replaced with "by a direct examination of those patients' medical records." This change, also taken verbatim from the statute, updates the rule. T.C.A. § 68-1-1003(f). Today most, but not all, reporting can be done off-site. Department personnel can remotely connect to a facility's network and casefind and abstract from the Department's office. "By a direct examination" captures both off- and on-site reporting.

- The second sentence contains the change at the heart of the proposed rule. The $50 per case maximum is deleted and replaced by a maximum of "$70 per hour, plus, if necessary, reasonable ancillary and travel expenses." With this change, the rule can achieve the statute's intention that the facility "shall reimburse the department for the department's reasonable expenses incurred in obtaining the information in this manner." T.C.A. § 68-1-1003(f). A per-hour, as opposed to a per-case, maximum is used to account for the wide variation in the amount of time necessary to complete a report. The proposed rule maintains what the Department may be reimbursed for ("casefinding, abstracting, coding, and editing") and would add reasonable ancillary and travel expenses, if necessary.

(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. §§ 68-1-1003, et. seq. (the purpose of which is to ensure an accurate and continuing source of data concerning cancer and to provide appropriate data for research purposes)

(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;

These rules affect larger facilities that diagnose and treat cancer as well as some smaller practices.

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

None.

(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;

These rules should not impact revenues or expenditures.

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

Gabriel Galletti, Assistant General Counsel, Department of Health.

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

Gabriel Galletti, Assistant General Counsel, 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

Department of Health, Office of General Counsel, 710 James Robertson Parkway, 5th Floor, Nashville, TN 37243, (615) 532-7663, gabriel.galletti@tn.gov.

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

None.

(Rule 1200-07-02-.03, continued)
Authority: *T.C.A. §§ 4-5-202, 4-5-209, 68-1-1001 et seq., 68-1-1002, 68-1-1003(a) and 68-1-1004.* ***Administrative History:*** *Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002. Public necessity rule filed August 3, 2007; effective through January 15, 2008. Amendment filed August 28, 2007; effective December 28, 2007. Amendment filed August 25, 2009; effective November 23, 2009.*

1200-07-02-.04 PARTICIPATION IN THE PROGRAM

(1) All hospitals, laboratories, facilities and health care practitioners shall report data concerning Tennessee patients who are diagnosed and/or treated for cancer.

(2) Health care practitioners are not required to report data on cancer patients who are directly referred to or have been previously admitted to a hospital or a facility for cancer diagnosis or treatment.

(3) All hospitals, laboratories, facilities and health care practitioners shall designate one (1) staff member to be responsible for reporting the cancer data and shall notify the department of the name, title, work address, work telephone number, and e-mail address (if available) of the designated staff member.

Authority: *T.C.A. §§ 4-5-202 and 68-1-1001 et seq.* ***Administrative History:*** *Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.*

1200-07-02-.05 CANCER CASE REPORTING

(1) Reportable Cancer Cases

(a) Any newly diagnosed in-situ or invasive cancer as defined by the TCR Policies and Procedures Manual is considered a reportable diagnosis. If a patient subsequently develops a new primary cancer, it shall be reported separately.

(2) Format for Reporting

(a) The format for reporting, the required codes, and the standards for completeness and quality are defined by the department in the TCR Policies and Procedures Manual.

(3) Data Items to be Reported

(a) The standardized report of cancer shall include as a minimum those data items required by the Tennessee Cancer Registry, a list of which is maintained in the TCR Policies and Procedures Manual. The report of cancer shall include the listed demographic, diagnostic, and treatment data as defined by the department.

(4) Deadline for Reporting

(a) Reporting shall occur no later than six months after the date of diagnosis of cancer in a patient. Reports shall be submitted to the department according to a time frame communicated by the department to each hospital, facility, laboratory, and health care practitioner.

(5) Failure to Report

(Rule 1200-07-02-.05, continued)

(a) A hospital, laboratory, facility, or health care practitioner that fails to report data or allow access to records, as required by T.C.A. § 68-1-1003, shall be informed in writing by the department that compliance is mandatory.

~~(b) If a hospital, laboratory, facility, or health care practitioner fails to provide the required data in the format specified by the department or if the data are of unacceptable quality, the Commissioner or the Commissioner's authorized representative may enter the facility to casefind and abstract the information. In these cases, the facility shall reimburse the department for the actual cost of casefinding, abstracting, coding and editing, a maximum of which is fifty dollars ($50) per case. A hospital, laboratory, facility or health care practitioner from whom reimbursement is sought may appeal the assessment of expenses under the Tennessee Uniform Administrative Procedures Act. The appeal shall be to the Commissioner in writing and within thirty (30) days of receipt of the assessment.~~

(b) If a hospital, laboratory, facility, or health care practitioner fails to provide the required data by the required deadline in the format specified by the department or if the data are of unacceptable quality, the Commissioner or the Commissioner's authorized representative may casefind and abstract the information by a direct examination of those patients' medical records. In these cases, the facility shall reimburse the department for the actual cost of casefinding, abstracting, coding, and editing, a maximum of which is seventy dollars ($70) per hour, plus, if necessary, reasonable ancillary and travel expenses. A hospital, laboratory, facility, or health care practitioner from whom reimbursement is sought may appeal the assessment of expenses under the Tennessee Uniform Administrative Procedures Act. The appeal shall be to the Commissioner in writing and within thirty (30) days of receipt of the assessment.

(6) Quality Assurance

(a) Staff members from the Tennessee Cancer Registry or their agents shall perform periodic quality assurance studies at all reporting facilities. These studies shall include:

1. casefinding to ensure that all cancer cases have been accessioned; and

2. reabstracting the records of cancer patients to ensure that all data have been transcribed and coded correctly.

(b) Reporting facilities shall assist TCR staff by providing the necessary medical records and the office space for conducting quality assurance activities.

(c) In order to improve the quality of the data, the TCR or their agents shall offer training for reporting facility personnel.

Authority: *T.C.A. §§ 4-5-202 and 68-1-1001 et seq.* ***Administrative History:*** *Original rule filed October 6, 1986; effective November 20, 1986. Amendment filed September 5, 1990; effective October 20, 1990. Repeal and new rule filed February 1, 2002; effective April 17, 2002.*

1200-07-02-.06 CONFIDENTIALITY

(1) T.C.A. § 68-1-1006 provides for the confidentiality of data obtained from the reports of cancer patients.

(2) TCR Responsibilities

(a) The commissioner shall take strict measures to ensure that all patient identifying information is treated as confidential and privileged. All employees or consultants,