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Effective Date: 12/23/2010

# 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*

|                                 |  |
|---------------------------------|--|
| <b>Agency/Board/Commission:</b> | Board of Respiratory Care  |
| <b>Division:</b>                |  |
| <b>Contact Person:</b>          | Anthony K. Czerniak, Assistant General Counsel                           |
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**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)**

| <b>Chapter Number</b> | <b>Chapter Title</b>   |
|-----------------------|--|
| 1330-01               | General Rules and Regulations Governing Respiratory Care Practitioners     |
| <b>Rule Number</b>    | <b>Rule Title</b>  |
| 1330-01-.24           | Endorsement of Respiratory Therapists to Provide Polysomnographic Services |

(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>)

Department of Health  
Board of Respiratory Care

Chapter 1330-01  
General Rules and Regulations Governing Respiratory Care Practitioners

New Rule

1330-01-.24 Endorsement of Respiratory Therapists to Provide Polysomnographic Services

- (1) In order for a licensee of this Board to practice polysomnography without obtaining licensure from the Polysomnographic Professional Standards Committee, the licensee must obtain an endorsement from this Board. In order to obtain an endorsement, a licensee shall provide this Board with the following:
- (a) A completed and signed polysomnographic services endorsement form, as approved by this Board; and
  - (b) Proof of possessing a valid, active, and unrestricted license as a Registered Respiratory Therapist or Certified Respiratory Therapist, issued by this Board; and
  - (c) One of the following:
    - 1. Certification by the National Board of Registered Polysomnographic Technologists as a registered polysomnographic technologist; or
    - 2. Certification by the National Board of Respiratory Care as a sleep disorder specialist; or
    - 3. Proof of completion of the Sleep Center or Sleep Lab Competency Checklist, as approved by this Board, signed by both the director of the sleep lab and medical director from a current employing facility, verifying a minimum of one hundred (100) hours in a sleep lab or sleep center, and outlining competency relative to the following topics, which include, but are not limited to:
      - (i) Patient safety, rapport, preparation, education and confidentiality;
      - (ii) Setup, function, calibration, operation and maintenance of all relative equipment;
      - (iii) Monitoring, recording, and analysis of physiologic data as defined under T.C.A. § 63-31-101(9)(a)(i);
      - (iv) Appropriate corrective and emergency procedures as appropriate, according to lab/center policies; and
      - (v) Implementation of the applicable treatment procedures according to lab/center policy and procedure.

Authority: T.C.A. §§ 63-31-107 and 63-27-104

\* 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) |
|------------------------------|-----|----|---------|--------|-------------------------|
| Theresa Dudley Hatcher       | X   |    |         |        |                         |
| Colleen Schabacker, R.R.T.   | X   |    |         |        |                         |
| Jeffrey Paul McCartney, M.D. |     | X  |         |        |                         |
| Gene Gantt, R.R.T.           |     |    |         | X      |                         |
| Brian Cook                   |     | X  |         |        |                         |
| Candace Partee, R.R.T.       | X   |    |         |        |                         |
| Rodger M. Major, R.R.T.      | X   |    |         |        |                         |
| Delmar Mack, R.R.T., Ed.D.   |     | X  |         |        |                         |

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Respiratory Care on 08/19/2010, 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: 06/25/10

Rulemaking Hearing(s) Conducted on: (add more dates). 08/19/10

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Date: 9/14/10

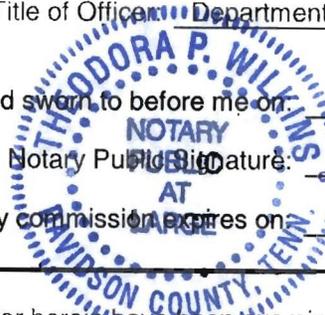
Signature: [Handwritten Signature]

Name of Officer: Anthony K. Czerniak  
 Assistant General Counsel  
 Title of Officer: Department of Health

Subscribed and sworn to before me on: 9/14/10

Notary Public Signature: [Handwritten Signature]

My commission expires on: 11/7/2011



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.  
 Robert E. Cooper, Jr.  
 Attorney General and Reporter  
9-23-10  
 Date

**Department of State Use Only**

Filed with the Department of State on: 9/24/10

Effective on: 12/23/10

[Handwritten Signature]



## **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**

##### **Chapter 1330-01-.24**

##### **Endorsement of Respiratory Therapists to Provide Polysomnographic Services**

The Division received three (3) written comments from the public prior to the August 19, 2010 rulemaking hearing. There were four (4) verbal comments received at the rulemaking hearing. All comments addressed the provisions of the proposed rule under 1330-01-.24(1)(c)(3).

Thomas Arrington, RPSGT, made a written comment before the rulemaking hearing addressing three (3) of the provisions set forth in the proposed rule under 1330-01-.24(1)(c)(3). His first comment addressed the provision of the proposed rule requiring at least 100 hours of competency relative to polysomnography. In particular, Mr. Arrington suggested that a significantly higher number of hours be required to receive endorsement by the Board.

In response to the first comment and suggestion by Mr. Arrington, the Board agreed, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue presented by Mr. Arrington and address any potential changes needed thereafter.

His second comment addressed the language requiring that the training by the respiratory therapist be in a sleep lab or sleep center. Mr. Arrington suggested that the hours of training in the sleep lab or sleep center should be performed in an accredited sleep facility, and that the language of the proposed rule be changed to reflect that accordingly.

In response to the second comment and suggestion by Mr. Arrington, the Board agreed that the hours of training in the sleep lab or sleep center should be performed in an accredited sleep facility, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue presented by Mr. Arrington and address any potential changes needed thereafter.

His third comment addressed the provision of the proposed rule requiring that the director of the sleep lab and medical director sign the competency checklist. Mr. Arrington suggested that the competency checklist should be signed by a board certified sleep physician.

In response to the third comment and suggestion by Mr. Arrington, the Board agreed that the competency checklist should be signed by a board certified sleep physician, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue presented by Mr. Arrington and address any potential changes needed thereafter.

Jackie Davis, President of the Tennessee Sleep Society, also made a written comment before the rulemaking hearing addressing the same issues and suggestions as Mr. Arrington.

In response, the Board agreed with the comments, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue presented by Ms. Davis and address any potential changes needed thereafter.

Brevard Haynes, M.D., also made a written comment before the hearing and a verbal comment during the hearing. Dr. Haynes' written and verbal comments and suggestions mirrored those of Mr. Arrington and Jackie Davis.

In response, the Board again agreed with the comments, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue presented by Dr. Haynes and address any potential changes needed thereafter.

Kelly A Carden, M.D., made a verbal comment at the rule making hearing that the proposed rule requiring at least 100 hours of competency relative to polysomnography was not a sufficient number of hours. Dr. Carden suggested that a significantly higher number of hours be required to receive endorsement by the Board.

In response to Dr. Carden's comment and suggestion the Board agreed, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue and address any potential changes needed thereafter.

Walter W. Holland, RPSGT, also representing the Tennessee Sleep Society, endorsed the comments and statements of both Dr. Haynes and Dr. Carden.

In response, the board agreed with the comments, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue and address any potential changes needed thereafter.

Keith Lovelady, M.D., also made a verbal comment at the rulemaking hearing that the proposed rule requiring at least 100 hours of competency relative to polysomnography was not a sufficient number of hours. Dr. Lovelady suggested that a higher number of hours be required to receive endorsement by the Board.

In response, the board agreed with the comment, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue and address any potential changes needed thereafter.

Dr. Lovelady made an additional verbal comment at the rulemaking hearing addressing the provision of the proposed rule requiring that the director of the sleep lab and medical director sign the competency checklist. Dr. Lovelady was not sure if the director of the sleep lab or the medical director would be competent to do so.

In response to Dr. Lovelady's second comment the Board agreed that the competency checklist should be signed by a board certified sleep physician, however the Board felt the rule was sufficient to promulgate in the interest of the health, safety and welfare of the citizens of the state of Tennessee, and decided that it would appoint a subsequent task force to revisit the issue and address any potential changes needed thereafter.

### **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

Pursuant to the regulatory Flexibility Act of 2007, 2007 Pub. Acts, c. 464, § 4, eff. June 21, 2007, the Department of Health submits the following regulatory flexibility analysis:

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

The proposed rule does not overlap, duplicate, or conflict with other federal, state, and local governmental rules.

- (2) Clarity, conciseness, and lack of ambiguity in the rule:

The proposed rule exhibits clarity, conciseness, and lack of ambiguity in the rule.

- (3) The establishment of flexible compliance and reporting requirements for small businesses:

The proposed rule does not create an ongoing reporting requirement and allows for flexible mechanisms for initial compliance.

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

There are no reporting requirements contained in the proposed rule.

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

There are no reporting requirements contained in the proposed rule.

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

The proposed rule does not establish design or operational standards.

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

The proposed rule creates no entry barriers or other effects that would stifle entrepreneurial activity, curb innovation, or increase cost.

## Economic Impact Statement

- (1) The 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, or directly benefit from the proposed rule:

Medical offices providing sleep services as well as sleep centers.

- (2) The 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 would require no new reporting or record keeping costs. There will be a small fee to obtain the initial certification.

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

The proposed rule should not adversely impact small businesses and consumers.

- (4) A description of 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:

This proposed rule should not have an economic impact on small businesses

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

Federal:           The Board is not aware of any Federal Counterparts:

State:             The Board is not aware of any State counterparts.

- (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:

It is not possible to exempt the impacted small businesses from all or any part of the requirements contained in the proposed rule because the impacted small businesses are the board's licensees and applicants. If there were to be an exemption, the proposed rules would have no actual effect.

## **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)

This new rule is not expected to 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 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 1330-01-.24 (1) outlines the three mechanisms that certified and registered respiratory therapists may utilize to gain endorsement by the Board of Respiratory Care to provide polysomnographic services pursuant to T.C.A. §63-31-107(a)(5). The first mechanism requires that the respiratory therapist be credentialed as a registered polysomnographic technologist by the board of polysomnographic technologists. The second mechanism requires that the respiratory therapist be credentialed as a sleep disorder specialist by the national board of respiratory care. The third mechanism requires that the respiratory therapist provide proof of completion of a minimum of one hundred (100) hours in a sleep lab, and submit a board approved Sleep Center or Lab Competency Checklist documenting the required hours and competency relative to polysomnography.

- (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 421 of the 2009 Public Acts codified in T.C.A. §§ 63-31-107(a)(5).

- (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 Respiratory Care, the persons affected by the rule are certified and registered Respiratory therapists, licensed in the State Tennessee who wish to provide polysomnographic services on or after July 1, 2010.

- (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;

Marva Swann, 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;

Marva Swann, Executive Director and I will explain the new rule at a scheduled meeting of the Committee.

- (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

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); [Anthony.k.Czerniak@tn.gov](mailto:Anthony.k.Czerniak@tn.gov). Marva Swann may be reached at the Department of Health, Health Related Boards, 227 French Landing, Suite 300, Nashville, Tennessee 37243 ((615) 532-5163); [Marva.Swann@tn.gov](mailto:Marva.Swann@tn.gov)

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

I, as well as the Executive Director, Marva Swann will provide any additional information requested by the Committee relative to the new rule.