G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Commerce and Insurance
DIVISION:	Tennessee Peace Officer Standards and Training Commission
SUBJECT:	ADA Compliance
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 38-8-104
EFFECTIVE DATES:	January 28, 2014, through July 27, 2014
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This emergency rule updates language in the current rules to reflect the statutory changes as they pertain to the Americans with Disabilities Act, adopted in Public Chapter 137 of 2013 regarding law enforcement officers.

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)

The rule will impact local governments.

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Sequence Number: D1-15-14
Rule ID(s): 5659-5661
File Date (effective date): 1/28/14
End Effective Date: 7/27/14

Emergency Rule Filing Form

Emergency rules are effective from date of filing for a period of up to 180 days.

Agency/Board/Commission: Department of Commerce and Insurance
Division: Tennessee Peace Officer Standards and Training Commission
Contact Person: Joseph Underwood, Chief Counsel
Address: 500 James Robertson Parkway, 8th Floor, Davy Crockett Tower
Zip: 37243
Phone: 615-741-3899
Email: Joseph.Underwood@tn.gov

Rule Type:
X Emergency Rule

Revision Type (check all that apply):
X Amendment
___ New
___ Repeal

Statement of Necessity:
Pursuant to T.C.A. § 38-8-104(c), the Peace Officer Standards and Training (POST) Commission is authorized to adopt and enforce such rules and regulations as may be necessary to carry out the provisions of T.C.A. § 38-8-101 et seq., relating to the establishment of uniform standards of training for the employment and training of law enforcement officers, including preemployment qualifications and requirements for officer certification. Moreover, the Commission possesses the authority pursuant to T.C.A. § 38-8-104(d) to establish criteria for determining whether to grant an exception to or waive the qualifications of minimum standards as provided in T.C.A. § 38-8-106.

This emergency rule is required by Public Chapter 137 of the 2013 Acts (codified in part in T.C.A. §§ 38-8-104(e) and 38-8-106(9)), enacted by the General Assembly and signed by the Governor on April 12, 2013. This rule is promulgated pursuant to T.C.A. §§ 38-8-104(e) and 38-8-106(9), to adopt applicable provisions of the Americans with Disabilities Act (ADA), 42 United States Code 12101, et. seq. The ADA codifies particular language regarding persons with mental impairments, but state rules and statutes did not use compatible language. Public Chapter 137 (2013) adopted the language from the ADA for statutes where applicable, and the amendments contained herein adopt those changes in the rules.

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/RuleTitle per row)

Chapter Number	**Chapter Title**
1110-02	Certification
Rule Number	**Rule Title**
1110-02-.03	Law Enforcement Officer Certification Requirements

Chapter Number	**Chapter Title**
1110-08	Part-Time/Temporary/Auxiliary Law Enforcement Officers
Rule Number	**Rule Title**
1110-08-.02	Preemployment Requirements

Chapter Number	**Chapter Title**
1110-09	Criteria for Waivers
Rule Number	**Rule Title**
1110-09-.04	Waiver of Preemployment Requirements

RULES
OF
THE TENNESSEE PEACE OFFICER STANDARDS AND TRAINING COMMISSION

CHAPTER 1110-02
CERTIFICATION

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1110-02-.02 Failure to Comply
1110-02-.03 Law Enforcement Officer Certification Requirements
1110-02-.04 Denial, Suspension, and Revocation of Certification

1110-02-.03 LAW ENFORCEMENT OFFICER CERTIFICATION REQUIREMENTS. All full-time commissioned law enforcement officers employed by an agency required to meet minimum standards must meet pre-employment requirements and, upon completion of the required basic training, will be issued a POST Certification.

(1) Full-time Commissioned Law Enforcement Officer Pre-employment Requirements. The Commission shall issue a certificate of compliance to any person who meets the qualifications for employment and satisfactorily completes a POST certified Basic Law Enforcement Training Academy. All persons employed as a full-time law enforcement officer, after July 1, 1982, must be certified by POST and shall comply with the following pre-employment requirements:

(a) Be at least eighteen (18) years of age;

(b) Be a citizen of the United States;

(c) Be a high school graduate or possess equivalence. No waivers will be granted for minimum education requirements;

(d) Not have been convicted of or pleaded guilty to or entered a plea of nolo contendere to any felony charge or to any violation of any federal or state laws or city ordinances relating to force, violence, theft, dishonesty, gambling, liquor and other alcoholic beverages or controlled substances;

(e) The agency must present a copy of any DD-214s, DD-215s and DD873s along with the application for certification.

1. The commission may consider a waiver from pre-employment requirements for a person who has been convicted of, or entered a plea of nolo contendere to any felony charge or to any violation of any federal or state laws or city ordinances relating to force, violence, theft, dishonesty, gambling, liquor and other alcoholic beverages or controlled substances when the offense was classed as a misdemeanor.

2. No waiver shall be granted while officer is under the jurisdiction of the court or considered on probation, whether supervised or unsupervised, and in the case of "driving while intoxicated" the officer shall have met all the requirements of the Tennessee Department of Safety and have been restored his/her permanent driving privileges under the laws of the State of Tennessee.

3. No waiver will be granted for a narcotics violation that could result in a felony charge.

4. The agency must present a written request for waiver for these charges and provide a copy of the final court disposition of the case.

(f) Not have been released or discharged under any other than honorable discharge from any of the armed forces of the United States;

(g) Have his fingerprints on file with the Tennessee Bureau of Investigation;

(h) Have passed a physical examination by a licensed physician;

(i) Have good moral character as determined by a thorough investigation conducted by the employing agency; and/or the POST Commission

(j) Have been certified by a Tennessee Licensed Health Care Provider qualified in the psychiatric or psychological fields as being free from any ~~disorder~~impairment, as set forth in the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association at the time of the examination, that would, in the professional judgment of the examiner, ~~impair~~ affect the ~~subject's~~ p e r s o n 's ability to perform ~~any~~ an essential function of the job, with or without a reasonable accommodation.

~~1. No waiver will be granted for mental disorders.~~

~~2.~~1. A new evaluation shall be required:

~~a.~~ (i) after a six (6) month break in full-time law enforcement service~~,~~; or,

~~b.~~ (ii) upon the request of the employing agency, for good cause.

2. If applicable, refer to Tenn. Comp. R. & Regs. 1110-09 Criteria for Waivers.

(k) Not have been previously decertified as a law enforcement officer by the POST Commission.

(l) Not have previously voluntarily surrendered their certification as a law enforcement officer.

(2) Training Requirements. Any officer seeking certification under these rules who conforms to pre-employment requirements shall, within six months of initial employment as a law enforcement officer, satisfactorily complete the Basic Law Enforcement Course as established in accordance with these rules. During this initial six-month period prior to attending the Basic Law Enforcement Course, the recruit must be paired with a Field Training Officer or other certified senior officer.

Commencing July 1, 1982, any time served as a full-time commissioned law enforcement officer in any Tennessee law enforcement agency is accumulative and will count as part of the six-month time limit.

(3) Application Requirement. No officer shall be certified under these rules unless application is made at such time and in such form as the Commission may require (T.C.A. § 38-8-104).

If after enrolling in an academy an officer does not successfully complete basic police training, he/she must return to the same academy under the following circumstances:

(a) to make up any portion not successfully completed.

(b) if dropped for academic or disciplinary reason.

(c) in the event an officer fails to successfully complete basic police training after returning for makeup he/she must retake the entire school.

(4) Verification Requirement. No officer shall be certified under these rules unless (T.C.A. § 38-8-104):

(a) The law enforcement agency employing said officer when the Basic Law Enforcement Course is begun shall submit, at such time and in such form as the Commission may require, verification that the officer (at the time the officer was employed) met the pre-employment requirements set forth in this chapter.

(b) The Director of the Academy where said officer satisfactorily completed Basic Law Enforcement School, established in accordance with these rules, shall submit verification, in such form as the Commission may require, that the officer has met the Basic Training requirements set forth in this chapter.

(c) The Commission may certify any person who has received training in another state when the Commission has determined that such training was at least equivalent to that required by the Commission for approved law enforcement education and training programs in this state and when such person has satisfactorily complied with all other requirements (T.C.A. § 38-8-107). Established criteria shall be that which governs the requirements set forth for completion of the Basic Law Enforcement Recruit School, as outlined in Chapter 7 of POST Rules.

1. Beginning July 1, 2010, any person whose basic training from another state has been substituted for Tennessee requirements must successfully attend the POST's three (3) week transition school within six (6) months of employment.

(5) Substitution of Experience for exempt/exempted officers. No officer shall be certified under these rules unless:

(a) The law enforcement agency employing said officer shall submit an Application for Certification, Confirmation of Psychological Examination, and Confirmation of Physical Examination, to verify that all preemployment requirements have been met.

(b) Beginning July 1, 2010, any person applying for substitution of experience must successfully attend the POST's three (3) week transition school within six (6) months of employment.

(6) Break in Full-Time Law Enforcement Service.

(a) Beginning July 1, 2010, certified officers who have had a five-year break, but less than a ten-year break in full-time law enforcement service must successfully attend the POST's three (3) week transition school within six (6) months of employment before their certification is reinstated. Officers with over a ten-year break in full-time law enforcement service shall be required to attend a Basic Law Enforcement Academy.

(b) Beginning July 1, 2010, officers who were certified under the Grandfather Clause of July 1, 1970, and have attended an approved basic law enforcement school, must successfully attend the POST's three (3) week transition school within six (6) months of employment if they have a five-year break in full-time service.

(c) Officers who were certified under the Grandfather Clause of July 1, 1970, and have not attended an approved basic law enforcement school, lose their grandfathered status if they have a break in service. However, these officers may apply for certification if they have had ten (10) years of full-time experience since July 1, 1970, and have had no longer than a five-year break in service. Beginning July 1, 2010, they are required to successfully attend the POST's three (3) week transition school within six (6) months of employment.

These officers may separate directly from one law enforcement agency and be employed as a full-time law enforcement officer by another law enforcement agency with no loss of certification as long as there is no break in service.

(d) Beginning July 1, 2010, officers who have attended an approved basic law enforcement school and who were not required to be certified at that time, may apply for certification based on this training within two (2) years of the date of completion of the basic law enforcement school. These officers must successfully attend the POST's three (3) week transition school within six (6) months of employment to qualify for certification after two (2) years and less than ten (10) years from the date of completion of the basic law enforcement school. Officers with over a ten-year break from the date of completion of the basic law enforcement school shall be required to attend a Basic Law Enforcement Academy.

(e) An officer's certification expires after separation of full-time employment from a law enforcement agency. A new application for certification is required for each new employment as a law enforcement officer.

Authority: *T.C.A. §§38-8-104, 38-8-105, 38-8-106, 38-8-107, 38-8-111, and 38-8-111(f).* ***Administrative History:*** *Original rule filed December 20, 1982; effective January 19, 1983. Amendment filed January 28, 1986; effective April 15, 1986. Amendment filed September 17, 1987; effective December 29, 1987. Amendment filed January 6, 1989; effective May, 1, 1989. Amendment filed November 13, 1989; effective February 28, 1990. Amendment filed August 4, 1992; effective November 29, 1992. Amendment filed October 25, 1993; effective March 1, 1994. Amendment filed April 19, 2002; effective August 28, 2002. Amendment filed October 2, 2006; effective February 28, 2007. Amendment filed March 18, 2010; effective June 16, 2010. Amendments filed March 11, 2011; effective June 9, 2011.*

RULES OF
THE TENNESSEE PEACE OFFICER
STANDARDS AND TRAINING COMMISSION

CHAPTER 1110-08
PART-TIME/TEMPORARY/AUXILIARY LAW ENFORCEMENT OFFICERS

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1110-8-.03	Training Requirements	1110-8-.06	Audit

1110-8-.01 DEFINITIONS.

(1) Part-time/Temporary/Reserve/Auxiliary Law Enforcement Officer is defined as any person employed by any municipality or any political subdivision of the state of Tennessee whose primary responsibility is to support the full-time law enforcement officers in the prevention and detection of crime, apprehension of offenders, assisting in the prosecution of offenders for appropriate remuneration in measure with specifically assigned duties and/or job description. Part-time law enforcement officers will work no more than twenty (20) hours per week or a total of no more than one hundred hours per month. Any law enforcement officer who works in excess of the maximum hours as specified herein will be reclassified to a full-time status and must meet all requirements for standards/training as mandated under the law and Peace Officer Standards and Training Commission rules.

Provided however, in any situation where an officer is temporarily assigned for a period of one (1) month or less, to work more than twenty (20) hours per week or a total of more than one hundred (100) hours per month, such officer shall not be reclassified to a full-time status.

(2) Special Deputy is defined within this section as any person who is assigned specific law enforcement functions as to the prevention and detection of crime and general laws of this state on a volunteer basis, whether working alone or with other law enforcement officers. Any law enforcement officer working on a volunteer basis shall receive no pay or benefits except for honorariums and may be utilized for an unlimited number of hours.

Authority: *T.C.A. § 38-8-101.* ***Administrative History:*** *Original rule filed January 6, 1989; effective May 1, 1989. Amendment filed April 19, 2002; effective August 28, 2002.*

1110-08-.02 PRE-EMPLOYMENT REQUIREMENTS.

(1) After January 1, 1989, any person employed/utilized as part-time/temporary/reserve/auxiliary law enforcement officer or as a special deputy shall:

(a) Be at least eighteen (18) years of age;

(b) Be a citizen of the United States;

(c) Be a high school graduate or possess equivalence. No waivers will be granted for minimum education requirements;

(d) Not have been convicted of or pleaded guilty to or entered a plea of nolo contendere to any felony charge or to any violation of any federal or state laws or city ordinances relating to force, violence, theft, dishonesty, gambling, liquor or controlled substances;

(Rule 1110-8-.06, continued)

1. The commission may consider a waiver from pre-employment requirements for a person who has been convicted of, or entered a plea of nolo contendere to any violation of any federal or state laws or city ordinances (excluding felony charges) relating to force, violence, theft, dishonesty, gambling, liquor (including driving while intoxicated), or controlled substances when the offense was classed as a misdemeanor.

2. No waiver shall be granted while officer is under the jurisdiction of the court or considered on probation, whether supervised or unsupervised, and in the case of "driving while intoxicated" the officer shall have met all the requirements of the Tennessee Department of Safety and have been restored his/her permanent driving privileges under the laws of the State of Tennessee.

3. A person who has had misdemeanor charges expunged may be considered for certification. It is the responsibility of the officer and employing agency to present information and court documents relating to expungement to the Commission.

4. No waiver will be granted for felony convictions or a narcotics violation that could result in a felony charge.

5. The agency must present a written request for waiver for these charges and provide a copy of the final court disposition of the case.

(e) Not have been released or discharged under any other than honorable discharge from any of the armed forces of the United States;

(f) Have his fingerprints on file with the Tennessee Bureau of Investigation;

(g) Have passed a physical examination by a licensed physician;

(h) Have good moral character as determined by a thorough investigation conducted by the employing agency; and

~~(i)~~ Have been certified by a Tennessee Licensed Health Care Provider qualified in the psychiatric or psychological fields as being free from any ~~disorder~~impairment, as set forth in the current edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association at the time of the examination ~~DSM~~, that would, in the professional judgment of the examiner, ~~impair~~ affect the ~~subject's~~ person's ability to perform ~~any~~ an essential function of the job, with or without a reasonable accommodation. If applicable, refer to Tenn. Comp. R. & Regs. 1110-09 Criteria for Waivers.

~~(j)~~

~~1. No waiver will be granted for mental disorders.~~

(2) Part-time/temporary/reserve/auxiliary law enforcement officers and special deputies who were employed prior to January 1, 1989 and have had continuous service are exempt from pre-employment requirements as long as they remain on active service with the department by which they are originally employed. Any part-time/temporary/reserve/auxiliary law enforcement officer or special deputy who has a break in service of any length whatsoever will be required to meet pre-employment and training standards.

Authority: *T.C.A. §§ 38-8-101 and 38-8-106.* ***Administrative History:*** *Original rule filed January 6, 1989; effective May 1, 1989. Amendment filed April 19, 2002; effective August 28, 2002. Amendment filed October 2, 2006; effective February 28, 2007.*

RULES
OF
THE TENNESSEE PEACE OFFICER STANDARDS

CHAPTER 1110-09
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1110-09-.03 Waivers of POST Transition School
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1110-09-.06 Waivers of Eight (8) months Full-Time Service

1110-09-.04 WAIVER OF PREEMPLOYMENT REQUIREMENTS. A waiver of preemployment requirements may be granted under the following circumstances:

(1) No person may be employed as a law enforcement officer, who requires a waiver under this section, until such waiver is granted. "Any person who shall appoint any applicant, who, to the knowledge of the appointee, fails to meet the minimum standards as set forth herein or required by the Commission, and any person who signs the warrant or check for the payment of the salary of any person who, to the knowledge of the signer, fails to meet the qualifications as a law enforcement officer as provided herein or required by the Commission, shall be guilty of a misdemeanor and, upon conviction, shall be subject to a fine not exceeding one thousand dollars ($1,000)".

(a) Military History - The Commission may waive preemployement requirements relating to the military history on an individual basis and depending on the circumstances.

1. Waivers may be granted from preemployment requirements for the following separations from military service:

(i) an Entry Level Separation

(ii) a General Discharge under Honorable Conditions.

2. Waivers will not be granted from preemployment requirements for the following separation from military service:

(i) Dishonorable Discharge

(ii) Bad Conduct Discharge

(iii) Other Than Honorable Discharge

(b) Criminal Activity - The Commission may consider a waiver from preemployment requirements relating to criminal activity on an individual basis and depending on the circumstances.

1. Waivers may be granted if the officer has been convicted of or pleaded guilty to or entered a plea of nolo contendere to any felony charge or to any violation of any federal or state law or city ordinance (excluding domestic violence) with the following charges:

(i) relating to force, violence, theft, dishonesty, gambling, liquor and other alcoholic beverages;

(ii) or controlled substances, as defined in the Tennessee Drug Control Act

compiled in Title 39, Chapter 17, Part 4, when the offense was classed as a misdemeanor.

2. The employing agency requesting waiver must present a copy of the final court disposition of the case.

3. Some of the factors to be considered when determining whether to grant a waiver shall be:

   (i) the amount of time since the offense;

   (ii) the amount of time since completion of the sentence;

   (iii) the type, circumstances and severity of the offense;

   (iv) the applicant's activities since the offense; and

   (v) the applicant's ability to carry a fire arm pursuant to federal and state law.

(c) Mental ~~Disorder~~ Impairment- A waiver ~~will~~ shall not be granted from preemployment requirements ~~relating to~~for a mental ~~disorder~~impairment that would affect the person's ability to perform an essential function of the job, with or without a reasonable accommodation.

(d) Education - A waiver will not be granted from preemployment requirements relating to minimum education requirements.

(e) Previous decertification or voluntary surrender of certification as a law enforcement officer – The Commission may waive preemployment requirements relating to previous decertification or voluntary surrender of certification as a law enforcement officer on an individual basis and depending on the circumstances.

1. Some of the factors to be considered when determining whether to grant a waiver shall be:

   (i) the circumstances surrounding and which lead to the previous decertification or voluntary surrender of certification as a law enforcement officer;

   (ii) the amount of time since the previous decertification or voluntary surrender of certification as a law enforcement officer;

   (iii) the applicant's activities since the offense; and

   (iv) the applicant's ability to carry a fire arm pursuant to federal and state law

Authority: *T.C.A. §§38-8-104, 38-8-105, and 38-8-106.* ***Administrative History:*** *Original rule filed August 4, 1992; effective November 29, 1992. Amendment filed April 19, 2002; effective August 28, 2002. Amendment filed October 6, 2006; effective February 28, 2007. Amendments filed March 18, 2010; effective June 16, 2010. Amendments filed March 11, 2011; effective June 9, 2011.*

* 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)
Robert Rhoades				X	
Glen Donoho				X	
Gerald Fanion	X				
Carl Jenkins	X				
Jeff Lewis	X				
James Wheeler	X				
Ric Wilson	X				
Brent Cherry	X				
Rita Baker	X				
David Bennett				X	
Franklin Lax	X				
Glenn Chrisman	X				
Bobby Williamson	X				
Kim Wallace	X				
David Woolfork				X	

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 11/15/2013

Signature: [signature]

Name of Officer: Joseph Underwood

Title of Officer: Chief Counsel for Fire Prevention & Law Enforcement

KELLY JOHNS STATE OF TENNESSEE NOTARY PUBLIC RUTHERFORD COUNTY

Subscribed and sworn to before me on: 11/15/2013

Notary Public Signature: [signature]

My commission expires on: 10/20/2014

All emergency 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.

[signature]
Robert E. Cooper, Jr.
Attorney General and Reporter

12-6-13
Date

Department of State Use Only

Filed with the Department of State on: 1/28/14

Effective for: 180 *days

Effective through: 7/27/14

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

Tre Hargett
Secretary of State

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G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Tennessee Board of Funeral Directors and Embalmers
DIVISION:	Regulatory Boards, Commerce & Insurance
SUBJECT:	Removal Service Fees
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 62-5-203
EFFECTIVE DATES:	January 3, 2014 through July 2, 2014
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This emergency rule, as required by the enactment of Public Chapter 437 of 2013, was filed to effectuate the registration of removal services for funeral directors and embalmers.

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)

The emergency rules adopted by the Tennessee Board of Funeral Directors and Embalmers, specifically pertaining to removal services, will have no impact on local governments.

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Division of Publications
312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
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Sequence Number: 01-02-14
Rule ID(s): 5653-5654
File Date (effective date): 1/3/14
End Effective Date: 7/2/14

Emergency Rule Filing Form

Emergency rules are effective from date of filing for a period of up to 180 days.

Agency/Board/Commission:	Tennessee Board of Funeral Directors and Embalmers
Division:	Department of Commerce and Insurance, Division of Regulatory Boards
Contact Person:	R. Benton McDonough
Address:	Office of Legal Counsel 500 James Robertson Parkway Davy Crockett Tower Nashville, Tennessee
Zip:	37243
Phone:	615-741-8509
Email:	Benton.mcdonough@tn.gov

Rule Type:
X Emergency Rule

Revision Type (check all that apply):
X Amendment
X New
___ Repeal

Statement of Necessity:

The Tennessee Board of Funeral Directors and Embalmers is required by the enactment of 2013 Public Act 437 to implement rules prior to January 1, 2014, in order to effectuate the registration of removal services under that Act. The implementation of these rules within the required time period precludes utilization of rulemaking procedures described in Tennessee Code Annotated, Title 4, Chapter 5, Part 2 for the promulgation of permanent rules.

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/RuleTitle per row)

Chapter Number	**Chapter Title**
0660-03	Fees
Rule Number	**Rule Title**
0660-03-.11	Removal Service Fees

Chapter Number	**Chapter Title**
0660-12	Removal Services

Rule Number	Rule Title
0660-12-.01	Removal Services

Amended Rules

Chapter 0660-03-.11
Fees

Rule 0660-03 Fees is amended by adding a new section to the end of the chapter which shall read:

0660-03-.11 Removal Service Fees

(1) An application for registration as a removal service shall be submitted on a form prescribed by the board and shall be accompanied by proof of liability insurance in the amount of one million dollars ($1,000,000.00) and a nonrefundable fee in the amount of three hundred fifty dollars ($350.00).

(2) The board may renew a certificate of registration provided that an application for renewal, accompanied by proof of liability insurance in the amount of one million dollars ($1,000,000.00) and a nonrefundable fee in the amount of two hundred fifty dollars ($250.00), is received by the board no later than the date of expiration.

Authority: T.C.A. §§ 62-5-203 and 62-5-318

New Rules

Chapter 0660-12
Removal Service

Rule 0660-12 Removal Service

Rule 0660-12-01 Removal Service

(1) No removal service, as defined in T.C.A. Title 62, Chapter 5, Part 1, shall operate in this state without first registering with the Funeral Board as a removal service.

(2) An application for registration as a removal service shall be submitted on a form prescribed by the board and shall be accompanied by a nonrefundable fee as set by the board and proof of liability insurance in an amount set by the board.

(3) The board may renew a certificate of registration provided that an application for renewal, accompanied by a nonrefundable fee set by the board and proof of liability insurance in an amount set by the board, is received by the board no later than the date of expiration.

Authority: T.C.A. §§ 62-5-203 and 62-5-318

* 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)
Wayne Hinkle	X				
Rob Helms	X				
David Neal	X				
W.T. Patterson	X				
Jane Gray Sowell	X				
Robert Starkey	X				
Anita Taylor	X				

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 1/3/2014

Signature:

Name of Officer: Michael D. Driver

Title of Officer: Chief Counsel, Regulatory Boards

MARGARET WILLIAMS STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY My Commission Expires 11-06-2017

Subscribed and sworn to before me on: 1/3/14

Notary Public Signature: Margaret A Williams

My commission expires on: 11/6/17

All emergency 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

Robert E. Cooper, Jr.
Attorney General and Reporter

1/3/2014
Date

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Filed with the Department of State on: 1/3/14

Effective for: 180 *days

Effective through: 7/2/14

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

Tre Hargett

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Board of Pharmacy
DIVISION:	Health Related Boards
SUBJECT:	Sterile Product Preparation in Pharmacy Practice Licensure Fee Increase
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 63-10-304
EFFECTIVE DATES:	January 31, 2014 through July 30, 2014
FISCAL IMPACT:	The agency has provided the following fiscal impact information:

Because this rule increases licensure fees, and creates a new supplementary registration, it is expected that it will have a significant impact on Board of Pharmacy revenues and expenditures. It is unclear how the fee changes will impact the numbers of licenses purchased biennially (e.g., it is possible that some entities which currently hold both manufacturer and pharmacy licenses will drop one of them), and whether they will result in a net gain or loss for the Board. The fee increases are also going to support three additional pharmacist-investigators, as well as an additional administrative staff person. Because the Board derives a significant portion of its revenues from civil penalties assessed due to regulatory violations, it is unclear whether the increased investigative staff will result in the collection of more civil penalties, or if the greater presence of investigators "in the field" and increased frequency of inspections will increase compliance and help licensees to better follow the law.

STAFF RULE ABSTRACT:
The proposed rules would extensively modify Rule Chapter 1140-07. New section 1140-07-.02 "Standards" would be created, and would contain requirements mandating that licensees who compound sterile products comply with sterility guidelines adopted by Board and new reporting requirements imposed by state law. Sections 1140-07-.03, 1140-07-.04, 1140-07-05, 1140-07.07 and 1140-07.08 are amended to require compliance with the Board sterility guidelines, rather than the specific and inadequate provisions currently effective. The proposed modifications to Section 1140-07-04 would require an expansion of the areas covered in licensees' policy and procedure manual, and would further require compliance with the policy and procedure manual.

The proposed modifications to Section 1140-07-.08 would also require licensees to perform a gap analysis between inspections by Board investigators, and would require licensees to report exceptions or deficiencies uncovered by those analyses to the Board.

The proposed modifications to Rule Chapter 1140-09 would create separate licensure categories for drug or device manufacturers and drug or device wholesalers/distributors. Currently, both hold the same license. Section 1140-09-.02 would be modified to require that owners or managers of such facilities submit to a criminal background check. The title of Section 1 140-09-.05 is amended to include the word "General" so that it now reads "Minimum Requirements for General Operation." A new section 1140-09-.06 would be created, titled "Minimum Requirements for Sterile Product Operation," which would require manufacturers or wholesaler/distributors to comply with Board guidelines for the manufacture or distribution of sterile drug products.

Impact on Local Governments

Pursuant to T.C.A. § 4-5-228(a), "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 financial impact on local governments."

The proposed rule amendments should not have a financial impact on local governments.

REGULATORY FLEXIBILITY ANALYSIS

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

The amended rules do 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.

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

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

Compliance and reporting requirements were intended to be as unobtrusive as possible, while still protecting public safety. The proposed rules also allow the Board of Pharmacy to grant exemptions from compliance and reporting requirements upon a showing of good cause.

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

The schedules and deadlines for compliance and reporting are objective and occur at regular intervals. The Board will also conduct outreach and provide education to stakeholders.

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

The reporting requirements are the same for both small and large businesses. The requirements are well-defined.

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

The proposed rules do not set any performance standards, but do establish design and operational standards. The proposed rules also allow the Board of Pharmacy to grant exemptions from these standards.

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

The amended rules create no entry barriers or other effects that would stifle legitimate entrepreneurial activity, curb innovation, or increase costs for legitimate businesses. Many of the requirements imposed by these proposed rules have already been adopted by a plurality of other states. Many of the proposed requirements are equal to, or less stringent than, equivalent federal statutes and rules. Most of the impacted stakeholders already comply with these other state and federal standards.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Tennessee Board of Pharmacy

Rulemaking hearing date: N/A

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:**

   Some pharmacies, hospitals, drug/medical device manufacturers, drug/medical device manufacturers/distributors, and other entities tangentially involved in the pharmaceutical and medical device industries may have to bear significant compliance costs.

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:**

   In keeping with the requirements imposed by Public Chapter 266, additional reporting requirements for compounding pharmacies must be satisfied. These reports can be prepared by clerical or administrative staff, but will likely be generated automatically by software.

   The proposed rules would also require some additional record-keeping requirements, which could be performed by clerical or administrative staff, but again will likely be facilitated or completed through the use of software.

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

   Many small businesses in the drug and device industry already comply with the standards proposed by this rule and will not bear any additional costs due to its implementation. These nationally-recognized standards have been implemented in dozens of states and largely equivalent to federal standards, so small businesses which routinely operate outside Tennessee or deal with federal authorities on a regular basis may derive some benefit from these rules, as they will not have any additional compliance costs. Unsophisticated, poorly managed small businesses, or those which purposely operate in legal grey-areas, will be negatively impacted by the proposed rules.

   The proposed rules are designed to protect the public and ensure the stability of drug supplies. Both of these would have a positive 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:**

   The proposed rules would allow the Board of Pharmacy to grant exemptions from the more burdensome requirements upon a showing of good cause. The Department of Health, in cooperation with the Board, is in the process of designing a form to facilitate the application for and consideration of exemptions to the proposed rules. There are no less burdensome, intrusive, or costly alternative methods which provide the same level of protection to the public. Due to the exigent circumstances surrounding the fungal meningitis outbreak and subsequent outbreaks of infections associated with unsafe compounded products, the proposed rules represent the best and only way to protect the public as well as the legitimacy of the pharmacy compounding industry.

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

   Federal: Currently, there is no exact analogue for these proposed rules in the federal laws. Similar federal rules imposed on drug manufacturers registered with FDA, known as "Good manufacturing Practices" are substantially more stringent than the proposed rules. However, there is pending federal legislation that, if passed, would impose standards

equivalent to the proposed rules.

State: Most other states have ~~adopted standards which mirror, or are largely equivalent~~ to, the proposed rules. A tiny minority of states have standards which are less stringent than those contained in the proposed rules.

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.

Small businesses, upon a showing of good cause, can apply for an exemption from certain provisions of the proposed rules. Such exemptions will allow these businesses to continue operating and providing critically needed drugs to those in need. A complete exemption from the proposed rules for small businesses would defeat the purpose of the proposed rule and places the public at risk.

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For Department of State Use Only

Sequence Number: 01-17-14
Rule ID(s): 5662-5664
File Date (effective date): 1/31/14
End Effective Date: 7/30/14

Emergency Rule Filing Form

Emergency rules are effective from date of filing for a period of up to 180 days.

Agency/Board/Commission:	Board of Pharmacy
Division:	
Contact Person:	Stefan Cange, Assistant General Counsel
Address:	665 Mainstream Drive, Nashville, Tennessee
Zip:	37243
Phone:-	615-741-1611
Email:	Stefan.Cange@tn.gov

Rule Type:
X Emergency Rule

Revision Type (check all that apply):
X Amendment
X New
___ Repeal

Statement of Necessity:
The Tennessee Board of Pharmacy ("Board") is proposing to promulgate emergency rules pursuant to Tenn. Code Ann. § 4-5-208 (a)(1) because it finds that "[a]n immediate danger to the public health, safety [and] welfare exists," and no other form of rulemaking authorized by Part 4, Chapter 5 of the Tennessee Code would adequately protect the public. The proposed rules would strengthen the current regulation of pharmacies, manufacturers, and wholesaler/distributors which produce compounded drugs and biologic products. The rules would enhance the Board's authority to halt the production of sterile compounded products, facilitate the recall and distribution of sterile compounded products which pose an imminent threat to public, health, and safety because the quality of the product has been compromised with contaminants such as fungal and/or bacterial agents which could cause disease. The proposed rules would also allow the quarantine or disposal of such unsafe products by the Board. The rules would strengthen the Board's ability to conduct investigations of pharmacies and other entities which produce sterile compounded products and significantly enhance the standards under which Tennessee licensed facilities operate when they are preparing sterile compounded products.

The proposed rules are needed because the Board is acutely aware of the danger that improperly compounded products pose. The United States has recently witnessed a public health disaster, the tragic outbreak of meningitis directly related to compounded sterile drugs which were administered to patients. These tainted drugs produced by a compounding pharmacy located in Massachusetts caused 15 deaths and 152 cases of illness of Tennesseans. Tennessee and national health officials are also investigating infections associated with the use of sterile products compounded by a Tennessee manufacturer. Due to a variety of reasons, including chronic drug shortages, sterile compounded products are being used with increasing regularity by health care providers. The Board understands that compounding pharmacies play a vital role in ensuring that patients have access to the drugs they need, but an appropriate level of regulation is necessary in this sector. The Board believes that the additional authority and strengthened standards in the proposed rules will save lives. It is imperative that the Board have the authority set forth in the rules in order to adequately regulate the production of compounded products by Tennessee licensed facilities because of the immediate danger to public health, safety, and welfare.

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**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.01	Definitions
1140-01-.02	Violations Constitute Unprofessional Conduct
1140-01-.08	Application for Pharmacy Practice Site, Manufacturer and Wholesaler Licenses
1140-01-.10	Fees
1140-01-.11	Controlled Substance Registration
1140-01-.12	Standards for Pharmacies and Prescription Department Security
1140-01-.13	Standards for Manufacturers and Wholesalers
1140-01-.14	Prescription Drugs Dispensed by Health Departments

Chapter Number	**Chapter Title**
1140-07	Sterile Product Preparation in Pharmacy Practice
Rule Number	**Rule Title**
1140-07-.02	Personnel
1140-07-.03	Physical Requirements
1140-07-.04	Policy and Procedure Manual
1140-07-.05	Labeling
1140-07-.06	Hazardous Products
1140-07-.07	Attire
1140-07-.08	Quality Assurance

Chapter Number	**Chapter Title**
1140-09	Manufacturers and Wholesalers
Rule Number	**Rule Title**
1140-09-.01	Manufacturer and Wholesaler Licensing
1140-09-.02	Minimum Information Required
1140-09-.03	Minimum Qualifications
1140-09-.04	Personnel
1140-09-.05	Minimum Requirements for Operation

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-01
INTRODUCTORY RULES

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1140-01-.01 DEFINITIONS.

(1) "ACPE" means the Accreditation Council for Pharmaceutical Education.

(2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.

(3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.

(4) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(5) "Blood fraction/component" means that part of blood separated by physical or mechanical means.

(6) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.

(7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.

(8) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.

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(9) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutic ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.

(Rule 1140-01-.01, continued)

(10)~~(8)~~"Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.

(11)~~(9)~~"Contact hour" means any hour of completed continuing pharmaceutical education programming which is:

(a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or

(b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).

(12)~~(10)~~"Continuing education unit" means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.

(13)~~(11)~~"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.

(14)~~(12)~~"Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.

(15)~~(13)~~"Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.

(16)~~(14)~~"Foreign pharmacy graduate" means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.

(17)~~(15)~~"Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.

(18)~~(16)~~"Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n):

(a) adult care facility;
(b) assisted living facility;
(c) correctional facility;
(d) developmental disability center;
(e) hospital;
(f) inpatient psychiatric center;
(g) intermediate care facility for the mentally retarded;
(h) mental health facility;
(i) nursing facility;
(j) personal care home;
(k) rehabilitation center;
(l) residential drug or alcohol treatment center;
(m) rest home;
(n) retirement center;
(o) sub-acute care facility; and

(Rule 1140-01-.01, continued)

(p) university health center.

(19)~~(17)~~"Institutional pharmacy practice site" means a pharmacy practice site serving patients within an institutional facility.

(20)~~(18)~~"Medication order" means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.

(21)~~(19)~~"National Association of Boards of Pharmacy (NABP)" means the professional organization that represents the individual state boards of pharmacy.

(22)~~(20)~~"Nuclear pharmacy practice site" means a pharmacy practice site providing radiopharmaceutical services.

(23)~~(21)~~"Patient counseling" means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.

(24)~~(22)~~"Pharmaceutical care" is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.

(25)~~(23)~~"Pharmacy internship" is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.

(26)~~(24)~~"Pharmacy practice site" means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.

(27)~~(25)~~"Preceptor" means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.

(28)~~(26)~~"Prescription department" means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.

(29)~~(27)~~"Quality assurance" means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.

(30)~~(28)~~"Radiopharmaceutical service" means, but is not limited to:

(a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;

(b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;

(c) the proper and safe storage and distribution of radiopharmaceuticals;

(d) the maintenance of radiopharmaceutical quality assurance;

(e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and

(f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.

(31)~~(29)~~"Reciprocity" means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.

(32)~~(30)~~"Shall" means that compliance is mandatory.

(33) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.

(34) "Sterile manufacturing" means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.

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(35)~~(31)~~"Third party pharmacy program" means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.

(36)~~(32)~~"Third party pharmacy program administrator" means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.

(37)~~(33)~~"Unit dose packaging" means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.

(38)~~(34)~~ "USP" means the United States Pharmacopeia.

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(39) "USP Standard" means any applicable standard published in the 2012 version of United States Pharmacopeia National Formulary guidelines.

(40) "USP 797" means the 2012 version of United States Pharmacopeia National Formulary General Chapter 797 "Pharmaceutical Compounding—Sterile Preparations."

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 6-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-304, 63-10-304(b)(1), 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.*

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

~~(1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-505(6).~~

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(Rule 1140-01-.01, continued)

(1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of *T.C.A. § 63-10-305(6).*

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Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-504(b)(1), and 63-10-505(6).* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.

(1) An applicant for a license to engage in the practice of pharmacy shall submit the following to the Board office at time of application:

(a) A completed application on a form approved by the Board;

(b) Application and registration fees established in rule 1140-01-.10; and

(c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials.

(d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for licensure will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for licensure and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.

(2) For the purpose of *T.C.A. § 63-10-506(d)*, a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."

(3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under *T.C.A. § 63-10-505*, unless the applicant can show cause why a license should be issued.

(4) No license shall be issued to a reciprocal applicant from a state which denies reciprocal privileges to a pharmacist currently licensed and in good standing in Tennessee.

(5) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

(6) An applicant initially licensed in another state and who wishes to obtain a Tennessee license may, in the discretion of the board, transfer to Tennessee the applicant's score on NAPLEX taken in another state. Provided, however, if the applicant has been licensed for twelve (12) or more months in another state, then the applicant shall apply for a license in Tennessee by reciprocity. No license shall be issued to a score transfer applicant from a state which denies score transfer privileges to a pharmacist currently licensed and in good standing in Tennessee.

(Rule 1140-01-.03, continued)
Authority: *T.C.A. §§ 63-10-101, 63-10-102(a), 63-1-116, 63-10-202, 63-10-304, 63-10-306, 63-10-404(2), (13), (17), and (26), 63-10-404(2), (13), (17), and (26), 63-10-504(b)(1), 63-10-506, and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed January 4, 2012; effective April 3, 2012.*

1140-01-.04 PHARMACY INTERNSHIP.

(1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand five hundred (1,500) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.

(a) The one thousand five hundred (1,500) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand one hundred (1,100) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.

(b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.

(c) Four hundred (400) of these hours may be acquired in non-traditional pharmacy internship programs which have received prior approval of the board.

(d) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-404(29), and 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed Mary 11, 1998; effective July 25, 1998.*

1140-01-.05 LICENSING EXAMINATIONS.

(1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.

(2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE®.

(3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.

(4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

(Rule 1140-01-.05, continued)

Authority: *T.C.A. §§ 63-10-304 and 63-10-306.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.*

1140-01-.06 SUMMARY SUSPENSION OF LICENSE.

Pursuant to *T.C.A. § 4-5-320*, if the board finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action.

Authority: *T.C.A. §§ 4-5-320, 63-10-101, 63-10-102, 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-505.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 15, 1989; effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.07 INACTIVE LICENSES AND LICENSE REINSTATEMENT.

(1) A pharmacist may apply for an inactive license by:

(a) Completing the biennial license renewal application form; and

(b) Paying the biennial renewal fee for an inactive license.

(2) A pharmacist maintaining an active license to practice pharmacy in another state or jurisdiction is ineligible for inactive license status in Tennessee.

(3) A pharmacist seeking active status for an inactive, delinquent, suspended or revoked license must fulfill the following minimum requirements.

(a) If the license has been inactive, delinquent, suspended or revoked for less than one (1) year, the pharmacist shall:

1. Provide written notice to the board requesting an active license;

2. Satisfy all past due continuing pharmaceutical education as required by the board; and

3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked.

(b) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than five (5) consecutive years, the pharmacist shall:

1. Provide written notice to the board requesting an active license;

2. Satisfy all past due continuing pharmaceutical education as required by the board;

3. Successfully complete the jurisprudence examination;

4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and

(Rule 1140-01-.07, continued)

5. Complete a period of pharmacy internship in Tennessee as follows.

(i) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than three (3) consecutive years, one hundred sixty (160) hours within ninety (90) consecutive days.

(ii) If the license has been inactive, delinquent, suspended or revoked for more than three (3) consecutive years but not more than five (5) consecutive years, three hundred twenty (320) hours within one hundred eighty (180) consecutive days.

(c) If the license has been inactive, delinquent, suspended or revoked for more than five (5) consecutive years, the pharmacist shall:

1. Provide written notice to the board requesting an active license;

2. Satisfy all past due continuing pharmaceutical education as required by the board;

3. Successfully complete the NAPLEX and jurisprudence examinations;

4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and

5. Complete a period of pharmacy internship of three hundred twenty (320) hours within one hundred eighty (180) consecutive days.

(d) Fulfill any other requirements which may be contained in any order of the board suspending or revoking the applicant's license.

(e) The board shall consider a written notice requesting reinstatement of an inactive, delinquent, suspended or revoked license within ninety (90) days of the notice being received by the director.

(f) The board shall consider a waiver upon request.

Authority: *T.C.A. §§ 63-10-101, 63-10-102, 63-10-210, 63-10-404(17), and 63-10-504(b)(1).* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Amendment filed April 11, 1979; effective July 30, 1979. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALER/DISTRIBUTOR LICENSES.

(1) Application for a license to operate as a pharmacy practice site, manufacturer or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.

(Rule 1140-01-.08, continued)

(2) An application for an existing pharmacy practice site, manufacturer or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer or wholesaler/distributor changes name, location or ownership.

(a) Transactions constituting a change of ownership include, but are not limited to, the following:

1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;

2. A partnership dissolves;

3. One partnership is replaced by another through the removal, addition or substitution of a partner;

4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and

5. Transfers between levels of government.

(b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives; and

3. Corporate stock transfers or sales, even when a controlling interest.

(3) No out-of-state pharmacy practice site, manufacturer or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer or wholesaler/distributor physically located out-of-state the following standards must be met.

(a) Pharmacy practice site.

1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.

2. Comply with all statutorily authorized directions and requests for information from the board.

3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.

(Rule 1140-01-.08, continued)

4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.

5. Maintain records of prescription orders dispensed to persons residing in Tennessee.

6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.

7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.

8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.

9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.

(b) Manufacturer or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.

2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located. Thereafter, the manufacturer or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer or wholesaler/distributor is physically located.

3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.

(4) Representatives of a manufacturer or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.

(5) Representatives of a manufacturer, or wholesaler/distributor conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer or wholesaler/distributor with the Board of Pharmacy in accordance with this chapter.

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(Rule 1140-01-.08, continued)

(6)~~(5)~~ It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.

(7)~~(6)~~ In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:

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(a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and

(b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.

Authority: *T.C.A. §§ 53-11-301, 53-14-104, 53-14-106, 53-14-107, 56-1-302(b)(1)(2), 63-10-101, 63-10-102(a), 63-10-203, 63-10-204, 63-10-210, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.09 RENEWAL OF LICENSES.

(1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.

(2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.

Authority: *T.C.A. §§ 53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1) and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.*

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1140-01-.10 FEES.

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(1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars ($50.00) plus cost of the examination and materials.

(2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars ($300.00).

(3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars ($125.00).~~ninety-six dollars ($96.00).~~ Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars ($125.00).~~ninety-six dollars ($96.00).~~ Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last

(Rule 1140-01-.10, continued)

day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars ($63.00).~~forty eight dollars ($48.00).~~

(4) Each person becoming registered as a pharmacy technician shall pay a registration fee of seventy-five dollars ($75.00).~~fifty dollars ($50.00).~~ Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars ($75.00).~~fifty dollars ($50.00).~~

(5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars ($300.00)~~one hundred sixty eight dollars ($168.00)~~ biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars ($300.00)~~one hundred sixty eight dollars ($168.00).~~

(6) All manufacturers and wholesalers/distributors of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars ($525.00)~~four hundred eight dollars ($408.00)~~, and thereafter a biennial renewal fee of five-hundred twenty-five dollars ($525.00)~~four hundred eight dollars ($408.00).~~

(7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy. ~~The fee for the board's publication of Pharmacy Drug Laws, Rules and Regulations shall be ten dollars ($10.00).~~

(8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health.~~Commerce and Insurance~~.

(9) The fee for certification of license examination grades shall be twenty five dollars ($25.00).

(10) The fee for a duplicate or revised pharmacist license wall certificate shall be twenty five dollars ($25.00).

(11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars ($10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.

(12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars ($10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.

(13) A penalty of fifty dollars ($50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.

(Rule 1140-01-.10, continued)

(14) Any licensee who wishes to modify the terms or conditions of a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall file those modifications with a non-refundable fee of five dollars ($5.00).

(15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars ($100.00)~~sixty dollars ($60.00)~~ biennially from the date of issuance.

(16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars ($250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars ($250.00).

Authority: *T.C.A. §§ 4-5-202, 63-10-102(a), 63-10-216, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508.* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed December 15, 1977; effective January 16, 1978. Amendment filed September 26, 1978; effective December 29, 1978. Repeal and new rule file February 7, 1983; effective March 9, 1983. Amendment filed May 23, 1986; effective August 12, 1986. Amendment filed January 26, 1987; effective April 29, 1987. Amendment filed October 1, 1987; effective January 27, 1988. Amendment filed November 18, 1989; effective February 28, 1989. Amendment filed October 18, 1990; effective January 29, 1991. Amendment filed May 3, 1991; effective August 28, 1991. Amendment filed December 22, 1992; effective March 31, 1993. Amendment filed June 25, 1993; effective September 28, 1993. Amendment filed October 19, 1996; effective February 28, 1996. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars ($40.00) and thereafter a biennial renewal fee of forty dollars ($40.00).

Authority: *T.C.A. §§ 53-10-303, 63-10-102(a), 63-10-404(6), 63-10-504(b)(1), 63-10-504(b)(1) and (2), and 63-10-508.* ***Administrative History:*** *Original rule filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.12 STERILE COMPOUNDING REGISTRATION

(1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

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(2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:

(a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or

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(Rule 1140-01-.12, continued)

(b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or

(c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or

(d) Been enjoined from operation by the court of any state or a federal court; or

(e) Been identified by the Commissioner of Health or the Commissioner's designee as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.

(3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:

(a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.

(b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.

1. Any recall order issued pursuant to subparagraph (6)(b) must be based on empirical evidence gathered, observed, or generated by qualified personnel including board investigators, the executive director of the Board of Pharmacy, epidemiological and infectious disease staff at the Department of Health, or personnel of the Food and Drug Administration, the Centers for Disease Control and Prevention, the United States Department of Agriculture, the United States Department of Health and Human Services, or the United States Department of Veterans' Affairs.

(c) The cessation of a particular activity or operation, including but not limited to the compounding or manufacture of a particular sterile product or class of sterile products, the use of laboratory equipment, aseptic techniques or sterilization procedures, or other activities related to the compounding, manufacture, preparation, propagation or processing of sterile products.

(d) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.

(4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

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(Rule 1140-01-.12, continued)

1140-01-.13 ~~1140-01-.12~~ STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.

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A license to operate a new or remodeled pharmacy practice site, or an existing pharmacy practice site which changes location or ownership, will not be issued unless the pharmacy practice site meets the following standards.

(1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.

(2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.

(3) The prescription department at the pharmacy practice site shall meet the following standards.

(a) The department shall have necessary counters and storage space.

(b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.

(c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.

(d) The department shall occupy a space of not less than one hundred eighty (180) square feet.

(e) The department shall have hot and cold running water and immediate area refrigeration.

(f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.

(g) Keys or other access devices to the physical barriers shall be subject to the following standards.

1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.

2. The pharmacist in charge shall place a key or other access device in a sealed envelope bearing the signature of the pharmacist in charge affixed across the seal and placed in a safe or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department.

(h) Access to the department is restricted to pharmacists, pharmacy interns and pharmacy technicians who are practicing at the pharmacy. Other persons designated by the pharmacist in charge may be allowed access but only during hours that a pharmacist is on duty.

(Rule 1140-01-.12, continued)

(i) Notwithstanding any rule or regulation to the contrary, a pharmacy which was established before June 6, 1945, and which serves food, and which has continuously had a soda fountain, may allow a customer to go through the pharmacy area to the restroom, and not be required to have a gate or door to separate the pharmacy from the restroom or other parts of the establishment.

(4) All licenses and certificates of registration for a pharmacy practice site shall at all times be conspicuously displayed at the practice site.

(5) If a pharmacy practice site is located in a mercantile establishment (such as a discount store, grocery store, department store, or other similar establishment), then such pharmacy practice site shall be:

(a) open for business during the same hours as the mercantile establishment, unless the pharmacy practice site is capable of being closed-off by physical barrier from floor to ceiling; and

(b) under the supervision of a pharmacist at all times; except as provided in rule 1140-03-.07.

(6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.

(7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.

(8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.

(9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: *T.C.A. §§ 63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.14 ~~1140-01-.13~~ STANDARDS FOR MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS.

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No license to operate a new or remodeled manufacturer or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: *T.C.A. §§ 63-10-404(18) and (37), and 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998.*

1140-01-.15 ~~1140-01-.14~~ PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.

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For purposes of *T.C.A. § 63-10-405*, the following drugs are hereby approved as not subject to abuse:

(1) Tuberculosis Control Agents:

(Rule 1140-01-.14, continued)

(a) Capreomycin Injection
(b) Cycloserine Capsules
(c) Ethambutol Tablets
(d) Ethionamide Tablets
(e) Isoniazid Tablets
(f) Para-Aminosalicyclate Tablets
(g) Pyrazinamide Tablets
(h) Rifampin Capsules
(i) Streptomycin Injection
(j) Tuberculin Skin Test (Mantoux only)
(k) Rifampin/Isoniazid
(l) Ofloxacin
(m) Rifampin-isoniazid-pyrazinamide

(2) Venereal Disease Control Agents:

(a) Ampicillin Capsules
(b) Doxycycline Capsules
(c) Erythromycin Tablets
(d) Penicillin

1. Benzathine Penicillin G Injection
2. Procaine Penicillin G Injection

(e) Probenecid Tablets
(f) Spectinomycin Injection
(g) Tetracycline Capsules
(h) Ceftriaxone
(i) Ciprofloxacin
(j) Lidocaine Injection
(k) Azithromycin
(l) Acyclovir Tablets, Ointments
(m) Trichloroacetic Acid
(n) Salicylic Acid
(o) Podophyllin/Salicylic Acid
(p) Aldara (Imiquimod)

(3) Biologicals/Immunizations:

(a) Antiserums
(b) Antitoxins
(c) Immune Serum Globulin
(d) Toxoids
(e) Vaccines
(f) Antigens

(4) Reproductive Health Agents:

(a) Metronidazole Tablets
(b) Oral Contraceptives
(c) Podophyllin
(d) Prenatal Vitamins
(e) Triple Sulfa Vaginal Cream/Tabs
(f) Vaginal Antifungal Cream/Tabs

(Rule 1140-01-.14, continued)

1. Clotrimazole
2. Miconazole
3. Nystatin
4. Terconazole (Terazole)

(g) Amino-Cerv
(h) Nitrofurantoin
(i) Ibuprofen, 600 mg Tablets
(j) Metronidazole (vaginal jell)
(k) Fluconazole Tablets
(l) Clindamycin Vaginal Cream
(m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)
(n) Medroxyprogesterone Acetate Injectable (Depo Provera®)
(o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)

(p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)

(5) Child Health Agents:

(a) Fluoride Tablets and Drops
(b) Lindane Cream, Lotion, Shampoo
(c) Mebendazole Tablets
(d) Pyrantel Pamoate Liquid
(e) Sulfadiazine Tablets
(f) Trimethoprim and Sulfamethoxazole
(g) Permethrin
(h) Crotamiton
(i) Nystatin Oral Suspension
(j) Nystatin Triamcinolone Cream
(k) Ibuprofen, Suspension Liquid

(6) Emergency Agents:

(a) Aminophylline Injection
(b) Benztropine Injection
(c) Diphenhydramine Injection
(d) Epinephrine Injection
(e) Glucagon Injection
(f) Hydralazine Injection
(g) Hydrocortisone Sodium Succinate
(h) Insulin, Regular
(i) Intravenous Fluids
(j) Oxygen
(k) Phenylephrine Injection
(l) Sodium Bicarbonate Injection
(m) Atropine Injection
(n) Nitroglycerin Sublingual Tablets
(o) Dexamethasone Injection
(p) Norepinephrine

(7) Antihypertensive Agents:

(a) Methyldopa
(b) Reserpine
(c) Hydrochlorothiazide

(Rule 1140-01-.14, continued)

(d) Hydralazine
(e) Propranolol
(f) Potassium Supplements
(g) Nicotine Patches

Authority: *T.C.A. §§ 63-10-404(14), 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2).* ***Administrative History:*** *Original rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010.*

(Rule 1140-7-.06, continued)

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-7
STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE

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1140-7-.01 APPLICABILITY.

The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of sterile products.

***Authority**: T.C.A. § 63-10-404(4),(11),(26),(28),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.02 STANDARDS

(1) All sterile products must be prepared in compliance with applicable USP 797 standards for pharmaceutical compounding.

(2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP 797.

(a) All waiver requests submitted pursuant to this part shall be submitted on a form approved by the Board of Pharmacy.

(b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part. Such authorization shall be for a set period of time as determined by the Board at the time of authorization.

(3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.

(4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of sterile products compounded and dispensed during the previous quarterly period and any other information as required by USP 797.

(a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.

(b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.

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(c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy and made available to the public on the Board of Pharmacy's website.

(5) Any licensed pharmacy which compounds and dispenses sterile products shall provide at a minimum upon request of the Board of Pharmacy the following information for any sterile drug product compounded, dispensed, traded, sold, or otherwise distributed:

(a) name, strength, and dosage form;

(b) quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding quarterly period;

(c) all components and an accurate statement of the weight or measure of each component;

(d) the beyond-use date;

(e) storage requirements;

(f) labels and labeling with appropriate beyond-use date and instructions for storage and use.

(6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:

(a) documentation of the name and strength of all drug products compounded over the past two (2) years;

(b) the sources and lot numbers of the components used in those drug products;

(c) the total number of dosage units compounded over the past two (2) years;

(d) the name of the person who prepared the drug product;

(e) the name of the pharmacist who approved the drug product;

(f) the name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;

(g) the results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.

1140-07-.03 ~~1140-7-.02~~ PERSONNEL.

(1) The pharmacist in charge or pharmacist designee shall be responsible for, at a minimum, the following:

(a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all prescription drugs and devices and related materials necessary in compounding and dispensing sterile products;

(b) Establishment of policies and procedures for the compounding and dispensing of sterile products;

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(c) Documentation of competency in aseptic techniques of all pharmacists, pharmacy interns and pharmacy technicians. The aseptic technique of each person compounding and dispensing sterile products shall be observed and evaluated as satisfactory during orientation and training and at least on an annual basis or whenever unacceptable techniques are observed or detected;

(d) Establishment of a quality assurance program;

(e) Reviewing and updating annually all policies and procedures; and

(f) Provision of sterile products on a twenty four (24) hour a day basis.

(2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.02 responsible for compounding or dispensing sterile products shall:

(a) Obtain practical and/or academic training in the compounding and dispensing of sterile products;

(b) Complete annual continuing education related to sterile product compounding and dispensing and utilization; and

(c) Maintain, in the pharmacy practice site, documentation of completion of the required training and continuing education.

(d) Use proper aseptic technique in all sterile product compounding as defined by the pharmacy practice site's policies and procedures.

(3) A pharmacist shall be available to respond to patients' and other health care practitioners' information needs on a twenty four (24) hour a day basis.

(4) The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.

(5) All pharmacists, pharmacy interns and pharmacy technicians must be qualified through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense sterile products.

(6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:

(a) Name of the person receiving the training or evaluation;
(b) Date(s) of the training or evaluation;
(c) General description of the topics covered; and
(d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.

***Authority**: T.C.A. § 63-10-404(4),(5),(8),(11),(14),(16),(26),(27),(29),(30), §63-10-504(b)(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.04 ~~1140-7-.03~~ PHYSICAL REQUIREMENTS.

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(1) Any facility that compounds sterile products shall comply with applicable physical requirements set out in the 2012 version of USP 797.

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~~Board of Pharmacyparagraph.~~

~~(1) Area, Equipment and Materials.~~

~~(a) 1. The sterile product compounding area shall be enclosed from other pharmacy practice site operations in order to minimize the potential for sterile product contamination.~~

~~2. This area shall be designed as a limited access area to avoid unnecessary traffic and airflow disturbances.~~

~~3. The enclosure of the sterile product compounding area may be achieved through the utilization of partitions, plastic curtains, or similar washable solid surface dividers.~~

~~4. Entrances to the sterile product compounding area must contribute to the enclosure.~~

~~5. Materials utilized to define the enclosure must extend from the floor to a minimum of the top of the hood.~~

~~6. All surfaces of the sterile product compounding area shall be washable, non-carpeted, and low particulate generating.~~

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~~7. No new construction or remodeling will be approved that is not either:~~

~~(i) Fully enclosed as noted in paragraphs (3), (4) and (5) above; or~~

~~(ii) Has documented engineering studies validating that air flow in a partially opened design creates an atmosphere that is equal to a fully enclosed design.~~

~~(b) For hand washing a sink with hot and cold running water shall be located in or adjacent to the area where sterile products are compounded.~~

~~(c) There shall be appropriate refrigeration for storing supplies and sterile products requiring refrigeration after being prepared and before being dispensed or administered to patients.~~

~~1. Documentation of refrigeration integrity shall be maintained in accordance with the pharmacy practice site's policies and procedures.~~

~~(d) The storage of prescription drugs and devices and related materials shall be under appropriate conditions (e.g., controlled temperature, well lighted, dry, clean, secure, and well ventilated).~~

~~1. Prescription drugs and devices and related materials shall not be stored in the sterile product compounding area in shipping containers (e.g., corrugated cardboard or other high particulate producing containers).~~

~~2. After removal from shipping containers, unit packaging will be acceptable for storage in the sterile product compounding area.~~

~~(e) All sterile product compounding must be performed within a Class 100 laminar flow hood, biologic safety cabinet (Class II, Type A) or within a Class 100 clean room.~~

~~(f) Laminar flow hoods, biologic safety cabinets (Class II, Type A) and Class 100 clean rooms shall be certified according to current federal standards for operational efficiency at least semi-annually.~~

~~(g) The laminar flow hood, biologic safety cabinet (Class II, Type A) or Class 100 clean room shall be kept running continuously; however, if the hood is turned off, the hood shall be functioning at least thirty (30) minutes before being used to compound sterile products, or according to recommendations of the manufacturer to achieve appropriate air velocity and a complete cleaning of the inside works before being used to compound sterile products.~~

~~(h) The sterile product compounding area shall be adequately ventilated so as not to interfere with laminar flow hood conditions and be used only for the compounding of sterile products.~~

~~(i) Prefilters in laminar flow hoods shall be changed at least quarterly and a written record of such change shall be maintained.~~

~~(j) The storage of prescription drugs, devices and related materials outside of the pharmacy shall be supervised and approved by the pharmacist in charge and inspected monthly to ensure that the products' safe storage is being maintained. These inspections shall be in accordance with rule 1140-4-.18.~~ ~~***Authority:*** *T.C.A. § 63-10-404(4),(8),(14), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*~~

1140-07-.05 ~~**1140-7-.04**~~ **POLICY AND PROCEDURE MANUAL.**

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(1) A policy and procedure manual related to sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for sterile compounding pursuant to USP 797, and shall, at a minimum, include:

(a) security;
(b) equipment;
(c) sanitation;
(d) reference materials;
(e) prescription drug and device and related material storage;
(f) prescription drug and device and related material compounding and dispensing;
(g) prescription drug and device and related material labeling and relabeling;
(h) prescription drug and device and related material destruction and returns;
(i) dispensing of sterile products;
(j) record keeping;
(k) quality assurance;
(l) quality control;
(m) duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;
(n) public safety relative to harmful sterile products, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;
(o) attire; ~~and~~
(p) pharmacist, pharmacy intern, and pharmacy technician training.
(q) compliance with all applicable USP standards; and

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(r) response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities

(2) Any licensed facility which engages in sterile compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.

(3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule, shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

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***Authority**: T.C.A. § 63-10-404(4),(8),(14),(26),(29),(30), § 63-10-504(b)(1),(2). **Administrative History:** Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed November 16, 1992; effective January 8, 1993. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.06 ~~1140-7-.05~~ LABELING.

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(1) At the time of dispensing of the sterile product, the dispensing container must bear a label which contains the following information:

(a) patient's name (if for outpatient use) or healthcare entity name;
(b) prescriber (s) name (if for outpatient use);
(c) pharmacy practice site name, address, and phone number (if for outpatient use);
(d) identification of the pharmacist who compounded the sterile product;
(e) when applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile product;
(f) name and amount of drug added;
(g) expiration date and, when applicable, expiration time, Beyond Use Dating (BUD);
(h) date of compounding;
(i) appropriate auxiliary label(s); and
(j) directions for use (if for outpatient), if applicable.

(2) Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

***Authority**: T.C.A. §63-10-404(11),(14),(19),(26),(28),(29),(30),(32),(34), §63-10-504(b(1),(2). **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.07 ~~1140-7-.06~~ HAZARDOUS PRODUCTS.

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(1) Physical Requirements.

(a) If the pharmacy practice site is engaged in the compounding of hazardous sterile products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.

(b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

(1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.

(2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.

(2) Dispensing.

(a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.

(b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.

(3) Training.

(a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:

1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and

2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.

(4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.

(5) Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.

(6) In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.

Authority: *T.C.A. § 63-10-404(4),(11),(26),(27),(28),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.08 ~~1140-7-.07~~ ATTIRE.

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(1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use respiratory precautions as set out in USP 797. ~~clean garments that generate low levels of particulate. Concerning clothing worn in a sterile product compounding area with a laminar flow hood or biologic safety cabinet (Class II, Type A), one (1) of the following must apply:~~

~~(a) Upon entering the sterile product compounding area, pharmacists, pharmacy interns and pharmacy technicians shall don an outer garment that generates a low level of particulate (e.g.,~~

~~clean laboratory jacket, disposable gown) before compounding sterile products. Upon leaving the sterile product compounding area, this outer garment shall be disposed of or left at the entrance of the sterile product compounding area and donned when re-entering the area.~~

~~(b) If scrubs or site specific clothing are donned for work in the sterile product compounding area, a laboratory jacket or outer covering shall be worn while outside the sterile product compounding area in order to protect the scrubs or site specific clothing from cross contamination. Upon entering the sterile product compounding area the lab jacket or outer covering shall be removed before compounding sterile products.~~

~~(2) All pharmacists, pharmacy interns and pharmacy technicians with respiratory conditions that may result in contamination of sterile products shall wear a mask.~~

~~(3) For the compounding of sterile products prior to receipt of specific medical or prescription orders and when the anticipated dispensing time may be greater than twenty eight (28) hours after preparation, clean, low particulate outer garments and gloves shall be required. Hair cover and a mask shall be required, unless a biologic safety cabinet (Class II, Type A) is utilized.~~

~~(4) If utilizing a Class 100 clean room without a laminar flow hood, the attire shall include a jumpsuit or surgical scrubs and head coverings that generate low levels of particulate, mask, shoe covers, and gloves.~~

~~(5) Attire specific to the compounding of hazardous sterile products is explained in rule 1140-7-.06.~~

Authority: *T.C.A. § 63-10-404(4),(26),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-07-.09 ~~1140-7-.08~~ QUALITY ASSURANCE.

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(1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.

(2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality sterile products.

(3) All quality assurance programs shall follow applicable USP standards.

(4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.

(5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: *T. C.A. § 63-10-404(26),(28),(29),(30), § 63-10-504(b)(1),(2).* ***Administrative History:*** *Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

(Rule 1140-9-.05, continued)

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-9
MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS

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1140-09-.01 ~~MANUFACTURER AND WHOLESALER LICENSING.~~ Manufacturers and Wholesaler/Distributors

(1) Every manufacturer or wholesaler/distributor, before engaging in the sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.

(a) Representatives of a manufacturer or wholesaler/distributor conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer or wholesaler/distributor with the Board of Pharmacy in accordance with this chapter.

(2) An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.

(3) The requirement of a license shall not apply to the following types of distributions:

(a) Intracompany sales;

(b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(c) The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; for purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;

(e) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a

prescription drug for emergency medical reasons; for purpose of this subparagraph, "emergency medical reasons" includes transfers of prescription drugs by a pharmacy practice site to alleviate a temporary shortage.

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(f) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase or trade a prescription drug, or the dispensing of a prescription drug pursuant to a medical or prescription order;

(g) The distribution of prescription drug samples by manufacturers' representatives; or

(h) The sale, purchase, or trade of blood and blood components intended for transfusion.

1. The sale, purchase, or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

***Authority**: T.C.A. § 63-10-404(2),(8),(14),(18),(37), § 63-10-504(b)(1), § 63-10-506(f). **Administrative History:** Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-09-.02 MINIMUM INFORMATION REQUIRED.

(1) The board shall require the following minimum information from each manufacturer or wholesaler/distributor applying for a license or any renewal of such license:

(a) The name, full business address, and telephone number of the manufacturer or wholesaler/distributor;

(b) All trade or business names used by the manufacturer or wholesaler/distributor;

(c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler/distributor for storage, handling, and distribution;

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(e) The name(s) of the owner and/or operator of the manufacturer or wholesaler/distributor, including:

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; ~~and~~

5. DEA registration number if applicable~~.~~; and

6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the

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vendor identified in the Board of Pharmacy's licensure application materials.

(2) Applicants seeking to register as sterile manufacturers shall provide the following materials to the Board of Pharmacy:

(a) Proof of registration with the Food and Drug Administration as a manufacturer and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary;

(b) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;

(c) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;

(d) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.

(3)~~(2)~~ Changes in any information in paragraphs (1) or (2) of this rule shall be submitted in writing to the Board of Pharmacy immediately.

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Authority: *T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1), § 63-10-506(f).* ***Administrative History:*** *Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-9-.03 MINIMUM QUALIFICATIONS.

(1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer or wholesaler/distributor:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples or distribution of controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the manufacturing or distribution of prescription drugs and prescription devices, including controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances, prescription drugs and prescription devices;

(f) Compliance with licensing requirements under previously granted licenses, if any;

(g) Compliance with requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required federal, state or local laws; and

(h) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

(2) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

Authority: *T.C.A. § 63-10-404(2),(6),(8),(14),(18),(37), § 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1999, effective July 25, 1998.*

1140-9-.04 PERSONNEL.

The board shall require that personnel employed by a manufacturer or wholesaler/distributor have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: *T.C.A. § 63-10-404(2),(18),(37), § 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-09-.05 MINIMUM REQUIREMENTS FOR GENERAL OPERATION.

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers and wholesalers/distributors:

(1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition, and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

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(2) Security.

(a) All facilities shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well-controlled.

2. The outside perimeter of the premises shall be well-lighted.

3. Entry into areas where prescription drugs and prescription devices are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide

protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) Storage. All prescription drugs and prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and devices, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(a) If no storage requirements are established for a prescription drug or prescription device it may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and prescription devices.

(c) The record keeping requirements in paragraph (6) of this section shall be followed for all prescription drugs and prescription devices.

(4) Examination of materials.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(c) The record keeping requirements in paragraph (6) of this section shall be followed for all incoming and outgoing prescription drugs.

(5) Returned, damaged, and outdated prescription drugs and prescription devices.

(a) Prescription drugs and prescription devices that are outside, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and prescription devices until destroyed or returned.

(b) Any prescription drugs and prescription devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be quarantined and physically separated from other prescription drugs and prescription devices until either destroyed or returned.

(c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer or wholesaler/distributor shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.

(d) The record keeping requirements in paragraph (6) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and prescription devices.

(6) Record keeping.

(a) Manufacturers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:

1. The source of the prescription drugs and prescription devices including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs and prescription devices were shipped;

2. The identity and quantity of the prescription drugs and prescription devices received and distributed or disposed of; and

3. The dates of receipt and distribution or other disposition of the prescription drugs and prescription devices.

(b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the prescription drugs and prescription devices.

(c) Records described in this paragraph that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(7) Written policies and procedures. Manufacturers and wholesalers/distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers and wholesalers/distributors shall include in written policies and procedures the following:

(a) A procedure whereby the older approved stock of a prescription drug or prescription device is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs and prescription devices. Such procedures shall be adequate to respond to recalls and withdrawals due to:

1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

2. Any voluntary action by the manufacturer or wholesaler/distributor to remove defective or potentially defective prescription drugs and prescription devices from the market; or

3. Any action undertaken to promote public health and safety by replacing of an existing product with an improved product or new package design.

(c) A procedure to ensure that manufacturers and wholesalers/distributors prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler/distributor or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.

(8) Responsible persons. Manufacturers and wholesalers/distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a description of such persons' duties and a summary of such persons' qualifications.

(9) Compliance with federal, state, and local law. Manufacturers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(a) Manufacturers and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Manufacturers and wholesalers/distributors that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.

(10) Salvaging and reprocessing. Manufacturers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: *T.C.A. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1).* ***Administrative History:*** *Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-09 .-06 MINIMUM REQUIREMENTS FOR STERILE PRODUCT OPERATION

(1) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:

(a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;

(b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;

(c) DEA regulations relating to controlled substances 21 CFR 1300-99.

(2) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or

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registration from the federal Food and Drug Administration shall comply with all applicable portions of USP 797.

(3) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.

(4) The Board of Pharmacy may waive any applicable standard or requirement of USP 797 upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.

Authority: T.C.A. § 63-10-404(8),(18),(33),(37), § 63-10-504(b)(1). Administrative History: Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

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* 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)
Charles E. (Buddy) Stephens, D.Ph.	X				
Jason Kizer, D.Ph	X				
Nina Smothers, D.Ph.	X				
Joyce McDaniel	X				
Will Bunch, D.Ph.	X				
Kevin K. Eidson, Pharm. D.		X			
Brenda Warren, D.Ph.		X			

I certify that this is an accurate and complete copy of an emergency rule(s), lawfully promulgated and adopted.

Date: 11/25/2013

Signature: David Reagan

Name of Officer: David Reagan, M.D., Ph.D

Title of Officer: Chief Medical Officer
Department of Health

MOLLIE A. GASS
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY, TENN.
My Commission Expires JULY 7, 2014

Subscribed and sworn to before me on: 11/25/13

Notary Public Signature: Mollie A. Gass

My commission expires on: 7/7/14

All emergency 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.

RECooper

Robert E. Cooper, Jr.
Attorney General and Reporter

1-29-14
Date

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Filed with the Department of State on: 1/31/14

Effective for: 180 *days

Effective through: 7/30/14

** Emergency rule(s) may be effective for up to 180 days from the date of filing.*

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Board of Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists
DIVISION:	Health Related Boards
SUBJECT:	Licensure and Continuing Education
STATUTORY AUTHORITY:	Tennessee Code Annotated, Sections 63-22-102 through 150
EFFECTIVE DATES:	April 7, 2014 through June 30, 2015
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rule changes qualifications and procedures whereby Tennessee has reciprocity with other states to license LPCs (licensed professional counselors) without examination. The rule also adds qualifications for temporary licensure, and amends the continuing education requirements by changing to a two-year cycle and doubling the relevant continuing education number references.

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.

Francis Martin, representing the Tennessee Mental Health Counselors Association commented:

> Generally the Association thinks the rules make many things cleaner and clearer, which they have been wanting. They endorse the changes.

The Board responded: Thank you.

Kim Speakman, representing the Tennessee Licensed Professional Counselors Association commented:

> Thank you for your work on the rule changes. They fully support all the changes because they believe it will make things much clearer and much better for all LPCs.

The Board responded: Thank you.

Board Member Bradley Bull commented: Could the term "foreign state" in the sections regarding reciprocity with other states be interpreted as foreign country too? Do we have any reciprocity with other nations? This should be clarified.

The Board responded: The rule will be changed to "state of the United States" to make it clear that we only have such agreements with other states.

Teddy Wilkins, Director for the Board commented: Under the requirements for education of LPC/MHSP, the requirement in (x) and (xiii) are the same so (xiii) should be deleted. It is a typo.

The Board responded: Good catch. That will be deleted.

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.

Pursuant to the Regulatory Flexibility Act of 2007, T.C.A. §§ 4-5-401, *et seq.*, the Department of Health submits the following regulatory flexibility analysis:

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

The proposed rules do not overlap, duplicate, or conflict with other federal, state, or local government rules.

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

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

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

The proposed rule amendments affect applicants seeking to become licensed professional counselors in Tennessee through initial licensure or through reciprocity. The proposed rules are not written with special consideration for the flexible compliance and/or reporting requirements because the licensing boards have, as their primary mission, the protection of the health, safety and welfare of Tennesseans. However, the proposed rules are written with a goal of avoiding unduly onerous regulations.

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

The compliance requirements throughout the proposed rules are as "user-friendly" as possible while still allowing the Board to achieve its mandated mission in regulating the licensing professional counselors and ensuring only qualified practitioners are licensed.

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

Compliance requirements are not consolidated or simplified for small businesses in the proposed rules for the protection of the health, safety and welfare of Tennesseans.

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

The standards required in the amendments do not necessitate the establishment of performance, design, or operational standards.

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

There are no unnecessary entry barriers or other effects in the proposed rules that would stifle entrepreneurial activity or curb innovation. Any barriers to entering the profession of licensed counseling are enacted for the health, safety and welfare of Tennesseans and are necessary.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

1. **Name of Board, Committee or Council:**

   Board of Licensed Professional Counselors, Licensed Marital and Family Therapists and Licensed Pastoral Therapists

2. **Rulemaking hearing date:** No rulemaking hearing date has been set yet.

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

   This rule may make it easier for applicants to obtain licenses or temporary licenses which allow them to open their own practice or affiliate with an existing practice to provide counseling services. Other than a possible increase in people engaged in counseling through these practices, it would have little to no effect on small businesses.

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

   None.

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

   Existing counseling practices may be able to expand by hiring temporarily licensed applicants as contract or affiliated practitioners.

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

   There will be no adverse impacts to existing small businesses.

7. **Alternatives to the proposed rule that will accomplish the same objectives but are less burdensome, and why they are not being proposed:**

   These rules are not burdensome, intrusive, or costly. In fact, they make it easier for people to understand the requirements to practice counseling in the State of Tennessee and easier to fulfill those requirements, thus making it easier to get a license.

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

   (a) **Federal:** The Commissioner is not aware of any federal counterparts. Counselors are not licensed by the federal government.

   (b) **State:** The Commissioner's proposed rule amendments are consistent with the qualifications for licensure in the T.C.A. §63-22-101 *et seq.*

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)

These rule amendments are not projected to impact local governments in any way.

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For Department of State Use Only

Sequence Number: 01-03-14
Rule ID(s): 5655
File Date: 1/7/14
Effective Date: 4/7/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists
Division:	Health Related Boards
Contact Person:	Johanna L. Barde, Assistant General Counsel
Address:	Office of General Counsel 220 Athens Way, Suite 210 Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-1611
Email:	johanna.barde@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 to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0450-01	General Rules Governing Professional Counselors
Rule Number	**Rule Title**
0450-01-.04	Qualifications for Licensure
0450-01-.05	Procedures for Licensure
0450-01-.12	Continuing Education

(Rule 0450-01-.03, continued)
effective June 24, 2002. Amendment filed April 17, 2007; effective July 1, 2007. Amendment filed November 26, 2008; effective February 9, 2009.

0450-01-.04 QUALIFICATIONS FOR LICENSURE.

(1) Professional Counselor by Examination. To be eligible to submit an application, a candidate must show completion of the following qualifications:

(a) Be at least 18 years of age.

(b) Must provide evidence that he is highly regarded in moral character and professional ethics (rule 0450-01-.05).

(c) Education. The educational requirements must be completed prior to the date of application.

1. Sixty (60) graduate semester hours, based upon a program of studies with a major in counseling, completed from an institution accredited by the Southern Association of Colleges and Schools, the Counsel for Accreditation of Counseling and Related Educational Programs, or a comparable accrediting body.

2. The graduate coursework should include, but is not limited to, core areas of (one course may satisfy study in more than one of the study areas):

(i) Theories of human behavior, learning and personality;

(ii) Abnormal behavior;

(iii) Theories of counseling and psychotherapy;

(iv) Evaluation and appraisal procedures;

(v) Group dynamics, theories and techniques;

(vi) Counseling techniques;

(vii) Multicultural counseling;

(viii) Ethics;

(ix) Research;

(x) Clinical practicum or internship (pursuant to T.C.A. § 63-22-104)

(d) A minimum of two (2) years of supervised post master professional experience consisting of not less than ten (10) hours per week and fifty (50) contact hours of supervision per year as defined by Rule 0450-01-.10 (1).

(e) Pass the examination pursuant to rule 0450-01-.08.

(f) Until receipt of a license to practice as a Professional Counselor, an applicant will be required to practice under supervision, pursuant to Rule 0450-01-.10.

(2) Upgrading from Certified Professional Counselor Status to Licensed Professional Counselor Status

(Rule 0450-01-.04, continued)

(a) Individuals certified on July 1, 1991, as professional counselors may upgrade from certification to licensure by any of the following methods:

1. Providing a copy of his current CPC renewal certificate and verification to the board's satisfaction, that he has had five years work experience, pursuant to rule 0450-01-.14, as a certified professional counselor.

2. Providing a copy of his current CPC renewal certificate and evidence that he has been certified by the NBCC.

3. Providing a copy of his current CPC renewal certificate and complying with the requirements pursuant to rule 0450-01-.04(1).

(b) Upgrading from Certified Associate Professional Counselor Status to Licensed Professional Counselor Status

1. Any person certified as an Associate Counselor on July 1, 1991, shall be deemed to be a Certified Professional Counselor, but only for the purpose of upgrading to Licensed Professional Counselor.

2. For the purpose of upgrading to Licensed Professional Counselor from Certified Associate Counselor, the board will accept a passing score on the PES examination, which was previously required for Associate Professional Counselors, as fulfilling the requirement of 0450-01-.08.

(3) Licensed Professional Counselor (LPC) by Reciprocity. Individuals seeking licensure by reciprocity must meet the following qualifications:

(a) Hold a current, undisciplined, professional counselor or equivalent license from another state of the United States which has entered into a mutual reciprocity agreement with the Tennessee Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists.

(b) Provide evidence that he or she is highly regarded in moral character and professional ethics.

(c) Pass the Tennessee Jurisprudence Examination pursuant to rule 0450-01-.08.

~~(3) Licensed Professional Counselor by Reciprocity. Individuals seeking licensure by reciprocity must meet the following qualifications:~~

~~(a) Hold a current professional counselor license from another state;~~

~~(b) Meet licensure requirements pursuant to Rule 0450-01-.04(1)(a) through (d); and~~

~~(c) Pass all the examinations required pursuant to Rule 0450-01-.08.~~

(4) Licensed Professional Counselor with Mental Health Services Provider designation (LPC/MHSP). To be eligible to submit an application, a candidate must show completion of the following qualifications:

(a) Be at least 18 years of age.

(b) Provide evidence that he or she is highly regarded in moral character and professional ethics.

(Rule 0450-01-.04, continued)

(c) Education. The educational requirements must be completed prior to the date of application.

1. Sixty (60) graduate semester hours, based upon a program of studies with a major in counseling, completed from an institution accredited by the Southern Association of Colleges and Schools, the Council for the Accreditation of Counseling and Related Educational Programs, or a comparable accrediting body;

2. The graduate coursework should include, but is not limited to, the following core areas (one course may satisfy study in more than one of the study areas):

(i) Theories of human behavior, learning and personality;

(ii) Abnormal behavior;

(iii) Theories of counseling and psychotherapy;

(iv) Evaluation and appraisal procedures;

(v) Group dynamics, theories and techniques;

(vi) Counseling techniques;

(vii) Multicultural counseling;

(viii) Ethics;

(ix) Research;

(x) Clinical practicum or internship (pursuant to T.C.A. § 63-22-104);

(xi) Use of the DSM;

(xii) Treatment and treatment planning

3. Pursuant to T.C.A. § 63-22-120, a minimum of nine (9) graduate semester hours of coursework must be "specifically related to diagnosis, treatment, appraisal and assessment of mental disorders." This will be interpreted to mean passing nine (9) semester hours, either during the course of a graduate degree or as post-graduate work, in courses in which diagnosis, treatment and treatment planning, appraisal and assessment of mental disorders, psychopathology, and the use of the DSM were the entire focus of the course or comprised a substantial portion of the course work.

(d) Meet the following requirements for post-masters professional experience:

1. Complete three thousand (3000) hours of supervised post-masters professional experience, including one hundred and fifty (150) contact hours of supervision obtained pursuant to Rule 0450-01-.10(6).

(i) One thousand and five hundred (1500) of the three thousand (3000) hours of supervised post-masters professional experience shall be face-to-face client contact hours.

(Rule 0450-01-.04, continued)

(ii) One thousand and five hundred (1500) of the three thousand (3000) hours of supervised post-masters professional experience shall be clinically-related activities;

(e) Pass the National Counselors Examination, the National Clinical Mental Health Counseling Examination, and the Tennessee Jurisprudence Exam pursuant to Rule 0450-01-.08.

~~(4) Professional Counselor with Mental Health Services Provider designation.~~

~~(a) Prior to submitting an application, each of the following qualifications must be met by a candidate for professional counselor with Mental Health Services Provider designation:~~

~~1. Be at least 18 years of age.~~

~~2. Must provide evidence that he is highly regarded in moral character and professional ethics (Rule 0450-01-.05).~~

~~3. Meet the following educational requirements prior to the date of application:~~

~~(i) Sixty (60) graduate semester hours, based upon a program of studies with a major in counseling, completed from an institution accredited by the Southern Association of Colleges and Schools, the Counsel for Accreditation of Counseling and Related Educational Programs, or a comparable accrediting body;~~

~~(ii) The graduate coursework should include, but is not limited to, the following core areas (one course may satisfy study in more than one of the study areas):~~

~~(I) Theories of human behavior, learning and personality~~

~~(II) Abnormal behavior and psychopathology~~

~~(III) Theories of counseling and psychotherapy~~

~~(IV) Evaluation and appraisal procedures~~

~~(V) Group dynamics, theories and techniques~~

~~(VI) Counseling techniques~~

~~(VII) Multicultural counseling~~

~~(VIII) Ethics~~

~~(IX) Research~~

~~(X) Use of the DSM~~

~~(XI) Treatment and treatment planning~~

~~(XII) Clinical practicum or internship (pursuant to T.C.A. § 63-22-104);~~

~~4. Meet the following requirements for post-masters professional experience:~~

(Rule 0450-01-.04, continued)

~~(i) Complete three thousand (3000) hours of supervised post-masters professional experience, including one hundred and fifty (150) contact hours of supervision obtained pursuant to Rule 0450-01-.10(6).~~

~~(I) One thousand and five hundred (1500) of the three thousand (3000) hours of supervised post-masters professional experience shall be face-to-face client contact hours.~~

~~(II) One thousand and five hundred (1500) of the three thousand (3000) hours of supervised post-masters professional experience shall be clinically-related activities;~~

~~5. Pass the examination pursuant to Rule 0450-01-.08.~~

~~(b) For the purpose of mental health service provider designation pursuant to T.C.A. § 63-22-150, "has completed a minimum of nine (9) graduate semester hours of coursework specifically related to diagnosis, treatment, appraisal and assessment of mental disorders" will be interpreted to mean passing nine (9) semester hours, either during the course of a graduate degree or as post-graduate work, in courses which include diagnosis, treatment and treatment planning, appraisal and assessment of mental disorders, psychopathology, and the use of the DSM, were the entire focus of the course or comprised a substantial portion of the course work.~~

(5) Licensed Professional Counselor with Mental Health Service Provider designation (LPC/MHSP), by reciprocity. Individuals seeking licensure by reciprocity as LPC/MHSPs must meet the following qualifications.

(a) Hold a current, undisciplined, professional counselor license with a Mental Health Service Provider designation, or its equivalent, from another state of the United States which has entered into a mutual reciprocity agreement with the Tennessee Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists.

(b) Provide evidence that he or she is highly regarded in moral character and professional ethics.

(c) Pass the Tennessee Jurisprudence Examination pursuant to rule 0450-01-.08.

~~(5) Licensed Professional Counselor with Mental Health Service Provider designation, by reciprocity. Individuals seeking licensure by reciprocity as Licensed Professional Counselors with Mental Health Service Provider designation must meet the following qualifications.~~

~~(a) Hold a current professional counselor license with a Mental Health Provider designation, or its equivalent, from another state.~~

~~(b) Meet licensure requirements pursuant to Rules 0450-01-.04(4)(a)1. through 4. and 0450-01-.04(4)(b).~~

~~(c) Pass all the examinations required pursuant to Rule 0450-01-.08.~~

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(6) Temporarily Licensed Professional Counselor with Mental Health Service Provider designation.

(a) A temporary license may be issued by the Board for an applicant for licensed professional counselor designated as a mental health service provider who has:

(Rule 0450-01-.04, continued)

1. Completed the academic course work and training (except for the required supervised professional experience) required for the license; and

2. Successfully passed the National Counselor Examination.

(b) A temporary license obtained pursuant to this section authorizes an applicant to perform the functions specified in T.C.A. § 63-22-150(5), while working under the supervision of an approved supervisor.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-22-102, 63-22-104, 63-22-107, 63-22-116, 63-22-120, 63-22-121 and Public Chapter 318, Acts of 1995.* ***Administrative History:*** *Original rule filed October 9, 1986; effective November 23, 1986. Repeal and new rule filed April 29, 1992; effective June 13, 1992. Amendment filed October 18, 1995; effective January 1, 1996. Amendment filed April 16, 1996; effective June 30, 1996. Amendment filed June 18, 1996; effective September 4, 1996. Amendment filed January 31, 2000; effective April 15, 2000. Amendment filed September 4, 2003 was effective November 18, 2003. However; Stay of effective date filed by the Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists on November 7, 2003; new effective date January 17, 2004. Amendment filed November 26, 2008; effective February 9, 2009. Amendments filed October 25, 2012; effective January 23, 2013.*

0450-01-.05 PROCEDURES FOR LICENSURE. To become licensed as a professional counselor in Tennessee a person must comply with the following procedures and requirements.

(1) Professional Counselor by Examination

(a) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet.

(b) An applicant shall respond truthfully and completely to every question or request for information contained in the form, and submit it along with all documentation and fees required by the form and this rule to the board's administrative office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all documentation be filed simultaneously.

(c) Applications for licensure will be accepted throughout the year and files which are completed on or before the 30th day prior to the meeting will ordinarily be processed at the next board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the board's office within 60 days of receipt of your application or the file will be closed.

(d) An applicant shall pay, at the time of application, the nonrefundable application fee as provided in rule 0450-01-.06.

(e) An applicant shall submit verification of having completed a supervised practicum or internship pursuant to T.C.A. § 63-22-104.

(f) An applicant shall submit with his application, a certified copy of his birth certificate.

(g) An applicant shall submit a clear and recognizable recently taken, bust photograph which shows the full head face forward from at least the top of the shoulders up.

(h) It is the applicant's responsibility to request a graduate transcript from his degree granting institution, pursuant to T.C.A. § 63-22-104, be submitted directly from the

(Rule 0450-01-.05, continued)

school to the board's administrative office. The institution granting the degree must be accredited, pursuant to rule 0450-01-.04(1), at the time the degree was granted. The transcript must show that the degree has been conferred and carry the official seal of the institution and reference the name under which the applicant has applied for licensure. The transcript must show at least 60 graduate semester hours, pursuant to rule 0450-01-.04(1). The educational requirements contained in this rule must be completed prior to the date of application for licensure.

(i) An applicant shall complete and submit the worksheet form for reporting course work.

(j) An applicant shall submit evidence of good moral character. Such evidence shall include at least two recent, within the preceding 12 months, original letters from professionals attesting to the applicant's personal character and professional ethics and typed on the signator's letterhead.

(k) An applicant shall submit evidence of completing a minimum of two (2) years supervised post-master's experience under the direction of an approved supervisor, pursuant to rule 0450-01-.04(1)(d).

(l) An applicant shall direct NBCC to submit directly to the Board's office evidence that he or she passed the National Counselor Examination pursuant to rule 0450-01-.08.

(m) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.

2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.

3. Loss or restriction of certification or licensure.

4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity, or any other civil action remedy recognized under any country's or state's statutory, common, or case law.

5. If the applicant discloses any of the above, the Board may require the applicant to appear before the Board to answer questions regarding the circumstances and regarding the applicant's fitness to practice in the State of Tennessee. The burden is on the applicant to prove by a preponderance of the evidence the circumstances of any of the above.

6. Any of the above may be grounds for denial or conditioning of the license if the Board determines it to be unprofessional conduct or conduct that violates T.C.A. §§ 63-22-101, et seq. or Board rules and regulations.

~~(k) An applicant shall submit evidence of a minimum of two (2) years supervised post-master's experience under the direction of an approved supervisor, pursuant to rule 0450-01-.10.~~

~~(l) An applicant shall direct NBCC to submit directly to the board's office evidence that he passed the NBCC examination, pursuant to rule 0450-01-.08.~~

~~(m) An applicant shall disclose the circumstances surrounding any of the following:~~

(Rule 0450-01-.05, continued)

~~1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.~~

~~2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.~~

~~3. Loss or restriction of certification or licensure.~~

~~4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity, or any other civil action remedy recognized under any country's or state's statutory, common, or case law.~~

(n) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(o) When necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.

(p) Personal resumes are not acceptable and will not be reviewed .

(q) Application review and licensure decisions shall be governed by rule 0450-01-.07.

(r) The burden is on the applicant to prove by a preponderance of the evidence that his course work, supervision, and experience are equivalent to the board's requirements.

(2) Licensed Professional Counselor by Upgrade.

(a) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet.

(b) Requests for upgrade will be accepted throughout the year and files which are completed on or before the 30th day prior to the meeting will ordinarily be processed at the next board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the board office within 60 days of receipt of your application or the file will be closed.

(c) An individual seeking to upgrade shall pay the nonrefundable upgrade review fee, pursuant to rule 0450-01-.06, upon submission of the upgrade application.

(d) An applicant shall respond truthfully and completely to every question or request for information contained in the form and submit it along with all documentation and fees required by the form and this rule to the board administrative office. It is the intent of this rule that steps necessary to accomplish the filing of the application and that all documentation be filed simultaneously.

(e) An individual currently registered with the board may upgrade his certification to licensure by providing a copy of his current CPC certificate and:

1. Submitting evidence that he holds a current certification from NBCC, or

2. Compliance with the requirements pursuant to rule 0450-01-.04(1), or

(Rule 0450-01-.05, continued)

3. Providing verification to the Board's satisfaction, that he has had five (5) years professional experience as a certified professional counselor.

(f) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.

2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.

3. Loss or restriction of certification or licensure.

4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity, or any other civil action remedy recognized under any country's or state's statutory, common, or case law.

5. If the applicant discloses any of the above, the Board may require the applicant to appear before the Board to answer questions regarding the circumstances and regarding the applicant's fitness to practice in the State of Tennessee. The burden is on the applicant to prove by a preponderance of the evidence the circumstances of any of the above.

6. Any of the above may be grounds for denial or conditioning of the license if the Board determines it to be unprofessional conduct or conduct that violates T.C.A. §§ 63-22-101, et seq. or Board rules and regulations.

(g) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(h) Where necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.

(i) Upgrade review and licensure decisions shall be governed by rule 0450-01-.07.

(j) Personal resumes are not acceptable and will not be reviewed.

(k) The burden is on the applicant to prove by a preponderance of the evidence that he possesses the qualifications to upgrade to licensure status.

(3) Licensed Professional Counselor (LPC) by Reciprocity

(a) The Board may issue a license to any individual who holds a current professional counselor license from another state of the United States which has entered into a mutual reciprocity agreement with the Tennessee Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists, and who meets the qualifications stated in rule 0450-01-.04(3).

(b) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet. An applicant shall pay, at the time of application, the nonrefundable application fee as provided in rule 0450-01-.06.

(c) Applications for licensure will be accepted throughout the year and files which are

(Rule 0450-01-.05, continued)

completed on or before the 30th day prior to the meeting will ordinarily be processed at the next Board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the Board office within sixty (60) days of receipt of the application or the file will be closed.

(d) An applicant shall respond truthfully and completely to every question or request for information contained in the form and submit it along with all documentation and fees required by the form and this rule to the Board administrative office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all documentation be filed simultaneously.

(e) An applicant shall submit a clear and recognizable, recently taken, bust photograph which shows the full head face forward from at least the top of the shoulders up.

(f) An applicant shall submit a certified photocopy of his or her birth certificate.

(g) An applicant shall submit evidence of good moral character. Such evidence shall include two recent, within the preceding twelve (12) months, original letters from professionals attesting to the applicant's personal character and professional ethics and typed on the signator's letterhead.

(h) An applicant shall submit a copy of his original certificate or license from the other state along with an official statement or affidavit from the appropriate certification or licensing agency in the other state which indicates that the certificate or license is in effect and in good standing, as well as under what provision such certificate or license was issued (i.e. grandfathering, examination, reciprocity, endorsement, etc.).

(i) An applicant must submit a copy of his renewal certificate with the number from the other state and expiration date.

(j) The applicant shall provide the Board with a copy of his state's certification or licensing law and rules in effect at the time the applicant was credentialed.

(k) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.

2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.

3. Loss or restriction of certification or licensure.

4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity or any other civil action remedy recognized under any country's or state's statutory, common, or case law.

5. If the applicant discloses any of the above, the Board has the right to require the applicant to appear before the Board to answer questions regarding the circumstances and regarding the applicant's fitness to practice in the State of Tennessee. The burden is on the applicant to prove by a preponderance of the evidence the circumstances of any of the above.

6. Regardless of the terms of a reciprocal agreement with another state, any of the

(Rule 0450-01-.05, continued)

above may be grounds for denial or conditioning of the license if the Board determines it to be unprofessional conduct or conduct that violates T.C.A. §§ 63-22-101, et seq. or Board rules and regulations.

(l) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(m) Where necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.

(n) Application review and licensure decisions shall be governed by rule 0450-01-.07.

(o) Personal resumes are not acceptable and will not be reviewed.

~~(3) Professional Counselor by Reciprocity~~

~~(a) The Board may issue a license to any individual who holds a current professional counselor license from another state if the applicant meets the qualifications stated in Rule 0450-01-.04(3).~~

~~(b) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet. An applicant shall pay, at the time of application, the nonrefundable application fee as provided in rule 0450-01-.06.~~

~~(c) Applications for licensure will be accepted throughout the year and files which are completed on or before the 30th day prior to the meeting will ordinarily be processed at the next board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the board office within 60 days of receipt of your application or the file will be closed.~~

~~(d) An applicant shall respond truthfully and completely to every question or request for information contained in the form and submit it along with all documentation and fees required by the form and this rule to the board administrative office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all documentation be filed simultaneously.~~

~~(e) An individual seeking to upgrade shall pay the nonrefundable upgrade review fee, pursuant to rule 0450-01-.06, upon submission of the upgrade application.~~

~~(f) An applicant shall submit a clear and recognizable recently taken, bust photograph which shows the full head face forward from at least the top of the shoulders up.~~

~~(g) An applicant shall submit a certified photocopy of his birth certificate.~~

~~(h) An applicant shall submit evidence of good moral character. Such evidence shall include two recent, within the preceding 12 months, original letters from professionals attesting to the applicant's personal character and professional ethics and typed on the signator's letterhead.~~

~~(i) An applicant shall submit a copy of his original certificate or license with number from other state in effect at the time the original license was issued.~~

(Rule 0450-01-.05, continued)

~~(j) An applicant must submit a copy of his renewal certificate with the number from the other state and expiration date.~~

~~(k) The applicant shall provide the board with a copy of his state's certification or licensing law and rules in effect at the time the applicant was credentialed.~~

~~(l) The applicant shall direct the appropriate certification or licensing agency in his state to send an official statement which indicates that such certificate or license is in effect and in good standing and under what provision such certificate or license was issued (i.e., grandfathering, examination, reciprocity, endorsement, etc.)~~

~~(m) An applicant shall disclose the circumstances surrounding any of the following:~~

~~1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.~~

~~2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.~~

~~3. Loss or restriction of certification or licensure.~~

~~4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity or any other civil action remedy recognized under any country's or state's statutory, common, or case law.~~

~~(n) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.~~

~~(o) Where necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.~~

~~(p) Application review and licensure decisions shall be governed by rule 0450-01-.07.~~

~~(q) Personal resumes are not acceptable and will not be reviewed.~~

~~(r) The burden is on the applicant to prove by a preponderance of the evidence that his certificate/license at the time of issuance was based on requirements that were at least equivalent to or exceeded Tennessee's current requirements.~~

(4) Licensed Professional Counselor with Mental Health Service Provider designation (LPC/MHSP).

(a) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet.

(b) An applicant shall respond truthfully and completely to every question or request for information contained in the form, and submit it along with all documentation and fees required by the form and this rule to the Board's administrative office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all documentation be filed simultaneously.

(c) Applications for licensure will be accepted throughout the year and files which are completed on or before the 30th day prior to the meeting will ordinarily be processed at

(Rule 0450-01-.05, continued)

the next Board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the Board's office within sixty (60) days of receipt of the application or the file will be closed.

(d) An applicant shall pay, at the time of application, the nonrefundable application fee as provided in rule 0450-01-.06.

(e) An applicant shall submit verification of having completed a supervised practicum or internship pursuant to T.C.A. § 63-22-104.

(f) An applicant shall submit with his application, a certified copy of his birth certificate.

(g) An applicant shall submit a clear and recognizable recently taken, bust photograph which shows the full head face forward from at least the top of the shoulders up.

(h) It is the applicant's responsibility to request a graduate transcript from his degree granting institution, pursuant to T.C.A. § 63-22-104, be submitted directly from the school to the Board's administrative office. The institution granting the degree must be accredited, pursuant to rule 0450-01-.04(4), at the time the degree was granted. The transcript must show that the degree has been conferred and carry the official seal of the institution and reference the name under which the applicant has applied for licensure. The transcript must show, pursuant to rule 0450-01-.04(4)(c)(3), at least sixty (60) graduate semester hours, including nine (9) from courses entirely or substantially pertaining to diagnosis, treatment, appraisal and assessment of mental disorders. The educational requirements contained in this rule must be completed prior to the date of application for licensure.

(i) An applicant shall complete and submit the worksheet form for reporting course work.

(j) An applicant shall submit evidence of good moral character. Such evidence shall include at least two (2) recent, within the preceding twelve (12) months, original letters from professionals attesting to the applicant's personal character and professional ethics and typed on the signator's letterhead.

(k) An applicant shall submit evidence of completing a minimum of two (2) years supervised post-master's experience under the direction of an approved supervisor, pursuant to rule 0450-01-.04(4)(d).

(l) An applicant shall direct NBCC to submit directly to the Board's office evidence that he passed the National Counselor Examination and the National Clinical Mental Health Counseling Examination pursuant to rule 0450-01-.08.

(m) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.

2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.

3. Loss or restriction of certification or licensure.

4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity, or any other civil action remedy recognized under any country's or state's statutory, common, or case law.

(Rule 0450-01-.05, continued)

5. If the applicant discloses any of the above, the Board has the right to require the applicant to appear before the Board to answer questions regarding the circumstances and regarding the applicant's fitness to practice in the State of Tennessee. The burden is on the applicant to prove by a preponderance of the evidence the circumstances of any of the above.

6. Any of the above may be grounds for denial or conditioning of the license if the Board determines it to be unprofessional conduct or conduct that violates T.C.A. §§ 63-22-101, et seq. or Board rules and regulations.

(n) An applicant shall cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(o) When necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.

(p) Personal resumes are not acceptable and will not be reviewed.

(q) Application review and licensure decisions shall be governed by rule 0450-01-.07.

(r) The burden is on the applicant to prove by a preponderance of the evidence that his course work, supervision, and experience are equivalent to the Board's requirements.

~~(4) Professional Counselor with Mental Health Service Provider designation.~~

~~(a) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet.~~

~~(b) An applicant for professional counselor with mental health service provider designation may file one (1) application and all required documentation, along with the non-refundable application fee required by Rule 0450-01-.06, pursuant to procedures outlined in paragraph (1) of this rule.~~

(5) Licensed Professional Counselor with Mental Health Service Provider designation (LPC/MHSP) by reciprocity.

(a) The Board may issue a license to any individual who holds a current, undisciplined professional counselor license with a Mental Health Provider designation, or its equivalent, from another state of the United States which has entered into a mutual reciprocity agreement with the Tennessee Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists, and who meets the qualifications stated in rule 0450-01-.04(5).

(b) An application shall be requested from the Board's administrative office or shall be downloaded from the Internet. An applicant shall pay, at the time of application, the nonrefundable application fee as provided in rule 0450-01-.06.

(c) Applications for licensure will be accepted throughout the year and files which are completed on or before the 30th day prior to the meeting will ordinarily be processed at the next Board meeting scheduled for the purpose of reviewing files. Supporting documents requested in these instructions must be received in the Board office within 60 days of receipt of the application or the file will be closed.

(Rule 0450-01-.05, continued)

(d) An applicant shall respond truthfully and completely to every question or request for information contained in the form and submit it along with all documentation and fees required by the form and this rule to the Board administrative office. It is the intent of this rule that all steps necessary to accomplish the filing of the required documentation be completed prior to filing an application and that all documentation be filed simultaneously.

(e) An applicant shall submit a clear and recognizable recently taken, bust photograph which shows the full head face forward from at least the top of the shoulders up.

(f) An applicant shall submit a certified photocopy of his birth certificate.

(g) An applicant shall submit evidence of good moral character. Such evidence shall include two recent, within the preceding 12 months, original letters from professionals attesting to the applicant's personal character and professional ethics and typed on the signator's letterhead.

(h) An applicant shall submit a copy of his original certificate or license from the other state along with an official statement or affidavit from the appropriate certification or licensing agency in the other state which indicates that the certificate or license is in effect and in good standing, as well as under what provision such certificate or license was issued (i.e. grandfathering, examination, reciprocity, endorsement, etc.).

(i) An applicant must submit a copy of his renewal certificate with the number from the other state and expiration date.

(j) The applicant shall provide the Board with a copy of his state's certification or licensing law and rules in effect at the time the applicant was credentialed.

(k) An applicant shall disclose the circumstances surrounding any of the following:

1. Conviction of any criminal law violation of any country, state, or municipality, except minor traffic violations.

2. The denial of certification or licensure application by any other state or the discipline of certification or licensure in any state.

3. Loss or restriction of certification or licensure.

4. Any civil suit judgment or civil suit settlement in which the applicant was a party defendant including, without limitation, actions involving malpractice, breach of contract, antitrust activity or any other civil action remedy recognized under any country's or state's statutory, common, or case law.

5. If the applicant discloses any of the above, the Board has the right to require the applicant to appear before the Board to answer questions regarding the circumstances and regarding the applicant's fitness to practice in the State of Tennessee. The burden is on the applicant to prove by a preponderance of the evidence the circumstances of any of the above.

6. Regardless of the terms of a reciprocal agreement with another state, any of the above may be grounds for denial or conditioning of the license if the Board determines it to be unprofessional conduct or conduct that violates T.C.A. §§ 63-22-101, et seq. or Board rules and regulations.

(l) An applicant shall cause to be submitted to the Board's administrative office directly

(Rule 0450-01-.05, continued)

from the vendor identified in the Board's licensure application materials, the result of a criminal background check.

(m) Where necessary, all documents required to be submitted shall be translated into English and such translation certified along with the original document as to authenticity by the issuing source.

(n) Application review and licensure decisions shall be governed by rule 0450-01-.07.

(o) Personal resumes are not acceptable and will not be reviewed.

~~(5) Temporary licensure for Professional Counselor with Mental Health Service Provider designation.~~

~~(a) A temporary license may be issued by the board for an applicant for licensed professional counselor designated as a mental health service provider who has:~~

~~1. Completed the academic course work and training (except for the required supervised professional experience) required for the license; and~~

~~2. Who has successfully passed all the required examinations, as provided in rule 0450-01-.08.~~

~~(b) A temporary license obtained pursuant to this section authorizes an applicant to perform the functions specified in T.C.A. § 63-22-150(5), while working under the supervision of a qualified supervisor.~~

~~1. A qualified supervisor is defined as one who is a Licensed Professional Counselor with Mental Health Service Provider designation, licensed marital and family therapist, licensed clinical social worker, licensed psychiatrist, licensed senior psychological examiner, or a licensed psychologist with health service provider designation, who has been licensed or certified at least five (5) years and who is in good standing with their respective licensing boards and professional associations.~~

~~2. As part of the application process for temporary licensure, the applicant must submit, on a form provided by the board, information about the proposed supervisor or supervisors. Should the proposed supervisor(s) meet the licensure requirements indicated in (b)(1) above, the board will approve that person(s) to do the supervision.~~

~~(c) In order to receive a temporary license, an applicant must submit to the board a completed application for temporary licensure as a LPC/MHSP, and meet all the requirements of 0450-01-.05(1) or (3), except as noted in this paragraph, including paying all the appropriate fees.~~

~~(d) No person may be issued more than one (1) temporary license, nor shall a temporary license be valid for more than three (3) years.~~

~~(e) If an applicant is granted a temporary license, the license shall remain valid until the board grants or denies the regular license application or until it shall become invalid for any of the following reasons:~~

~~1. Expiration of the three year period.~~

~~2. Failure to continue in supervision during the three year period the license may be valid.~~

(Rule 0450-01-.05, continued)

~~3. Change of supervisors without notifying the board, submitting the credentials of the proposed supervisor, and obtaining the board's approval.~~

~~(f) When a temporary license holder is notified by the board that his temporary license is invalid for any reason, the applicant shall return the temporary license to the board office within ten (10) days. The applicant is expected to cause his supervisor to notify the board of any reason he is aware of that the license should become invalid. The board will notify the supervisor when the temporary license becomes invalid.~~

~~(g) To replace the temporary license with a regular license, the applicant shall notify the board in writing, using a form provided by the board, and present supporting documentation demonstrating the satisfactory completion of the required Post Master's supervised experience in a clinical setting which meets the requirement of 0450-01-.10 (5). The board shall then grant or deny the regular license application, based on satisfactory completion of all requirements for licensure.~~

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(6) Temporary licensure for Licensed Professional Counselor with Mental Health Service Provider designation (LPC/MHSP).

(a) An applicant for licensure as an LPC/MHSP may file an application for temporary licensure by submitting the non-refundable application fee required by Rule 0450-01-.06, and an application for licensure with all required documentation, pursuant to procedures outlined in paragraph (4) of this rule, except as follows:

1. The applicant need not show proof of the post-master's supervisory hours required by 0450-01-.05(4)(k).

2. The applicant need not show proof of having passed the National Clinical Mental Health Counseling Examination or the Tennessee Jurisprudence Examination.

3. The applicant must submit information about the proposed supervisor or supervisors, including proof that the supervisor meets the qualifications of 0450-01-.10(1) and a copy of the proposed supervisory agreement or employment contract.

(b) No person may be issued more than one (1) temporary license, nor shall a temporary license be valid for more than three (3) years.

(c) If an applicant is granted a temporary license, the license shall remain valid until the Board grants or denies the regular license application or until it shall become invalid for any of the following reasons:

1. Expiration of the three (3) year period.

2. Failure to continue in supervision during the three year period the license may be valid.

3. Change of supervisors without notifying the Board, submitting the credentials of the proposed supervisor, and obtaining the Board's approval.

(d) When a temporary license holder is notified by the Board that his temporary license is invalid for any reason, the applicant shall return the temporary license to the Board office within ten (10) days. The applicant is expected to cause his supervisor to notify the Board of any reason he is aware of that the license should become invalid. The Board will notify the supervisor when the temporary license becomes invalid.

(Rule 0450-01-.05, continued)

(e) To replace the temporary license with a regular license for LPC/MSHP, the applicant shall:

1. Notify the Board in writing of intention to seek licensure, using the form provided by the Board.

2. Present proof of the following:

i. Completion of the required Post Master's supervised experience in a clinical setting which meets the requirement of 0450-01-.10; and

ii. Passage of the National Clinical Mental Health Counseling Examination and the Tennessee Jurisprudence Examination.

3. Upon receipt of the materials specified in Parts 1 and 2 the Board shall consider the previously submitted licensure application appropriately supplemented and grant or deny the regular license application, based on satisfactory completion of all requirements for licensure.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-22-102, 63-22-104, 63-22-107, 63-22-110, 63-22-116, 63-22-117, 63-22-120, 63-22-121, and 63-22-150.* ***Administrative History:*** *Original rule filed October 9, 1986; effective November 23, 1986. Repeal and new rule filed April 29, 1992; effective June 13, 1992. Amendment filed April 16, 1996; effective June 30, 1996. Amendment filed June 18, 1996; effective September 4, 1996. Amendment filed January 29, 1998; effective April 14, 1998. Amendment filed August 16, 2002; effective October 30, 2002. Amendment filed October 30, 2002; effective January 13, 2003. Amendment filed July 16, 2003; effective September 29, 2003. Amendment filed September 4, 2003 was effective November 18, 2003. However, stay of effective date filed by the Board for Professional Counselors, Marital and Family Therapists, and Clinical Pastoral Therapists on November 7, 2003; new effective date January 17, 2004. Amendment filed March 17, 2006; effective May 31, 2006. Amendment filed November 26, 2008; effective February 9, 2009.*

0450-01-.06 FEES.

(1) The fees authorized by statutes are established as follows:

(a) Application fee - A nonrefundable fee to be paid by all applicants including those seeking licensure by reciprocity. It must be paid each time an application for licensure is filed.

(b) Duplicate Certificate or License Fee - A nonrefundable fee to be paid when an individual requests a replacement for a lost or destroyed "artistically designed" license.

(c) Endorsement/Verification Fee - A nonrefundable fee paid for each certification, verification, endorsement of an individual's record for any purpose.

(d) Late Renewal Fee - A nonrefundable fee to be paid when an individual fails to timely renew his certificate or license.

(e) License Fee - A nonrefundable fee to be paid prior to the issuance of the "artistically designed" license.

(f) Renewal fee - A nonrefundable fee to be paid by all license and certificate holders. This fee also applies to individuals who reactivate a retired or lapsed certificate or license.

(Rule 0450-01-.11, continued)
Authority: *T.C.A. §§ 4-5-202 and 63-22-108.* ***Administrative History:*** *Original rule filed April 29, 1992; effective June 13, 1992.*

0450-01-.12 CONTINUING EDUCATION.

(1) Basic Requirements.

(a) Each person registered with the Board is required to complete twenty (20) clock hours of continuing education every two (2) calendar years.

(b) Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists shall complete thirty (30) clock hours of continuing education every two (2) calendar years. A person who holds three certificates and/or licenses shall complete forty (40) clock hours of continuing education every two (2) calendar years. In each case, at least ten (10) clock hours shall be directly related to the practice of each profession for which the person is licensed or certified.

(c) Ethics and Jurisprudence Course Requirement:

1. Three (3) clock hours of the twenty (20) clock hour biennial requirement shall, pertain to the following subjects:

(i) Professional ethics; and/or

(ii) Tennessee Code Annotated, Title 63, Chapter 22; and/or

(iii) Official Compilation, Rules and Regulations of the State of Tennessee, Chapter 0450-01.

2. Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists shall have three (3) clock hours of the thirty (30) clock hour biennial requirement pertain to ethics and jurisprudence.

3. Those persons who hold three (3) certificates and/or licenses shall have three (3) clock hours of the forty (40) clock hour biennial requirement pertain to ethics and jurisprudence.

~~(a) Each person registered with the board is required to complete 10 clock hours of continuing education during each calendar year.~~

~~(b) Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists shall complete fifteen (15) clock hours of continuing education each calendar year. A person who holds three (3) certificates and/or licenses shall complete twenty (20) clock hours of continuing education each calendar year. In each case, at least five (5) clock hours shall be directly related to the practice of each profession for which the person is licensed or certified.~~

~~(c) Ethics and Jurisprudence Course Requirement~~

~~1. Three (3) clock hours of the ten (10) clock hour annual requirement shall, every two (2) years, pertain to the following subjects:~~

~~(i) Professional ethics; and/or~~

(Rule 0450-01-.12, continued)

~~(ii) Tennessee Code Annotated, Title 63, Chapter 22; and/or~~

~~(iii) Official Compilation, Rules and Regulations of the State of Tennessee, Chapter 0450-1.~~

~~2. Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists shall have three (3) clock hours of the fifteen (15) clock hour annual requirement pertain to ethics and jurisprudence every two (2) years.~~

~~3. A person who holds three (3) certificates and/or licenses shall have three (3) clock hours of the twenty (20) clock hour annual requirement pertain to ethics and jurisprudence every two (2) years.~~

(d) Those persons supervising applicants for licensure under the provisions of 0450-01-.10 shall have three (3) clock hours of the twenty (20) clock hour biennial requirement pertain to counseling supervision or related supervision topics.

(e) A person is not required to complete continuing education for a profession in the calendar year that his or her license was initially approved.

~~(d) A person is not required to complete continuing for a profession in the calendar year that his/her license and/or certificate was initially approved.~~

(2) Acceptable Continuing Education - Acceptable continuing education shall consist of master or doctoral level course work from a nationally or regionally accredited institution of higher education; attendance at educational events sponsored or approved by national, state, regional, or local professional associations in the field; or events related to the practice of the profession for which a nationally or regionally accredited institution of higher education grants CEUs.

(3) Multi-Media - Notwithstanding the provisions of paragraph (2) and part (5) (b) 3., continuing education courses may be presented in the traditional lecture and classroom formats or, with successful completion of a written post experience examination to evaluate material retention, in Multi-Media formats.

(a) Multi-Media courses may include courses utilizing:

1. The Internet
2. Closed circuit television
3. Satellite broadcasts
4. Correspondence courses
5. Videotapes
6. CD-ROM
7. DVD
8. Teleconferencing

(Rule 0450-01-.12, continued)

9. Videoconferencing

10. Distance learning

(b) A maximum of ten (10) clock hours may be received for multi-media courses during the two (2) calendar year period. Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Martial and Family Therapists and Pastoral Therapists may receive a maximum of fifteen (15) clock hours for multi-media courses during the two (2) calendar year period. Those persons who hold three (3) certificates and/or licenses may receive a maximum of twenty (20) clock hours for multi-media courses during the two (2) calendar year period.

~~(b) A maximum of five (5) clock hours may be received for multi-media courses during each calendar year. Those persons who hold two (2) certificates and/or licenses regulated by the Tennessee Board for Professional Counselors, Marital and Family Therapists and Clinical Pastoral Therapists may receive a maximum of seven and one-half (7½) clock hours for multi-media courses during each calendar year. Those persons who hold three (3) certificates and/or licenses may receive a maximum of ten (10) clock hours for multi-media courses during each calendar year.~~

(4) Documentation

(a) Each person registered with the board must retain proof of attendance and completion of all continuing education requirements. This documentation must be retained for a period of four years from the end of the calendar year in which the continuing education was acquired. This documentation must be produced for inspection and verification, if requested in writing by the board during its verification process. The board will not maintain continuing education files.

(b) The board will conduct a randomly selected audit of individual records to assure that the continuing education requirements have been met. An individual's records may be audited during consecutive renewal periods.

(c) If audited, the individual must, within 15 working days of a request from the board, provide evidence of continuing education activities. Such evidence must be by submission of one or more of the following:

1. Certificates verifying the individual's attendance at the continuing education programs described above.

2. An individual submitting a program as evidence of attendance at a continuing education event will also be required to submit two or more of the following for each program submitted: registration receipt, signed program, cancelled check, hotel bill, name badge, or an original letter on official stationary signed by a professional associate who attended.

3. An original letter on official institution stationery from the instructor of the graduate level course verifying that the course was completed and listing the number of credit hours of attendance completed by the individual.

4. Official transcript verifying credit hours earned. One semester credit hour is equivalent to 10 clock hours for the purpose of certification renewal. Credit for auditing will be for the actual clock hours in attendance, not to exceed the academic credit.

(Rule 0450-01-.12, continued)

(5) Continuing Education Course Approval - Courses to be offered for credit toward the continuing education requirement must, unless otherwise provided, receive prior approval from the Board. Unless otherwise provided, all courses shall be offered within Tennessee.

(a) Course approval procedures

1. Pre-approved course providers - Continuing education courses which pertain to the practice of counseling shall be considered approved if provided or sanctioned by the following entities:

(i) American Association for Marriage and Family Therapy;

(ii) American Association of Pastoral Counselors;

(iii) American Association of Sex Educators, Counselors, and Therapists;

(iv) American Counseling Association;

(v) American Psychiatric Association;

(vi) American Psychological Association;

(vii) National Association of Social Workers;

(viii) Any state professional association affiliated with the national associations listed in subparts (i) through (vii);

(ix) National Board for Certified Counselors;

(x) Nationally or regionally accredited institutions of higher education, including graduate courses and continuing education courses; and

(xi) Any state regulatory agency for professional counseling in the United States.

2. Course approval procedure for other course providers

(i) Unless pre-approved as provided in part (5) (a) 1, the course provider must have delivered to the Board's Administrative Office at least thirty (30) days prior to a regularly scheduled meeting of the Board that precedes the course, documentation which includes all of the following items which must be resubmitted if substantive changes are made after receipt of approval from the Board:

(I) course description or outline;

(II) names of all lecturers;

(III) brief resume of all lecturers;

(IV) number of hours of educational credit requested;

(V) date of course;

(VI) copies of materials to be utilized in the course; and

(Rule 0450-01-.12, continued)

(VII) how verification of attendance is to be documented.

(ii) Notwithstanding the provisions of the introductory language of this paragraph, any clinic, workshop, seminar or lecture at national, regional, state and local meetings of counselors will be recognized for continuing education credit by the Board if

(I) the course provider has complied with the provisions of subpart (5) (a) 2 (i); or

(II) the course provider is exempt from needing prior approval as provided in part (5) (a) 1.

(iii) Notwithstanding the provisions of subparagraph (3) (a), out-of-state continuing education providers may seek course approval if they are a professional counseling regulatory agency or association from a state that borders Tennessee; and

(I) the course provider has complied with the provisions of subpart (5) (a) 2 (i); or

(II) the course provider is exempt from needing prior approval as provided in part (5) (a) 1.

3. Course approval procedure for individual licensees and certificate holders

(i) Any licensee or certificate holder may seek approval to receive credit for successfully completing continuing education courses by delivering to the Board's Administrative Office at least thirty (30) days prior to a regularly scheduled meeting of the Board that precedes the course, everything required in items (5) (a) 2 (i) (I) through (VII) which must be resubmitted if substantive changes are made after receipt of approval from the Board; and

(ii) To retain course approval, the licensee or certificate holder must submit a course evaluation form, supplied by the Board, to the Board's Administrative Office within thirty (30) days after successfully completing the course.

(b) Continuing education credit will not be allowed for the following:

1. Regular work activities, administrative staff meetings, case staffing/reporting, etc.

2. Membership in, holding office in, or participation on boards or committees, business meetings of professional organizations, or banquet speeches.

3. Independent unstructured or self-structured learning.

4. Training specifically related to policies and procedures of an agency may not be counted.

5. Non-counseling content courses - examples: finance or business management.

(6) Continuing Education for Reactivation of Certificate or License

(a) Reactivation of retired certificate or license

(Rule 0450-01-.12, continued)

1. An individual whose certificate or licensure has been retired for one year or less will be required to fulfill continuing education requirements as outlined in this rule as a prerequisite to reinstatement. Those hours will be considered replacement hours and can not be counted during the next certification or licensure renewal period.

2. Any individual requesting reactivation of a certificate or license which has been retired must submit, along with the reactivation request, verification which indicates the attendance and completion of 10 hours of continuing education which must have been begun and successfully completed within 12 months immediately preceding the date of requested reinstatement. The continuing education hours completed to reinstate a retired certificate or license shall not be credited toward the continuing education hours required to be completed by the end of the calendar year following reinstatement.

3. The board, upon receipt of a written request and explanation, may waive or condition any or all of the continuing education for reactivation of a retired certificate or license in emergency situations.

(b) Reactivation of revoked licensure or certification - No person whose license or certificate has been revoked for failure to comply with continuing education may be reinstated without complying with these requirements. Continuing education will accumulate at the same rate as that for those licenses and certificate holders which are active. The required clock hours of continuing education must have been begun and successfully completed within twelve (12) months immediately preceding the date of reinstatement. A license or certificate which has been revoked for noncompliance with the continuing education requirement shall also be subject to the late renewal fee pursuant to rule 0450-01-.06.

(c) Reactivation of expired licensure - No person whose license or certificate has expired may be reinstated without submitting evidence of continuing education. The continuing education hours documented at the time of reinstatement must equal the hours required, had the license or certificate remained in an active status, and must have been successfully completed within twelve (12) months immediately preceding the date of reinstatement.

(d) Continuing education hours obtained as a prerequisite for reactivating a license or certificate may not be counted toward the calendar year requirement.

(7) Waiver or Extension of Continuing Education Requirements.

(a) The Board may grant a waiver of the need to attend and complete the required clock hours of continuing education or the Board may grant an extension of the deadline to complete the required clock hours of continuing education if it can be shown that compliance is beyond the physical or mental capabilities of the person seeking the waiver.

(b) Waivers or extension of the deadline will be considered only on an individual basis and may be requested by submitting the following items to the Board's Administrative Office prior to the expiration of the calendar year (December 31) in which the continuing education is due:

1. A written request for a waiver or deadline extension which specifies which requirements are sought to be waived or which deadline is sought to be

(Rule 0450-01-.12, continued)

extended, and a written and signed explanation of the reason for the request; and

2. Any documentation which supports the reason(s) for the waiver or deadline extension requested or which is subsequently requested by the Board.

(c) A waiver or deadline extension approved by the Board is effective only for the calendar year for which either is sought.

(8) Violations

(a) Any licensee or certificate holder who falsely certifies attendance and completion of the required hours of continuing education requirements, or who does not or can not adequately substantiate completed continuing education hours with the required documentation, may be subject to disciplinary action.

(b) Prior to the institution of any disciplinary proceedings, a letter shall be issued to the last known address of the individual stating the facts or conduct which warrant the intended action.

(c) The licensee or certificate holder has thirty (30) days from the date of notification to show compliance with all lawful requirements for the retention of the license or certificate.

(d) Any licensee or certificate holder who fails to show compliance with the required continuing education hours in response to the notice contemplated by subparagraph (b) above may be subject to disciplinary action.

(e) Continuing education hours obtained as a result of compliance with the terms of a Board Order in any disciplinary action shall not be credited toward the continuing education hours required to be obtained in any renewal period.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-22-102, and 63-22-108.* ***Administrative History:*** *Original rule filed April 29, 1992; effective June 13, 1992. Amendment filed June 18, 1996; effective September 4, 1996. Amendment filed July 31, 2000; effective October 14, 2000. Amendment filed April 30, 2002; effective July 14, 2002. Amendment filed July 16, 2003; effective September 29, 2003. Amendment filed July 30, 2003; effective October 13, 2003. Amendment filed July 21, 2004; effective October 4, 2004. Amendment filed October 18, 2004; effective January 1, 2005. Amendment filed March 23, 2007; effective June 6, 2007. Amendment filed November 26, 2008; effective February 9, 2009.*

0450-01-.13 PROFESSIONAL ETHICS. All licensees and certificate holders shall comply with the current code of ethics adopted by the American Counseling Association, except to the extent that it conflicts with the laws of the state of Tennessee or the rules of the Board. If the code of ethics conflicts with state law or rules, the state law or rules govern the matter. Violation of the code of ethics or state law or rules may subject a licensee or certificate holder to disciplinary action.

(1) The certified professional counselor and licensed professional counselor and anyone under his supervision shall conduct their professional practice in conformity with the legal, ethical and professional standards promulgated by the Board under its current statutes and rules and regulations.

(2) Each applicant and certificate holder or licensee is responsible for being familiar with and following this code of ethics.

(3) A copy of the code of ethics may be obtained by writing the American Counseling Association, 5999 Stevenson Avenue, Alexandria, VA 22304.

* 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)
Steven Caldwell	X				
James Philpott	X				
Susan Hammonds-White	X				
Bradley Bull	X				
Janet Scott				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Licensed Professional Counselors, Licensed Marital and Family Therapists, and Clinical Pastoral Therapists on 06/21/2013, 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: 04/16/2013

Rulemaking Hearing(s) Conducted on: (add more dates). 06/21/2013

Date: 7/10/13

Signature: Johanna L Barde

Name of Officer: Johanna L. Barde

Title of Officer: Assistant General Counsel, Department of Health

Subscribed and sworn to before me on: 7-10-13

Notary Public Signature: Suzanne Mechkowski

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

SUZANNE MECHKOWSKI STATE OF TENNESSEE NOTARY PUBLIC SUMNER COUNTY

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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

1-2-14
Date

Department of State Use Only

Filed with the Department of State on: 1/7/14

Effective on: 4/7/14

Tre Hargett
Secretary of State

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G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Environment and Conservation
DIVISION:	Air Pollution Control
SUBJECT:	Title V Major Source Fees
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 68-201-101 et seq.
EFFECTIVE DATES:	April 8, 2014 through June 30, 2015
FISCAL IMPACT:	The agency has provided the following fiscal impact information: It is estimated that this revision will result in increased state revenues of approximately $846,500. The increase is necessary because employee salaries were increased as a result of the Mercer salary study and because of changes the Division is making to improve permitting efficiency. The Division has a backlog of Title V permits and permit amendments that must be reduced to meet its commitment to the Environmental Protection Agency (EPA). Expenditures are predicted to increase by approximately $934,000 for the 2013-2014 fiscal year.
STAFF RULE ABSTRACT:	Section 502(b)(3)(A) of the Federal Clean Air Act requires Tennessee, as an EPA approved program, to collect "an annual fee, or the equivalent over some other period, sufficient to cover all reasonable (direct and indirect) costs required to develop and administer the permit program requirements of this title". Failure to meet this requirement would cause the state to be in violation of federal law and force the EPA to collect the fee from these sources using their presumptive fee rate, a significantly higher rate than is proposed; in addition to causing other consequences. To collect this required annual fee, the Department proposes to amend its rules to collect an annual fee of $7,500 from all major sources, and, for major sources with allowable emission rates that exceed 250 tons per year, an addition per ton fee based upon either actual emissions or permitted allowable emissions.

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.

Comment: As long as the Division fulfills the commitments it made to work with the TCCI over the next year by providing additional detail regarding the breakdown of roles and services provided by each full-time employee and provides additional background data for the next year's fees, TCCI has no objection to the current proposed fee schedule.

Response: The Division will fulfill these commitments.

Comment: TCCI is supportive of finding an appropriate alternative methodology for calculating and assessing administrative fee for Title V sources that funds the program without penalizing industries for reducing the total tonnage of their emissions.

Response: The Department is willing to discuss this issue with representatives of the Chamber.

Comment: TCCI does not object to the proposed plan of application and the Title V fee increases included in the public hearing on Rule 1200-03-26-.02 and the Division's Workload Analysis as long as such increases are justified.

Response: No response necessary.

Comment: TCCI reserves the right, pursuant to Tenn. Code Annotated § 4-5-204(c), to present oral comments to the Board prior to its consideration and adoption of new fee rules and the workload analysis for 2013-2014.

Response: No response necessary.

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.

This rulemaking amendment to subparagraph (d) of paragraph (9) of rule 1200-03-26-.02 Construction and Annual Emission Fees is federally mandated and, hence, exempt from the provisions of the Regulatory Flexibility Act of 2007, Acts 2007, § 6 of Public Chapter 464. The rule subject to this amendment is part of the requirements of § 502(b)(3)(A) of the Federal Clean Air Act which is the source of the requirement for Tennessee to collect "an annual fee, or the equivalent over some other period, sufficient to cover all reasonable (direct and indirect) costs required to develop and administer the permit program requirements of this title".

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)

The Department anticipates that this amended rule will not have a financial impact on local governments.

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For Department of State Use Only

Sequence Number: 01-04-14
Rule ID(s): 5656
File Date: 1/8/14
Effective Date: 4/8/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Environment and Conservation
Division:	Air Pollution Control
Contact Person:	Lacey J. Hardin
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor Nashville, Tennessee
Zip:	37243
Phone:	(615) 532-0545
Email:	Lacey.Hardin@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 to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-03-26	Administrative Fees Schedule
Rule Number	**Rule Title**
1200-03-26-.02	Construction and Annual Emission Fees

(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)

Amendments

Chapter 1200-03-26
Administrative Fees Schedule

Paragraph (9) of Rule 1200-03-26-.02 Construction and Annual Emission Fees is amended by deleting subparagraph (d) in its entirety and substituting instead the following:

(d) 1. Every source subject to this paragraph shall pay an annual fee of $7,500.

2. In addition to the annual fee of part 1 of this subparagraph, all sources with allowable emission rates greater than 250 ton per year (excluding carbon monoxide) shall pay the following:

(i) The rate at which major source actual-based annual emission fees are assessed for non-EGU sources shall be ~~$40.00~~ $39.00 per ton and the rate at which major source allowable-based annual emission fees are assessed for non-EGU sources shall be ~~$29.50~~ $28.50 per ton. ~~Notwithstanding any calculation of an annual fee using these rates, the annual fee that each major source is to pay shall not be less than $7,500~~

(ii) The rate at which major source actual-based annual emission fees are assessed for EGU sources shall be $56.00 per ton and the rate at which major source allowable-based annual emission fees are assessed for EGU sources shall be $45.50 per ton.

3. ~~These~~ The annual emission fee rates required by part 2 of this subparagraph remain in effect until the effective date of an amendment to this subparagraph. Any revision to these rates must result in the collection of sufficient fees to fund the activities identified in subparagraph (1)(c) of this rule. These fee rates shall be supported by the Division's annual workload analysis that is approved by the Board.

4. For purposes of this subparagraph, an electric utility generating unit (EGU) means any steam electric generating unit or stationary combustion turbine that is constructed for the purpose of supplying more than one-third of its potential electric output capacity and more than 25 MW net-electrical output to any utility power distribution system for sale. Also, any steam supplied to a steam distribution system for the purpose of providing steam to a steam electric generator that would produce electrical energy for sale is considered in determining the electrical energy output capacity of the affected EGU.

Authority: T.C.A. §§ 68-201-101 et seq., and 4-5-201 et seq.

* 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)
J. Ronald Bailey				X	
Thomas Beehan				X	
John Benitez	X				
Elaine Boyd	X				
Karen Cisler	X				
Wayne T. Davis	X				
Stephen Gossett	X				
Shawn A. Hawkins				X	
Helen Hennon				X	
Richard Holland	X				
John Roberts	X				
Larry Waters	X				
Jimmy West	X				
Alicia Wilson	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Air Pollution Control Board on 12/11/2013, 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: 10/09/13

Rulemaking Hearing(s) Conducted on: (add more dates). 12/03/13

Date: December 11, 2013

Signature: Barry R. Stephens

Name of Officer: Barry R. Stephens

Title of Officer: Technical Secretary

MALCOLM H. BUTLER STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY, TENN.

Subscribed and sworn to before me on: December 12, 2013

Notary Public Signature: Malcolm H. Butler

My commission expires on: 1-11-2017

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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

1-7-14
Date

Department of State Use Only

Filed with the Department of State on: 1/8/14

Effective on: 4/8/14

Tre Hargett
Secretary of State

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G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Environment and Conservation
DIVISION:	Water Resources
SUBJECT:	Elimination of soil mapping services and associated fees, modification of fee structure for subdivision evaluation and plat approval.
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 68-221-401
EFFECTIVE DATES:	April 8, 2014 through June 30, 2015
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	The department proposes to eliminate soil mapping services that compete with the private sector and remove the fee category from the rule. In the 1960s and 1970s, the vast majority of subdivision approvals and permits were based on percolation tests. Beginning in the late 1970s, soil mapping became the preferred method for evaluating the suitability of soils to effectively treat domestic wastewater. Early in this transition, state-employed soil consultants provided the majority of the soil-mapping services associated with the program. As the program evolved, private soil scientists entered the market. Current rules require private soil scientists providing services in support of the program be approved by the state. Presently, the vast majority of soil mapping is performed by private soil consultants. This proposal removes soil mapping as a service provided by the state and places all soil mapping services in the private sector. The department proposes to modify the fee structure for subdivision evaluation and plat approval to a sliding scale that more accurately distributes review costs. Field work is critical to effective soil evaluation. Historically, the fee for subdivision evaluation and plat approval has been $65 per lot. However, for plat consideration with a limited number of lots, the fee does not cover review costs. The department proposes a fee of $150 per lot for one or two lots on a proposed plat; and, $100 per lot for three to ten

lots on a proposed plat. Plats containing more than ten lots will be assessed $1,000 ($100 per lot) for the first ten lots plus $65 for each additional lot.

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.

Comment: Several commenters requested the ratio of state appropriations to fees for the subsurface sewage disposal program to insure that the statutory limit set by T.C.A. § 68-203-104(d)(3) is in compliance.

Response: The proposed amendments would result in fee collections of approximately 60% of the total revenue for the subsurface sewage disposal program, which is well below the statutory limit of 71%.

Comment: A commenter requested an explanation of the Division's proposal to increase fees in light of the state revenue numbers as this action appears inconsistent with the express language of T.C.A. 68-203-104(a)(3).

Response: The proposed fee amendments are not inconsistent with the language of T.C.A. § 68-203-104(a)(3), The state appropriation to the heritage subsurface sewage disposal program for current fiscal year was increased.

Comment: A commenter requested the amount of state appropriation allotted to this division for FY 2013-14, the amount allotted in 2012-13, and the amount of anticipated appropriation for FY 2014-15.

Response: In FY 2012-13, the legacy Division of Water Pollution Control (WPC) was appropriated $9,424,700; the legacy Division of Water Supply DWS) was appropriated $1,002,200; and the legacy Groundwater Protection Division (GWP) was appropriated $2,155,400. When combined into the Division Water Resources the total appropriated for this period was $12,582,300 (WPC 74.9%, DWS 8%, GWP 17.1%). For FY 2013-14, the Division of Water Resources was appropriated $13,435,100; an increase of $852,800 from the previous fiscal year. The percentage of allocations to the legacy programs within the Division of Water Resources would have increase by proportionally to each program. Since the Administration is in the process of developing the recommended budget for FY 2014-15, which the Governor will submit to the General Assembly in late January 2014, we are not able to determine the amount that will be appropriated. However, we do not anticipate that the appropriation will be decreased.

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.

(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.

Those small business and consulting firms that provide soil mapping services will benefit from the proposed rule change. This rule change will result in the Department no longer providing soil mapping services and in doing so will direct this work to the private sector. There are an estimated 30 – 50 such businesses within Tennessee. The proposed rule change will also raise subdivision evaluation fees for subdivisions in areas not served by public sewer – particularly those with only a few lots. The majority of subdivisions with only a few lots are proposed by existing land owners that elect to further divide their property. This change will affect small businesses that are involved with residential developments. For example, per the proposed rule: if a developer buys a five-acre tract of land in an area that is not served by sewer and proposes to create a five-lot subdivision the cost for this service would increase from $325 to $500 ($35 per lot); if a developer buys a three-acre tract in an area that is not served by sewer and proposed to create a two-lot subdivision the cost for this service would increase from $130 to $300 ($85 per lot); if a developer buys a 50-acre tract in an area that is not served by sewer and proposes to create 30 lots the fee for this service would increase from $1,950 to $2,300 (~$12 per lot).

(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.

No additional reporting, recordkeeping or administrative costs are anticipated by this rule change.

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

Small businesses providing soil mapping services will benefit from the additional workload. Buyers of lots in new subdivisions will likely bear the cost of the increased fee. However, at most the increase will be $85 per lot.

(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.

The proposed rule change is expected to benefit small businesses in that the Department will no longer be providing a service. This service can be provided by private soil scientists. The increase of fees associated with the evaluation of subdivision lots is weighted toward those subdivisions with minimal number of lots. The fee increase is proposed to more appropriately fund the support (staff, transportation, office review) for smaller subdivisions. The existing fee, while appropriate for larger subdivisions, did not appropriately fund the Department's service for those subdivisions with only a few lots. The Department is not aware of any alternative means of providing this regulatory mandated service.

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

This proposed rule does not increase permitting requirements nor does the rule attempt to increase the population of permitted activities. This proposed rule is specific to fees for services. The proposed fee changes are an outgrowth of an assessment of the services that the Department provides and the fees that are assessed for those services. Funding ratios (fees/state appropriations) vary from program to program within the state. Furthermore, other states have varied means of funding practices which makes direct comparison of fees impractical.

(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 change will benefit small businesses providing soil mapping services. Exempting small businesses from the increased fee associated with subdivision evaluations would benefit small businesses that buy property for the purpose of subdividing and resale; however, the benefit would be minimal. The additional expense would be factored in to the process of buying, developing, and selling subdivision lots and ultimately borne by the consumer.

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)

The Department anticipates that these amendments will not have a financial impact on local governments.

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Sequence Number: 01-05-14
Rule ID(s): 5657
File Date: 1/8/14
Effective Date: 4/8/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Environment and Conservation
Division:	Water Resources
Contact Person:	Britton Dotson
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 11th Floor Nashville, Tennessee
Zip:	37243
Phone:	(615) 532-0774
Email:	Britton.Dotson@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 to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0400-48-01	Regulations to Govern Subsurface Sewage Disposal Systems
Rule Number	**Rule Title**
0400-48-01-.21	Fees for 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)

Amendments

Chapter 0400-48-01
Regulations to Govern Subsurface Sewage Disposal Systems

Rule 0400-48-01-.21 Fees for Services is amended by deleting it in its entirety and replacing it with the following so that, as amended, the rule shall read:

0400-48-01-.21 Fees for Services.

(1) Fees for services are assessed pursuant to the following:

	Specific Procedure Covered by Fee	Fee
~~(a)~~	~~General intensity soil mapping to determine eligibility for percolation tests.~~	~~Eighty dollars ($80) per acre, with eighty dollars ($80) being the minimum for each separate acre or part of acre to be mapped.~~
~~(b)~~	~~High intensity soil mapping (sufficient for final approval, 1" = 100' scale) of single lots, or tracts where lots have been staked, or where tracks are gridded (100' grid staking) for residential, commercial, industrial, institutional or recreational users.~~	~~Two hundred dollars ($200) per acre, with two hundred dollars ($200) being the minimum for each separate acre or part of acre to be mapped.~~
~~(c)~~	~~Extra-high intensity soil mapping for alternative disposal system.~~	~~Two hundred fifty ($250) dollars per acre, with two hundred fifty ($250) dollars being the minimum for each separate acre or part of acre to be mapped.~~
~~(d)~~(a)	Conventional, chamber, EPS and large diameter gravelless pipe subsurface sewage disposal systems permit application processing, making inspections and other regulatory activities relative to the construction of new conventional, chamber and large diameter gravelless pipe subsurface sewage disposal systems and modification or expansion of existing systems because of additions resulting in added wastewater flow, but not for repair of malfunctioning systems. Permits shall be granted or denied within forty-five (45) days of receipt of all necessary information.	Four hundred dollars ($400) up to one thousand (1,000) gpd design flow plus one hundred dollars ($100) for each additional one thousand (1,000) gpd flow, or portion thereof.
~~(e)~~(b)	Alternative subsurface sewage disposal systems permit application up to one thousand (1,000) gpd. design flow processing (excluding chamber, EPS and large diameter gravelless pipe systems), making inspections and other enforcement activities relative to the construction of alternative subsurface sewage disposal systems and modification or expansion of existing systems because of additions resulting in added wastewater flow, but not for repair of malfunctioning systems. Permits	Five hundred dollars ($500) plus one hundred fifty dollars ($150) for each additional one thousand (1,000) gpd flow, or portion thereof.

	shall be granted or denied within forty-five (45) days of receipt of all necessary information.	
~~(f)~~(c)	Experimental subsurface sewage disposal systems permit application processing, making inspections and other enforcement activities relative to the construction of experimental subsurface sewage disposal systems and expansion of systems because of additions resulting in added wastewater flow, but not for repair of malfunctioning systems. Permits shall be granted or denied within forty-five (45) days of receipt of all necessary information.	Five hundred dollars ($500).
~~(g)~~(d)	Subdivision ~~E~~evaluation and plat approval for individual lots - Evaluations of lots within proposed subdivisions to determine and to specify limitations on their usability for subsurface sewage disposal systems.	~~Sixty five dollars ($65) per evaluated lot.~~
	Two lots or less	One hundred fifty dollars ($150) per lot
	Three lots to ten lots	One hundred dollars ($100) per lot
	Greater than ten lots	One thousand dollars ($1,000) for the first ten lots plus sixty five dollars ($65) for each additional lot
~~(h)~~(e)	Inspections of existing subsurface sewage disposal systems.	Two hundred dollars ($200) per inspection.
~~(i)~~(f)	Installer and Pumper Permits - Enforcement activities relative to sewage system installers and septic tank pumpers. Permits shall be granted or denied within forty-five (45) days of the date of application.	Two hundred dollars ($200) per annual permit for pumpers and installers. The $200 annual installer permit applies to installation of conventional, chamber, EPS and large diameter gravelless pipe systems. If an installer wishes to be permitted for installation of alternative systems, an additional one hundred dollars ($100) applies for each type of alternative system.
~~(j)~~(g)	Sewage Surveys - Activities involved in the inspections and surveying of subsurface sewage disposal systems.	Actual costs.
~~(k)~~(h)	Water Samples - Collection of water samples for bacteriological laboratory analysis, but does not include samples collected in enforcement activities.	
	1. Mail Deliver	One hundred fifteen dollars ($115) per sample.
	2. Direct Deliver	Two hundred fifteen dollars ($215) per sample.
~~(l)~~(i)	Plans Review - Review of designs for large conventional or large alternative subsurface	Seven hundred fifty dollars ($750) per proposed system.

	sewage disposal systems to the point of permit issuance.	
~~(m)~~	~~Plat approval for individual lots.~~	~~Sixty five dollars ($65) per evaluated lot.~~
~~(n)~~(j)	Domestic Septage Disposal Site Permit - Permit application processing, making inspections and other regulatory activity relative to domestic septage disposal sites Permits shall be granted or denied within forty-five (45) days of receipt of all necessary information.	Four hundred dollars ($400).
~~(o)~~(k)	Training - Non-state agencies and individuals.	Calculated costs.
~~(p)~~(l)	Certificate of Verification by homeowners of existing system.	One hundred dollars ($100).

Authority: T.C.A. §§ 68-221-401 et seq., 68-203-101 et seq. and 4-5-201 et seq.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of the Department of Environment and Conservation on 12/18/2013, 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: 10/18/13

Rulemaking Hearing(s) Conducted on: (add more dates). 12/10/13

BETH B. SMITH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY, TENN.
My Commission Expires JULY 6, 2015

Date: December 18, 2013

Signature: [signature]

Name of Officer: Robert J. Martineau, Jr.

Title of Officer: Commissioner

Subscribed and sworn to before me on: December 18, 2013

Notary Public Signature: [signature]

My commission expires on: July 6, 2015

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.

[signature]
Robert E. Cooper, Jr.
Attorney General and Reporter

1-7-14
Date

Department of State Use Only

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Filed with the Department of State on: 1/8/14

Effective on: 4/8/14

[signature]
Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Environment and Conservation
DIVISION:	Water Resources
SUBJECT:	Environmental Protection Fund Fees
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 69-3-101 et seq.
EFFECTIVE DATES:	April 4, 2014 through June 30, 2015
FISCAL IMPACT:	This amendment is estimated to increase revenue by approximately $2.28 million annually. This estimate is based on the actual workload from the previous year.
STAFF RULE ABSTRACT:	The Heritage Water Pollution Control Program has been operating at a deficit for several years and after taking significant steps to reduce operating expenses, the Division of Water Resources is proposing to restructure a set of specific fees in an effort to create a division structure that is sustainable, fair, and preserves the department's ability to act expeditiously in the permitting process. The rules are being amended to adjust some fees to be more commensurate with the level of time and effort required by the division to deliver those services, and create fees for services that have been provided at no cost to the applicants. Specifically these proposed rules: • Modify the fee structure supporting permit application fees associated with 401 certifications and Aquatic Resource Alteration Permits (ARAP), including notices of intent for coverage under a general permit, based on level of effort required to process these requests. • Increase application fees for construction stormwater permits, while also providing additional ability to ensure the fee is commensurate with the level of effort required to process permit requests. • Assesses a fee to cover the cost of soil scientist and engineering services required to approve decentralized wastewater systems, which are becoming an increasingly

important and effective alternative to the traditional wastewater management, particularly in areas that are not served by sewer lines and treatment plants.

• Create an annual maintenance fee structure for long-term construction stormwater general permit coverages, specifically those that exceed one year.

• Create an annual maintenance fee for individual ARAP permits that require monitoring of permitted activities or compensatory mitigation.

• Include a fee for the review of Force Mains, which is an important component of water system design.

• Create a fee for Engineering Report reviews.

• Increase that annual maintenance fee for gravel dredging permits from $140 to $300. This increase will support annual inspection of commercial gravel dredging sites and annual renewals.

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.

Comment: A commenter contends that several of the proposed permitting fee increases represent an increase of 500%.

Response: Services for which no fees are currently being assessed would now be assessed a fee of $500 if not exempted by the current general permit. This does not represent a 500% increase but does represent a $500 fee where there had been no fee. General permits provide a relatively stream-lined, expedient tool by which activities with common, low-impact scopes of work are authorized to be conducted. Historically, services associated with general permits have been provided by TDEC technical and administrative staff at no cost to the applicants. These services include: developing and maintaining the general permits; assessing Notices of Intent from applicants seeking coverage under the general permits for completion, applicability and appropriate scope; providing Notice of Coverage to the applicant or Notice of Denial based on staff assessment; site inspections as necessary; and, processing Notices of Termination. TDEC considers the general permit process to be a clear benefit to the regulated community and the process has proven to be successful. However, for TDEC to be able to continue to provide services necessary to support the general permit process, appropriate fees must be assessed. A $500 fee, assessed to the beneficiary of the service, is considered by TDEC to be appropriate in support of the services rendered. In turn the applicants benefit from the advantages that the general permit process provides.

When General Permits were first allowed, it was anticipated that 15 to 20% of all permit applications would be for General Permits and 80 to 85% of the permit applications would be for individual permits. With this expectation, the Division did not initially collect general permit fees, although authorized to do so. However, because of the expedited time applicants receive via the general permit process, now most permit applications (80 to 85%) are general permit notices of intent. Given this fact, the Division and Department cannot continue to provide this service for free. Our workload analysis demonstrates that the fee proposed is representative of the Department's cost to process general permits.

The General Permit assists both the permit applicants and the Department. Permit processing time is reduced by at least 66%. The general permit respects the time value of money and environmental protection. Its permit terms and conditions are consistent statewide and cost less to process than an individual permit.

Comment: A commenter maintains that TDEC's proposed fee increases will have a direct financial impact on county highway departments.

Response: TDEC agrees that the fee rule proposal will have a direct financial impact on the county highway departments. However, the proposed rule change associated with ARAP fees does not propose to change any portion of the permitting or coverage process. Those activities necessitating notification to TDEC will still require the same notification. The activities that are beyond the scope of exemptions identified in the specific general permit will require the submittal of the $500 fee with the notification. The increase in administrative costs associated with this proposal would be associated with generating and tracking the payment associated with the notification. The requirement for providing notification to TDEC is not proposed for change.

Reference was made by this commenter that three of the general ARAP permits commonly used by the highway departments were classified by the highway departments as "day to day" and "daily" operational permits. The highway departments are currently required to submit notification

and obtain authorization by TDEC for coverage under these permits prior to conducting the activity, unless the activity is exempt as described in the specific general permit. If the activities are exempt, no notification would be necessary and no fee would be assessed. The fee proposal will not change the process of obtaining coverage under a general permit or the need for authorization to begin the actual work.

To reduce cost and when appropriate, the regulations allow for the less costly but effective general permit as an alternative to the individual permit. The process to issue general permits requires the expenditure of division resources. To continue to make these resources readily available TDEC must amend its rules to recover these costs.

Comment: Some commenters believe that stream and wetland restoration projects (other than restoration conducted for the purpose of compensatory mitigation) should receive an exemption.

Response: TDEC agrees that stream and wetland restoration projects intend to advance the health of water bodies and can result in better water quality or aquatic habitat and as such are not akin to projects which degrade water quality. However, tracking the locations of these activities, providing oversight/consultation and insuring that the impact to the water resource through construction of the restoration project is minimized are activities for which TDEC will expend resources. As such, the $500 fee is applicable to stream and wetland restoration projects.

Comment: Some commenters maintain that mining plan review fees are too low. Commenters request TDEC impose a plan review fee of $25/acre not to exceed $5,000 for all coal mines, non-coal mines, and quarries, but retain the $250 fee for reclamation.

Response: TDEC agrees that the commenter's proposal has merit. However, this particular fee rule category is not proposed for change in the current filing. TDEC will consider this suggestion for future rulemakings.

Comment: Two commenters believe that one year is too short of a time frame for projects. The time frame needs to be at least 2 years from date of issuance or there should be a 1 year extension beyond the first year at no costs. The annual fees should not begin until at least the end of the 2nd year from issuance. Most projects will take at least 2 years to complete and the 1 year requirement is too short.

Response: The proposed annual maintenance fee is to support services that are commonly rendered in support of longer term projects. TDEC agrees that some projects that are not completed in their first year may be completed in their second year. However, a project being completed within two years does not minimize the need for TDEC's involvement, and need for supporting fees, throughout the timeframe for the project. Assessing an annual fee in support of regulatory oversight of active projects has been a long-standing practice for other Water Resources programs. The general permit fee proposed covers the cost of permit processing and on-site monitoring.

Comment: Two commenters believe that post project monitoring should not be assessed on the front end. A review by TDEC should occur at the end of the project and then once accepted as completed per plan the fee should be paid for the five year post project monitoring. This should be assessed at $100 per year for the number of years of monitoring and should not be assessed at the beginning of the project but upon approval by TDEC at completion of the project but prior to beginning the maintenance period.

Response: Mitigation plans and/or monitoring requirements for a particular project are known at the time of permit issuance. Thus at time of permit issuance TDEC knows that we will have continued involvement in support of the project at least through the term of the mitigation and/or monitoring plan – irrespective of whether we can deem the project "complete" at the end of the period. It is at the time of permit issuance that the applicant for the project is present and committing to the

term of the project. TDEC considers permit issuance to be the most practical point within the project to receive payment for the services that we are committing to provide for the term of the project.

Comment: Commenters requested that the Department define points of impact.

Response: TDEC interprets "Points of Impact" to mean discreet physical locations on one or more jurisdictional water features within an overall project (common plan of development), at which regulated alteration activities are proposed. A definition has been added to subparagraph (2)(a) of Rule 0400-40-11-.02 to clarify this issue.

Comment: A commenter believes that under item (v) municipalities should have the right to maintain and repair their structures without having to pay a fee to TDEC. This is required for the safety and welfare of the motoring public and is a hindrance to the safety of the general public. Please exempt city maintenance activities from this requirement.

Response: Item (2)(a)1(v) of Rule 0400-40-11-.02 proposes to assess a $500 fee for projects seeking coverage under a general permit. General permits provide a relatively stream-lined, expedient tool by which activities with common, low-impact scopes of work are authorized to be conducted. Historically, services associated with general permits have been provided by TDEC technical and administrative staff at no cost to the applicants. These services include: developing and maintaining the general permits; assessing Notices of Intent from applicants seeking coverage under the general permits for completion, applicability and appropriate scope; providing Notice of Coverage to the applicant or Notice of Denial based on staff assessment; site inspections as necessary; and, processing Notices of Termination. TDEC considers the general permit process to be a clear benefit to the regulated community and the process has proven to be successful. However, for TDEC to be able to continue to provide services necessary to support the general permit process, appropriate fees must be assessed. A $500 fee, assessed to the beneficiary of the service, is considered by TDEC to be appropriate in support of the services rendered. In turn permit applicants benefit from the advantages that the general permit process provides.

The proposed rule change associated with ARAP fees does not propose to change any portion of the permitting or coverage process. Those activities necessitating notification to TDEC will still require the same notification. The activities that are beyond the scope of exemptions identified in the specific general permit will require the submittal of the $500 fee with the notification. The requirement for providing notification to TDEC is not proposed for change.

City agencies/municipalities are not authorized to conduct work under the general permit, unless specifically exempted by the general permit, without providing notification to TDEC and obtaining written authorization from TDEC to conduct the work.

Comment: A commenter believes that the statement in the second line (of "vii") should be changed to "or" as follows: Projects that replace, restore or repair public infrastructure **or** remediate damages from flooding or storm events "or" qualify for federal disaster assistance are exempt from subparts (i), (ii), (iii), (iv), (v), and (vi) of this part.

Response: Consistent with the proposed subpart (2)(a)1(vii) of Rule 0400-40-11-.02, the existing regulations exempt certain projects from having to obtain permit coverage if the project qualifies for federal disaster assistance and are for natural events of the most destructive type, thus the federal emergency designation. TDEC intends to maintain this exemption. Extending the exemption to any projects resulting from flooding or storm events would not be in keeping with current regulations.

Comment: There should be two additional categories of size (construction stormwater permits). One should be 10-20 acres for $1,000 and the second should be 5-10 for $500.

Response: The proposed acreage category changes are based on the perspective of staff that regularly provide these services. Per their experience the proposed categories appropriately represent

thresholds of work magnitude. While the commenter's proposal is not illogical, TDEC intends to maintain its current proposal.

Comment: A commenter suggested that the wording of item (vi) should read "Projects less than 1 acre but part of a larger overall development." The fee should be lowered but charged on a per lot basis and not just $100 per application that way each lot can get a notice of termination.

Response: The wording of this category is proposed for change to "Projects seeking subsequent coverage under an actively covered larger common plan of development or sale." The $100 fee is intended to fund the administrative costs associated with adding operators to an existing coverage which, in certain cases, is an option to the regulated community. The fee will also compensate the Division for its activities associated with the "lots" where construction events that are not part of the initial SWPPP occur, such as, driveway construction, installation of subsurface utilities, construction of basements and grading activities. Typically, these activities are performed by someone other than the original SWPPP applicant and if pollution occurs, it is the responsible for the "smaller lot owner." This service has not historically been assessed a fee. The proposed fee is not intended to capture an additional permit population. No change in permitting practices is proposed.

Comment: A commenter requested that the ratio of state appropriations to fees for the water pollution control program be separately calculated to insure that the statutory 50% limit is met and another commenter asked how the proposed amendments would be impacted by the ratios set forth in the law.

Response: The proposed fee amendments would result in fee collections representing 39.4% of the total revenue for the program, which make the fee collections anticipated to be well within the 50% limit of T.C.A. § 68-203-104(d)(3).

Comment: A commenter requested an explanation of the Division's proposal to increase fees in light of the state revenue numbers as this action appears inconsistent with the express language of T.C.A. 68-203-104(a)(3).

Response: The proposed fee amendments are not inconsistent with the language of T.C.A. § 68-203-104(a)(3), The state appropriation to the heritage water pollution control program for current fiscal year was increased.

Comment: A commenter asked how much money the proposed increase/modification in fees will generate and how the money for the increase/modification will be spent.

Response: The proposed fee rule modification will result in an estimated net revenue increase to the Division of Water Resources of approximately $2.28 million toward the water pollution control program revenue. The money will be spent to maintain an appropriate level of technical and administrative staff needed to provide timely document review, permitting, inspection, and technical assistance services to the regulated community.

Comment: A commenter requested TDEC to provide a workload analysis report for at least the last 5 years, covering activities affecting the proposed fees and any related state appropriation. Include any backlog or pending matters.

Response: The workload analysis for the last 5 years is not available in a consistent format for all heritage water divisions; however a detailed workload report for the consolidated division will be provided to the commenter.

Comment: A commenter asked how the proposed changes will benefit municipalities and other affected parties, to identify problems within the existing rules, to identify remedies/solutions to these problems that the proposed rules correct, simplify, or areas in which they decrease spending, and how the increase/modification in fees will improve services to municipalities.

Response: Adequate funding is necessary for TDEC to maintain a quality regulatory program that is approved by the EPA and that delivers quality and timely services. Receiving quality and timely services directly benefits municipalities. The rules are being amended to adjust some fees to be more commensurate with the level of time and effort required by the division to deliver those services and create fees for services that have been provided at no cost to the applicants. Without adequate funding the program will lose resources and that will result in costly delays and inadequate regulatory oversight.

Comment: A commenter requested the amount of state appropriation allotted to this division for FY 2013-14, the amount allotted in 2012-13, and the amount of anticipated appropriation for FY 2014-15.

Response: In FY 2012-13, the legacy Division of Water Pollution Control (WPC) was appropriated $9,424,700; the legacy Division of Water Supply DWS) was appropriated $1,002,200; and the legacy Groundwater Protection Division (GWP) was appropriated $2,155,400. When combined into the Division Water Resources the total appropriated for this period was $12,582,300 (WPC 74.9%, DWS 8%, GWP 17.1%). For FY 2013-14, the Division of Water Resources was appropriated $13,435,100; an increase of $852,800 from the previous fiscal year. The percentage of allocations to the legacy programs within the Division of Water Resources would have increase by proportionally to each program. Since the Administration is in the process of developing the recommended budget for FY 2014-15, which the Governor will submit to the General Assembly in late January 2014, we are not able to determine the amount that will be appropriated. However, we do not anticipate that the appropriation will be decreased.

Comment: A commenter questioned whether the proposed annual maintenance fee for water withdrawal ARAP permits will apply to utility districts that provide drinking water.

Response: This proposed fee will only apply to those permittees that are not currently paying a maintenance fee under Rule 0400-45-01-.32 Fees for Public Water Systems.

Comment: A commenter maintains that TDEC has not complied with T.C.A. § 68-203-103(3) to justify that a fee increase is warranted.

Response: In accordance with T.C.A. § 68-203-103(3), the Board of Water Quality, Oil and Gas is making the required determination at its December 17, 2013 meeting. The Division of Water Resources will be presenting the relevant information required by the statute to enable the Board to make the required determination. The Division has made the information available that justified the need for a fee increase during the comment period to all interested parties. TDEC maintains that it has complied with the requirements of Title 68, Chapter 203 Tennessee Environmental Protection Fund in order to successfully amend the fees required by Rule 0400-40-11-.02.

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.

(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.

The Division anticipates those small businesses that are involved in property development and construction, in which land disturbance and alterations to aquatic resources are common, to be affected by these proposed rules. All small businesses of this type statewide would be affected. The Division also anticipates that small businesses providing decentralized wastewater services will be affected. There are less than 10 such businesses statewide.

The Division anticipates that small business providing services related to soil mapping and hydrologic determinations will be positively affected by these proposed rules. The Division estimates there are approximately 50 to 75 such small businesses statewide.

(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.

No additional reporting requirements are required by these proposed rules. No increase in the population of permitted activities or those requiring permits is proposed. There will be additional recordkeeping required in that some services that were historically not assessed a fee will be assessed a fee through these proposed rules. The type of forms to be completed by the applicant will remain the same and the reporting requirements will remain the same.

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

The proposed rule will increase permitting costs for small businesses that develop property (residential, commercial and industrial) whereby land disturbance and aquatic resource alteration are common. Costs of keeping these permits active for long periods of time will also increase. The Division anticipates these costs to be ultimately projected to the consumers that benefit from these activities.

Small businesses and consumers will also continue to benefit from timely permitting and support services that an adequately-staffed program provides.

(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.

The Division considers this rule to be necessary to more appropriately fund the program. Other cost-cutting activities have been, and continue to be, implemented. Additional staff reductions will likely occur without these proposed rules becoming effective. Additional staff reductions will affect the program's ability to provide timely permitting and support services.

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

This proposed rule does not increase permitting requirements nor does it attempt to increase the population of permitted activities. These proposed rules are specific to fees for services. The proposed fee changes are an outgrowth of an assessment of the services that the Division provides and the fees that are assessed for those services. Funding ratios (fees/state appropriations) vary from program to program within the state. Furthermore, other states have varied means of funding practices which makes direct comparison of fees impractical.

(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.

The effect of exempting small businesses from all or any part of the requirements contained in the proposed rule will result in the inability of the Division to continue to fund the services that are critical in

support of the authority delegated to the Division by the Environmental Protection Agency. Furthermore, lack of funding will affect the program's ability to provide services to these small businesses in a timely manner.

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)

The Department anticipates that these amendments will have a financial impact on local governments.

Department of State
Division of Publications
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Nashville, TN 37243
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Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 01-10-14
Rule ID(s): 5658
File Date: 1/14/14
Effective Date: 4/14/14

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. T.C.A. § 4-5-205

Agency/Board/Commission:	Environment and Conservation
Division:	Water Resources
Contact Person:	Britton Dotson
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 11th Floor Nashville, Tennessee
Zip:	37243
Phone:	(615) 532-0774
Email:	Britton.Dotson@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 to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0400-40-11	Environmental Protection Fund Fees
Rule Number	**Rule Title**
0400-40-11-.02	Fees

(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)

Amendments

Chapter 0400-40-11
Environmental Protection Fund Fees

Paragraph (1) of Rule 0400-40-11-.02 Fees is amended by deleting subparagraph (c) in its entirety and substituting instead the following:

(c) 1. Except for part 2 of this subparagraph, ~~Permit~~ permit annual maintenance fees shall be paid to the Department for every year the permit is in effect by the permittee. The annual maintenance fee shall be due within 45 days of issuance of an invoice.

2. Maintenance fees for post-project monitoring with fixed time periods shall be assessed in total at the time of permit issuance.

Authority: T.C.A. § 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

Rule 0400-40-11-.02 Fees is amended by deleting paragraph (2) in its entirety and substituting instead the following:

(2) Schedule of Fees

(a) The Application Fees for the processing of applications for 401 certifications and ARAP permits and notices of intent for coverage under ~~the~~ a general permit ~~for discharges of storm water associated with construction activity~~ and for decentralized wastewater systems shall be as follows:

1. 401 Certification ~~of 404 permit~~ or ARAP (Capped at $5,000):

(i)	Projects ~~equal to or greater than 10 acres or equal to or greater than 1,000 feet linear~~ with 5 or more points of impact and requiring compensatory mitigation	~~$2,500~~ $5,000
(ii)	Projects ~~less than 10 acres or less than 1,000 feet linear~~ not requiring compensatory mitigation, any number of impact points	~~$1,000~~ $2,500
(iii)	Projects with less than 5 points of impact, with or without mitigation requirements	$2,500
~~(iii)~~(iv)	Watershed District Projects	~~$ 750~~ $1,000
(v)	Projects seeking Notice of Coverage under a general permit	$500
~~(iv)~~(vi)	Personal Residence or Family Farm	$50
~~(v)~~(vii)	Projects that replace, restore or repair public infrastructure or remediate damages from flooding or storm events and qualify for federal disaster assistance are exempt from subparts (i), (ii), (iii), ~~and~~ (iv), (v) and (vi) of this part.	

For the purposes of part 1 of this subparagraph, points of impact shall mean discreet physical locations on one or more jurisdictional water features within an overall project (common plan of development), at which regulated alteration activities are proposed.

2. Construction Stormwater permits:

(i)	Projects equal to or greater than 150 acres	~~$7,500~~ $10,000

(ii)	Projects equal to or greater than 50 acres and less than 150 acres	~~$4,000~~ $6,000
(iii)	Projects equal to or greater than 20 acres and less than 50 acres	~~$1,000~~ $3,000
(iv)	Projects equal to or greater than 5 acres and less than ~~50~~ 20 acres	$1,000
~~(iv)~~(v)	Projects equal to or greater than 1 acre and less than 5 acres	$250
~~(v)~~	~~Projects less than 1 acre~~	~~$ 0~~
(vi)	Projects seeking subsequent coverage under an actively larger common plan of development or sale	$100

3. Decentralized Wastewater Systems

(i)	Systems greater than 0.075 MGD	$1,000 plus $150 for each additional 0.02 MGD
(ii)	Systems greater than 0.05 MGD and less than 0.075 MGD	$1,000
(iii)	Systems greater than 0.02 MGD and less than 0.05 MGD	$750
(iv)	Systems less than 0.02 MGD	$500

(b) Permit Annual Maintenance Fees shall be as follows for these categories of permitted activities (Capped at $15,000):

1.	Gravel Dredging	~~$140~~ $300
2.	Gravel Dredging for Personal Residence or Family Farm	$0
3.	Major Industrial Treatment Facility:	
(i)	Flow equal to or greater than 10 MGD	$10,380
(ii)	Flow equal to or greater than 1 MGD and less than 10 MGD	$8,650
(iii)	Flow equal to or greater than 0.5 MGD and less than 1 MG	$6,920
(iv)	Flow equal to or greater than 0.1 MGD and less than 0.5 MGD	$5,190
(v)	Flow less than 0.1 MGD	$3,460
4.	Minor Industrial Treatment Facility:	
(i)	Flow equal to or greater than 10 MGD	$6,920
(ii)	Flow equal to or greater than 1 MGD and less than 10 MGD	$5,190
(iii)	Flow equal to or greater than 0.5 MGD and less than 1 MGD	$3,460
(iv)	Flow equal to or greater than 0.1 MGD and less than 0.5 MGD	$1,380
(v)	Flow less than 0.1 MGD	$690
5.	Treated ~~Washwater~~ Wastewater Dischargers with flows <0.001 MGD	$140

6. Stormwater Discharge Permits associated with Industrial Activities:

(i)	Facilities equal to or greater than 500 acre	$970
(ii)	Facilities equal to or greater than 400 acres and less than 500 acres	$900
(iii)	Facilities equal to or greater than 300 acres and less than 400 acres	$830
(iv)	Facilities equal to or greater than 200 acres and less than 300 acres	$760
(v)	Facilities equal to or greater than 100 acres and less than 200 acres	$690
(vi)	Facilities equal to or greater than 50 acres and less than 100 acres	$620
(vii)	Facilities equal to or greater than 25 acres and less than 50 acres	$550
(viii)	Facilities equal to or greater than 10 acres and less than 25 acres	$480
(ix)	Facilities equal to or greater than 5 acres and less than 10 acres	$420
(x)	Facilities equal to or greater than 1 acres and less than 5 acres	$350
(xi)	Facilities equal to or greater than 0 acres and less than 1 acre	$0

7. Sewage Treatment Facility Flow:

(i)	Flow equal to or greater than 5 MGD	$10,380
(ii)	Flow equal to or greater than 4.5 MGD and less than 5 MGD	$10,030
(iii)	Flow equal to or greater than 4 MGD and less than 4.5 MGD	$9,690
(iv)	Flow equal to or greater than 3.5 MGD and less than 4 MGD	$9,340
(v)	Flow equal to or greater than 3 MGD and less than 3.5 MGD	$9,000
(vi)	Flow equal to or greater than 2.5 MGD and less than 3 MGD	$8,300
(vii)	Flow equal to or greater than 2 MGD and less than 2.5 MGD	$7,610
(viii)	Flow equal to or greater than 1.5 MGD and less than 2 MGD	$6,920
(ix)	Flow equal to or greater than 1 MGD and less than 1.5 MGD	$6,230
(x)	Flow equal to or greater than 0.75 MGD and less than 1 MGD	$5,540
(xi)	Flow equal to or greater than 0.5 MGD and less than 0.75 MGD	$4,840
(xii)	Flow equal to or greater than 0.25 MGD and less than 0.5 MGD	$3,460
(xiii)	Flow equal to or greater than 0.1 MGD and less than 0.25 MGD	$1,730
(xiv)	Flow equal to or greater than 0.075 MGD and less than 0.1 MGD	$1,040

8. Small Mechanical Facility flow less than 0.075 MGD $690

9. Small Non-Mechanical Facility flow less than 0.075 MGD $350

10. Non-Discharging Facility:

	(i)	Influent flow equal to or greater than 0.5 MGD	$4,840
	(ii)	Influent flow equal to or greater than 0.1 MGD and less than 0.5 MGD	$2,770
	(iii)	Influent flow equal to or greater than 0.075 MGD and less than 0.1 MGD	$1,380
	(iv)	Influent flow less than 0.075 MGD	$350
	(v)	Satellite collection systems	$1,380
	(vi)	Pump and haul	$350
11.	Other Waste or Wastewater Operations Requiring Permit		$1,380
12.	General Permits		
	(i)	For construction activities that exceed 1 year under general permit coverage:	
		(I) Projects equal to or greater than 150 acres	$3,750
		(II) Projects equal to or greater than 50 acres and less than 150 acres	$2,000
		(III) Projects equal to or greater than 20 acres and less than 50 acres	$1,000
		(IV) Projects equal to or greater than 5 acres and less than 20 acres	$500
		(V) Projects equal to or greater than 1 acre and less than 5 acres	$125
	(ii)	All other activities (other than ~~stormwater or~~ concentrated animal feeding operations or minor activities that require no notification to obtain general permit coverage)	$350
13.	Concentrated animal feeding operations covered by an individual permit		$350
14.	Municipal Pretreatment Programs as defined in subparagraph (2)(a) of Rule 0400-40-11-.01:		
	(i)	Large Pretreatment Program	$6,920
	(ii)	Medium Pretreatment Program	$4,150
	(iii)	Small Pretreatment Program	$1,380
15.	Mining:		
	(i)	Area equal to or greater than 500 acres	$6,920
	(ii)	Area equal to or greater than 400 acres and less than 500 acres	$6,230
	(iii)	Area equal to or greater than 300 acres and less than 400 acres	$5,540
	(iv)	Area equal to or greater than 200 acres and less than 300 acres	$4,840

(v)	Area equal to or greater than 100 acres and less than 200 acres	$4,150
(vi)	Area equal to or greater than 75 acres and less than 100 acres	$3,460
(vii)	Area equal to or greater than 50 acres and less than 75 acres	$2,770
(viii)	Area equal to or greater than 25 acres and less than 50 acres	$2,080
(ix)	Area equal to or greater than 10 acres and less than 25 acres	$1,380
(x)	Area equal to or greater than 5 acres and less than 10 acres	$1,040
(xi)	Area less than 5 acres	$690

(Note: Fees are based on area being mined or area not yet reclaimed.)

16.	Mining Reclamation	$350
17.	Stormwater Discharge Permits for Municipal Separate Storm Sewer Systems (MS4):	
(i)	Large MS4s	$10,380
(ii)	Medium MS4s	$6,920
(iii)	Small MS4s	$3,460
18.	401 Certification or ARAP permits that require monitoring of permitted activities or compensatory mitigation	$500
19.	Water Withdrawal ARAP permits that require monthly operational reports, provided an annual maintenance fee has not been paid under Rule 0400-45-01-.32	$1,000

(c) Plan Review Fees shall apply to new facilities as well as the expansion or modification of existing facilities. If the submittal includes more than one listed category, the fee will be the sum of the fees listed for each individual category. Review of plans documents will not commence until all fees required by these rules are paid in full. Plan Review Fees shall be as follows (Capped at $1,500):

1.	Major Industrial Wastewater Treatment Facility:	
(i)	Flow equal to or greater than 5 MGD	$1,500
(ii)	Flow less than 5 MGD	$1,000
2.	Minor Industrial Wastewater Treatment Facility:	
(i)	Flow equal to or greater than 0.1 MGD	$ 500
(ii)	Flow less than 0.1 MGD	$ 250
3.	Sewage Treatment Facility:	
(i)	Flow equal to or greater than 5 MGD	$1,500
(ii)	Flow equal to or greater than 1MGD and less than 5 MGD	$1,000
(iii)	Flow equal to or greater than 0 .075 MGD and less than 1 MGD	$ 500

(iv) Flow less than 0.075 MGD $ 250

4. Collection Systems or Force Main:

~~(i) Collection Lines —~~

$25.00 per 250 feet or portion thereof of sewage collection line or force main excluding service laterals. Total fee not to exceed $1,500.

5. Equalization Basins:

(i)	Holding capacity equal to or greater than 5 million gallons (MG)	$ 300
(ii)	Holding capacity equal to or greater than 1 MG and less than 5 MG	$ 200
(iii)	Holding capacity equal to or greater than 0.075 MG and less than 1 MG	$ 100
(iv)	Holding capacity less than 0.075 MG	$ 50

6. Pumping Stations:

(i)	Design capacity equal to or greater than 5 MGD	$ 300
(ii)	Design capacity equal to or greater than 1 MGD and less than 5 MGD	$ 200
(iii)	Design capacity equal to or greater than 0.075 MGD and less than 1 MGD	$ 100
(iv)	Design capacity less than 0.075 MGD (Does not include grinder pumps for septic tanks and septic tank effluent pumps)	$ 50

7. Mining Operations:

(i)	Coal	$ 250
(ii)	Non-Coal — $25.00 per acre, not to exceed	$1,500
(iii)	Reclamation	$ 250
(iv)	Quarries	$ 250

8. Wastewater Plant and/or Collection System Modification:

The plans review fee for modifications to wastewater plants and/or collection systems shall be 20% of the full review fee based on the category and size of the resulting facility.

(d) Delegated Plans Review Authority:

Units of local government, which have been granted plans review authority, shall pay an annual fee of $1,000. Failure of local government to pay this fee will be cause for the revocation of plans review authority.

(e) Engineering Report Review

1. Major Industrial Wastewater Treatment Facility:

(i)	Flow equal to or greater than 5 MGD	$1,500
(ii)	Flow less than 5 MGD	$1,000

2. Minor Industrial Wastewater Treatment Facility:

(i)	Flow equal to or greater than 0.1 MGD	$500
(ii)	Flow less than 0.1 MGD	$250

3. Sewage Treatment Facility:

(i)	Flow equal to or greater than 5 MGD	$1,500
(ii)	Flow equal to or greater than 1 MGD and less than 5 MGD	$1,000
(iii)	Flow equal to or greater than 0.075 MGD and less than 1 MGD	$500
(iv)	Flow less than 0.075 MGD	$250

Authority: T.C.A. § 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

Subparagraph (a) of paragraph (3) of Rule 0400-40-11-.02 Fees is amended by deleting it in its entirety and replacing it with the following so that, as amended, the subparagraph shall read:

(a) Fees resulting from application for a permit, maintenance of a permit or plans review, shall be made Payable and Mailed to the Department of Environment and Conservation; Attention: Environmental Protection Fees — Water ~~Pollution Control~~ Resources.

Authority: T.C.A. § 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

Subparagraph (a) of paragraph (5) of Rule 0400-40-11-.02 Fees is amended by deleting it in its entirety and replacing it with the following so that, as amended, the subparagraph shall read:

(a) Any person required to pay any fee specified in this rule, who disagrees with the calculation or applicability of the fee, may petition the Board of Water Quality, Oil and Gas ~~Control Board~~ for a hearing. In order to perfect a hearing, the objecting party must present to the Technical Secretary of the Board, not later than 15 days after the fee due date:

1. a petition for hearing, and

2. the total amount of the fee.

Authority: T.C.A. § 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

* 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)
James W. Cameron III	X				
Jill E. Davis				X	
Mayor Kevin Davis		X			
Derek Gernt	X				
John Guoynes	X				
C. Monty Halcomb	X				
Chuck Head	X				
Charlie R. Johnson	X				
Judy Manners	X				
John McClurkan	X				
Frank McGinley		X			
D. Anthony Robinson	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Water Quality, Oil and Gas on 12/17/2013, 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: 10/18/13

Rulemaking Hearing(s) Conducted on: (add more dates). 12/10/13

CAROL L. GRICE STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY, TENN.

Date: December 17, 2013

Signature: James W. Cameron III

Name of Officer: James W. Cameron III

Title of Officer: Chair

Subscribed and sworn to before me on: December 17, 2013

Notary Public Signature: Carol L. Grice

My commission expires on: June 21, 2016

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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

1-14-13
Date

Department of State Use Only

Filed with the Department of State on: 1/14/14

Effective on: 4/14/14

Tre Hargett
Secretary of State

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