G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Finance and Administration
DIVISION:	TennCare
SUBJECT:	Reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and Federally Qualified Health Center Look-Alikes
STATUTORY AUTHORITY:	Tennessee Code Annotated, Sections 4-5-202, 71 -5- 105, 71-5-107, 71 -5-109, 71-5-118, and 71 -5-130
EFFECTIVE DATES:	July 13, 2019 through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rulemaking hearing rule is being promulgated to provide the reimbursement methodology necessary to determine appropriate reimbursable costs and payments for TennCare services provided by RHCs, FQHCs and FQHCLAs to TennCare enrollees. NOTE: Rule not submitted in redline form.

Public Hearing Comments

TennCare received comments from 26 individuals and organizations in response to this rulemaking. The comments and TennCare's responses are summarized below.

One commenter suggested an alternative to the reimbursement methodology in the rule whereby TennCare would establish a flat rate for RHCs. In response, TennCare expressed its view that a flat rate cannot adequately account for the significant variation in locations, patient mixes, and services represented by clinics around the state. No modifications were made to the rule based on this comment.

Several commenters expressed concern about the length of time needed to set rates under the current payment system. In response, TennCare noted that the rule adds a new requirement that in all circumstances rates must be finalized within 120 days of the facility providing all information necessary to set the rate. TennCare interpreted these comments as supportive of the rule's provision establishing a timeframe for setting final rates. No modifications were made to the rule based on these comments.

Two commenters suggested that the rule be clarified to specify that the 120-day timeframe for the Comptroller to set final rates begins upon the Comptroller's receipt of all necessary information from the provider. TennCare agreed with these suggestions and modified the rule accordingly.

One commenter suggested that the provision of the rule specifying that the Comptroller may grant no more than one extension to a provider that has been asked to submit additional documentation is unnecessary, since the also rule specifies that extensions are granted at the discretion of the Comptroller. TennCare agreed with this recommendation and removed the provision in question from the rule.

Multiple commenters expressed concern that the provisions of the rule would be applied retroactively to established PPS rates. In response, TennCare clarified that it is not the intent of the rule to recoup from rates applicable to prior years by applying new requirements that appear only in this rule.

A number of commenters expressed concern about the rule's limitation on reimbursement for administrative expenses. In response, TennCare noted that a reasonable limitation on administrative expenses is appropriate, helps minimize the risk of fraud, waste, and abuse, and helps protect the integrity of the payment system. The cap in the rule was based on a comprehensive statewide rate analysis performed by the Comptroller. One commenter expressed support for the rule's proposed cap on administrative expenses. TennCare thanked this commenter for his support. No modifications were made to the rule based on these comments.

One commenter questioned why the rule limits compensation for clinic owners. In response, TennCare clarified that nothing in the rule limits compensation for the owners of FQHCs or RHCs. Clinics continue to have discretion to establish their own salaries. The rule caps the amount of compensation for owners that can be considered an allowable expense for enhanced reimbursement through the prospective payment system. This cap is intended to help minimize the risk of fraud, waste, and abuse. No modifications were made to the rule based on this comment.

A few commenters objected to the exclusion of imputed owners' salaries in the rule. In response, TennCare noted that imputed salaries represent costs that were not actually paid by the clinic, and disallowing these costs helps protect the payment system from fraud, waste, and abuse. No modifications were made to the rule based on these comments.

One commenter expressed concern that the rule appeared not to account for reimbursement for clinic owners who perform both direct care and administrative duties. In response, TennCare clarified that it is not TennCare's intent to implement a rule that prevents owners from being reimbursed for both direct care and administrative work. TennCare modified the pertinent rule language to clarify that this is allowed.

Several commenters expressed concern about the rule's limitation on allowable reimbursement for compensation of clinic owners to 1 FTE. These commenters believed this limitation would have an adverse impact on providers who consistently work more than 40 hours per week. In response, TennCare elected to raise the applicable limit in the rule to 1.5 FTE. TennCare further clarified that for clinic owners and related parties, no more than 1 FTE per individual can be claimed for administrative hours.

Several commenters expressed concern that the rule's indexing of salaries and wages to the Tennessee Occupational Employment and Wage Rates would negatively impact clinics' ability to recruit and hire providers. In response, TennCare noted that the limit applies only to clinic owners and related parties, and thus, should not affect a clinic's ability to recruit new providers. Some commenters also objected to applying this limit on reimbursement for compensation of clinic owners. TennCare noted that reasonable limits on reimbursement for compensation of owners are necessary in order to help prevent the possibility of fraud, waste, and abuse in the payment system. No modifications were made to the rule based on these comments.

A few commenters expressed concern that the rule appeared to prohibit the use of productivity-based salaries. In response, TennCare clarified that the rule does not limit or prohibit the use of productivity-based salaries. No modifications were made to the rule based on these comments.

Multiple commenters expressed concern about the requirement in the rule for the annual submission of Medicaid cost reports. These commenters suggested that this required submission would represent an additional administrative burden for providers. One commenter suggested alternative documentation requirements to those outlined in the rule. In response, TennCare noted that cost reports are needed to ensure the appropriateness of payments and to minimize the risk of fraud, waste, and abuse. TennCare noted that its intent is to limit the cost report to as few data elements as possible in order to minimize administrative burden on clinics to the extent possible. No modifications were made to the rule based on these comments.

One commenter objected to a provision in the rule allowing the Comptroller to request additional information from providers. This commenter recommended that the rule should contain an exhaustive list of all documentation that could be requested. This commenter also recommended that the rule specify that the Comptroller may not deny any reasonable request from a provider for an extension in providing additional documentation. In response, TennCare noted that the Comptroller must maintain the ability to collect all necessary information in order to set the most accurate rates and guard against fraud, waste, and abuse in the payment system. No modifications were made to the rule based on these comments.

Several commenters objected to the rule's prohibition on contingency fee-based contracts. In response, TennCare noted that it is deeming these contracts impermissible in order to minimize the risk of fraud, waste, and abuse. One commenter expressed support for the rule's exclusion of contingency fee-based contracts. TennCare thanked this commenter for his support. No modifications were made to the rule based on these comments.

Multiple commenters expressed concern that the rule has no provision for providers to appeal decisions made by TennCare or the Comptroller's office. TennCare agreed with these commenters, and added a rule providing for such an appeals process.

One commenter suggested that the rule contains inconsistent standards as to what constitutes reasonable costs. TennCare respectfully disagreed with the commenter's assessment. No modifications were made to the rule based on this comment.

One commenter suggested that interim rates be set using statewide figures rather than regional figures for independent and provider-based RHCs. In response, TennCare noted that it is electing to calculate interim rates on the basis of Grand Division in order to account for regional variation in the cost of providing care and clinic operations. No modifications were made to the rule based on this comment.

One commenter suggested that the rule should include language addressing the reconciliation of primary care payments made under an interim rate to the payments that would have been made under the final rate and making any necessary additional payments. TennCare agreed with this recommendation and added corresponding language to the rule. The language added to the rule reflects the practice within the current payment system of adjusting payments upward or downward depending on the relationship between the interim rate and the final rate.

One commenter requested clarification as to whether certain information requirements in the rule would apply to all health centers or be limited to new health centers. In response, TennCare clarified that these requirements will apply to all FQHCs and RHCs. Based on consultation with the Comptroller, TennCare believes this list of information is necessary to protect the integrity of the payment system. No modifications were made to the rule based on this comment.

One commenter expressed concern about TennCare's use of paid visits as the basis for PPS/APM payments, and noted that similar paid visit policies have been challenged in other states. In response, TennCare noted that it believes the language in the rule related to paid claims is consistent with applicable state and federal laws and regulations. However, in response to this concern, TennCare added language to the rule to allow for reconsideration of visits denied by the MCO in limited circumstances.

One commenter requested that the rule be clarified to explicitly allow health centers to submit core visits and non-core visits performed on the same day as two visits. TennCare agreed with the commenter's recommendation and modified the rule accordingly.

One commenter suggested that the rule allows the Comptroller too much discretion to determine reasonable costs and suggested that more objective standards be included in the rule. In response, TennCare noted that the rule provides a significant level of detail concerning what constitutes allowable costs. No modifications were made to the rule based on this comment.

One commenter recommended the deletion of language from the rule concerning the Comptroller's ability to review cost reports for reasonableness. TennCare regards altering this language to be unnecessary as the rule already contains references to federal reasonableness language and adds new reasonableness requirements. These are the basis for determinations of reasonableness. No modifications were made to the rule based on this comment.

One commenter requested that language be added to the rule concerning changes that impart a change in type, intensity, duration, or amount. In response, TennCare noted that it regards the addition of this language as unnecessary, because such changes in type, intensity, duration, or amount are already addressed in the rule. No modifications were made to the rule based on this comment.

One commenter requested that language be added to the rule concerning changes in scope that occur when the state imposes new requirements on managed care organizations, which in turn result in new requirements for health clinics. TennCare agreed with the commenter's recommendation and added the requested language to the rule. The language added by TennCare applies when a change in requirements results in an increase in clinic costs of at least five percent.

One commenter suggested that TennCare replace the language related to change in scope in the rule in favor of TennCare's existing change of scope policy. In response, TennCare noted that much of the language cited by the commenter is necessary for the new payment system. TennCare agreed with a portion of the comment that it is unnecessary to first set an interim rate and then a final rate for a change of scope, and amended the rule accordingly to align with the current practice of using the facility's current rate until the final rate can be set.

One commenter expressed concern that the provision of the rule concerning reimbursement via quarterly settlements based on the final PPS rate is inconsistent with current procedures. In response, TennCare clarified that the rule does not change current procedures for submission of visits with regard to a main facility and its satellites, and that in fact, this provision of the rule is intended to make explicit that visits at satellites can be eligible for settlement. No modifications were made to the rule based on this comment.

One commenter requested clarification as to the use of the term "market basket measure" in the rule. In response, TennCare clarified that this term refers to the market basket established under Section 1834 of the Social Security Act. No modifications were made to the rule based on this comment.

One commenter requested confirmation that the review of all PPS rates by the Comptroller described in the rule will apply only to standard BIPA PPS rates. In response, TennCare confirmed that the commenter's understanding of the rule was accurate. No modifications were made to the rule based on this comment.

One commenter objected to a provision of the rule concerning circumstances in which a PPS rate may be frozen, and suggested that this provision is inconsistent with federal requirements. Upon review, TennCare elected to modify the rule to clarify that PPS rates will not be frozen.

One commenter requested that TennCare or the Comptroller provide information to health centers concerning which type of rate they have (PPS or APM). Although outside the scope of this rulemaking, TennCare agreed to work with the Comptroller to provide this information. No modifications were made to the rule based on this comment.

One commenter requested clarification concerning how a health center that has elected the APM can opt out of the APM and return to PPS. In response, TennCare noted that once an RHC, FQHC, or FQHCLA is on an APM rate, it permanently stays on an APM rate. There is no mechanism for returning to a standard BIPA PPS rate. No modifications were made to the rule based on this comment.

One commenter noted that the state is required to demonstrate that an APM is equal to or greater than the BIPA PPS rate and inquired how TennCare intends to demonstrate this. In response, TennCare noted that it is aware of its obligations concerning APMs, and will annually demonstrate that the APM is higher than the BIPA PPS rate, as calculated using methodology in the rule. No modifications were made to the rule based on this comment.

One commenter suggested that the rule should clearly state which service categories will be subject to a secondary PPS rate or a PPS rate outside of core reimbursement. In response and in an effort to clarify the rule's intent by reflecting all rates that are set outside of the core, TennCare added "optometry" to the relevant section of the rule.

One commenter requested clarification about the meaning of "Grand Division" in the rule. TennCare clarified that for purposes of TennCare rules, Grand Division has the same meaning as that located at T.C.A. 4-1-2. No modifications were made to the rule based on this comment.

One commenter questioned a provision in the rule allowing facilities to submit partial-year cost reports in instances when a complete fiscal year of data may not be available due to a change in ownership or a facility being new. TennCare elected to remove this provision of the rule in order to prevent confusion and unnecessary administrative burden for providers.

Two commenters questioned a provision in the rule allowing new RHCs and FQHCs to submit budgeted cost reports. TennCare elected to remove this provision of the rule in order to prevent confusion and unnecessary administrative burden for providers.

One commenter asked about the availability of the supplemental Medicaid cost report format. In response, TennCare indicated that the cost report will be available in the near future (prior to the rule's implementation), and that TennCare will communicate about the Medicaid cost report with the provider community. Another commenter requested that providers be allowed to review and provide feedback on the visit reporting template prior to its implementation. In response, TennCare noted that it intends to provide opportunities for review and feedback on the visit submission template. No modifications were made to the rule based on these comments.

One commenter requested clarification about the requirement in the rule for facilities to submit a written statement of the entity's maximum hours per day. To clarify, TennCare responded that facilities are required to report the hours of operation that the facility is available to provide FQHC/RHC services. No modifications were made to the rule based on this comment.

One commenter requested clarification about the documentation that will be required for the compensation of sole proprietors, partners, and single member LLCs to be considered reasonable and allowed on the cost report. To clarify, TennCare responded by noting that these requirements are addressed in the rule at 1200-13-10-.06(2)(b). No modifications were made to the rule based on this comment.

One commenter expressed concern and two commenters requested clarification about a provision in the rule concerning the periodic rebasing of clinics that have elected the Alternative Payment Methodology (APM). In response, TennCare confirmed that this rebasing applied only to clinics that have elected the APM. By rule, the APM must be at least as high as the standard BIPA PPS rate (as calculated using the new rule methodology), and a facility must elect to be reimbursed using the APM. No modifications were made to the rule based on these comments.

One commenter requested clarification about the support that will be required to document reasonable costs for the allocation of hospital costs to rural health clinics. To clarify, TennCare responded by noting that hospital-based RHCs will be required to submit hospital cost reports and supporting documentation as detailed at Rule 1200-13-10-.04(2). No modifications were made to the rule based on this comment.

Several commenters expressed concern about the proposed list of CPT codes for allowable visits. In response, TennCare noted that it has decided to implement a list of CPT codes in response to concerns that the current

system is unclear as to what constitutes a visit. TennCare also clarified that while the rule implements the use of a list, the rule does not speak to specific items that are included on the list. TennCare has developed a preliminary list of codes, and intends to work with the provider community to arrive at the most appropriate list of codes. In addition, in cases where the CPT codes list is missing a code that a provider believes to qualify as a visit, the rule provides a mechanism for the provider to submit that code separately and request that it be added to the CPT codes list. No modifications were made to the rule based on these comments.

One commenter observed that the reasonableness standards in the rule for codes not on the CPT codes list pertain to the reasonableness of costs, and not the reasonableness of visits. This commenter suggested that this point be clarified in the rule. TennCare agreed with the commenter's observation and modified the rule accordingly.

One commenter suggested that TennCare use HCPCS codes rather than CPT codes as the basis for how qualifying visits are identified. In response, TennCare noted that it has determined that CPT codes are a more accurate representation of the data TennCare needs to collect in order to operate the prospective payment system. No modifications were made to the rule based on this comment.

One commenter expressed concern regarding the rule's applicability to specific types of encounters that are excluded from the definition of allowable or reimbursable visits, particularly as they pertain to TennCare's payment reform initiatives. In response, TennCare clarified that those specific services will not be eligible to be reported as a visit and settled at the PPS rate. No modifications were made to the rule based on this comment.

One commenter expressed concern that "medication therapy management" is not counted as a visit in the rule. In response, TennCare clarified that the rule does not prohibit providers from performing medication management, but clarifies that a limited set of services defined as "medication therapy management" do not constitute a visit for purposes of enhanced reimbursement. No modifications were made to the rule based on this comment.

One commenter expressed concern as to the rule's application to patient-centered medical home (PCMH) services. In response, TennCare pointed out that the commenter appeared to have misunderstood the rule, and that payments for PCMH services are specifically carved out of the reimbursement methodology in the rule. No modifications were made to the rule based on this comment.

One commenter suggested that the definition of administrative costs in the rule should contain additional detail. TennCare respectfully disagreed with this suggestion and noted that the definition of administrative costs in the rule is adequate for implementation of the rule. No modifications were made to the rule based on this comment.

One commenter suggested modifications to the rule's definition of covered services. Upon review, TennCare determined that the definition in question is not necessary for implementation of the rule and elected to remove the definition from the rule.

One commenter suggested a clarification to the definition of FQHC in the rule. TennCare agreed with the commenter's suggestion and updated the rule to reflect this recommendation. Another commenter suggested removing a Medicare-related citation to the CFR from the rule's definition of FQHC. Upon review, TennCare elected to remove the citation in question from the definition of FQHC in the rule.

One commenter expressed concern about the definition of visit in the rule. In response, TennCare noted that the rule's definition is consistent with current practice, which TennCare does not intend to change. However, this does not mean that eligible CPT codes performed by some other provider types would not be eligible for settlement. No modifications were made to the rule based on this comment.

One commenter suggested that the provisions of the rule pertaining to determination of reimbursable visits are not in alignment with federal law. TennCare agreed with the commenter that any services that are required to be compensated according to federal laws and regulations would also be required to be compensated under Tennessee's payment system. TennCare elected to add clarifying information as to which services are reimbursed under non-core PPS rates to Rule 1200-13-10-.11.

One commenter suggested that TennCare tether reasonable cost determinations to applicable Medicare cost reimbursement principles. In response, TennCare noted that it believes that specific criteria for reasonableness are necessary in the rule to provide greater transparency and clarity to the payment system, while also protecting taxpayer dollars. No modifications were made to the rule based on this comment.

One commenter suggested that TennCare should limit the number of RHCs to one per county and/or one per specialty per county. In response, TennCare noted that this recommendation is outside the scope of this rulemaking. No modifications were made to the rule based on this comment.

One commenter expressed support for the rule because it would only allow reasonable costs to be included in the cost report. TennCare thanked the commenter for his support. No modifications were made to the rule based on this comment.

Multiple commenters expressed general concern about the rule's potential impact on rural health clinics in Tennessee. In response, TennCare noted that the purpose of these rules is to add transparency and clarity to the prospective payment system in Tennessee, to ensure the appropriateness of payments, and to minimize the risk of fraud, waste, and abuse in the payment system. No modifications were made to the rules based on these comments.

One commenter criticized the lack of clear cost reporting guidelines in the current reimbursement system. In response, TennCare noted that one of the purposes of these rules is to add transparency and clarity to the prospective payment system in Tennessee. No modifications were made to the rules based on this comment.

Multiple commenters expressed concern about TennCare's moratorium on new Rural Health Clinics entering the TennCare program. Although the RHC moratorium is not the subject of Rule Chapter 1200-13-10, TennCare noted that the moratorium was enacted in response to a significant increase in the potential for fraud, waste, and abuse, and that it is TennCare's intention to lift the moratorium once Rule Chapter 1200-13-10 is in effect. No modifications were made to the rule based on these comments.

One commenter requested clarification about payment processes that will be used for clinics that were certified as Rural Health Clinics during the moratorium. Although the RHC moratorium is not the subject of Rule Chapter 1200-13-10, TennCare noted that it has issued separate guidance on this subject. No modifications were made to the rule based on this comment.

One commenter suggested that TennCare establish an advisory body comprised of rural health providers and their representatives to advise TennCare on reimbursement and other issues related to rural health services. Although outside the scope of this rule, TennCare noted in response that it has communicated with various members of the provider community throughout the development of the new reimbursement methodology, including provider associations, individual clinics and owners, and consultants that support FQHCs and RHCs. TennCare values the input that providers have offered and intends to remain engaged with the provider community as the rule is implemented. No modifications were made to the rule based on this comment.

One commenter suggested that MCOs participating in the TennCare program should be required to allow patients to select FQHCs as their primary care provider. In response, TennCare clarified that TennCare enrollees are currently able to select any qualified provider in their MCO's network, including FQHCs, as their designated primary care provider, and that this choice is not affected by this rule. No modifications were made to the rules based on this comment.

Regulatory Flexibility Addendum

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

1. The 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 rule will impact health centers that are Rural Health Clinics. TennCare estimates that there are currently approximately 100 Rural Health Clinics in the state that are also small businesses.

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

   The rule requires affected health centers to submit a Medicaid cost report, which will be used by TennCare to establish payment rates. The reporting, recordkeeping, and other administrative processes associated with these cost reports are not substantially different than what is otherwise already required for health centers.

3. A statement of the probable effect on impacted small businesses and consumers;

   The rule will have no impact on consumers. Small businesses impacted by the rule will benefit from greater transparency, clarity, consistency, and uniformity in the payment system. Because the rule establishes clear standards for acceptable costs, health centers will experience less ambiguity around payment and lower levels of audit risk.

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;

   There are no less burdensome, less intrusive, or less costly methods of achieving the purpose and objectives of the rule.

5. A comparison of the proposed rule with any federal or state counterparts; and

   There are no federal or state counterparts to the rule.

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 purpose of the rule is to provide greater transparency, clarity, consistency, and uniformity to the payment system for Rural Health Clinics and Federally Qualified Health Centers. Because a significant number of Rural Health Clinics are also small businesses, exempting small business from the rule would prevent the rule from achieving this objective. The rule does not provide for exemptions for small businesses.

Impact on Local Governments

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

The rule chapter is not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule chapter is being promulgated to provide the reimbursement methodology necessary to determine appropriate reimbursable costs and payments for TennCare services provided by RHCs, FQHCs and FQHCLAs to TennCare enrollees.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The rule chapter is lawfully adopted by the Division of TennCare in accordance with T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109, 71-5-118 and 71-5-130.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The persons and entities most directly affected by this rule chapter are TennCare enrollees, providers, and managed care contractors. The governmental entities most directly affected by this rule chapter is the Tennessee Comptroller of the Treasury, and the Division of TennCare, Tennessee Department of Finance & Administration.

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

The rule chapter was approved by the Tennessee Attorney General. No additional opinion was given or requested.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The promulgation of this rule chapter is anticipated to have a minimal impact on state and local government revenues and expenditures.

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

Donna K. Tidwell
Deputy General Counsel

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

Donna K. Tidwell
Deputy General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

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

GW10119024dt

On April 3, 2019, the Government Operations Committee filed a 75-day stay of the effective date of the rules; new effective date July 13, 2019. See page 25.

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Sequence Number: 01-28-19
Rule ID(s): 8530
File Date: 1/29/19
Effective Date: 4/29/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Division of TennCare
Contact Person:	George Woods
Address:	Division of TennCare 310 Great Circle Road Nashville, TN
Zip:	37243
Phone:	(615) 507-6446
Email:	george.woods@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-13-10	Reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and Federally Qualified Health Center Look-Alikes
Rule Number	**Rule Title**
1200-13-10-.01	Definitions
1200-13-10-.02	Determination of Reimbursable Costs for RHCs, FQHCs, or FQHCLAs
1200-13-10-.03	Medicaid Cost Reporting
1200-13-10-.04	Standard Reimbursement for a New RHC, FQHC, or FQHCLA
1200-13-10-.05	Determination of a Reimbursable Visit
1200-13-10-.06	Determination of Reasonable Costs
1200-13-10-.07	Change in Scope and Final PPS or APM Rate Adjustment
1200-13-10-.08	Standard Reimbursement for an Existing RHC, FQHC, or FQHCLA
1200-13-10-.09	Alternative Payment Methodology for an RHC, FQHC, or FQHCLA
1200-13-10-.10	Auditing of Provider-Reported Data
1200-13-10-.11	PPS Rates Outside of Core Reimbursement Rate
1200-13-10-.12	Provider Appeals
1200-13-10-.13	Implementation of this Chapter

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Sequence Number: 04-06-19
Rule ID(s): N/A
File Date: 4/3/19
Effective Date: 4/3/19

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission:	Tennessee Department of Finance and Administration
Division:	Division of TennCare
Contact Person:	Doug Garrett
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Zip:	37243
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Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/29/19*
Rule Original Effective Date: *04/29/19*
Length of Stay (not to exceed 75 days): 75 days
New Effective Date of Rule Filing: *07/13/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

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1200-13-10-.02	Determination of Reimbursable Costs for RHCs, FQHCs, or FQHCLAs
1200-13-10-.03	Medicaid Cost Reporting
1200-13-10-.04	Standard Reimbursement for a New RHC, FQHC, or FQHCLA

1200-13-10-.05	Determination of a Reimbursable Visit
1200-13-10-.06	Determination of Reasonable Costs
1200-13-10-.07	Change in Scope and Final PPS or APM Rate Adjustment
1200-13-10-.08	Standard Reimbursement for an Existing RHC, FQHC, or FQHCLA
1200-13-10-.09	Alternative Payment Methodology for an RHC, FQHC, or FQHCLA
1200-13-10-.10	Auditing of Provider-Reported Data
1200-13-10-.11	PPS Rates Outside of Core Reimbursement Rate
1200-13-10-.12	Provider Appeals
1200-13-10-.13	Implementation of this Chapter

Date: 04/03/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 3, 2019

8/20/2019

Notary Public Signature: Tamika Lee Whitmore

My commission expires on: 8/20/2019

Department of State Use Only

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Tre Hargett
Secretary of State

2019 APR -3 PM 3:15

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

Rules of the Tennessee Department of Finance and Administration, Division of TennCare, are amended by replacing repealed Chapter 1200-13-10 with a new Chapter 1200-13-10 Reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and Federally Qualified Health Center Look-Alikes which shall read as follows:

Rules
of
Tennessee Department of Finance and Administration
Division of TennCare

Chapter 1200-13-10
Reimbursement for Rural Health Clinics, Federally Qualified Health Centers, and Federally Qualified Health Center Look-Alikes

Table of Contents

1200-13-10-.01 Definitions
1200-13-10-.02 Determination of Reimbursable Costs for RHCs, FQHCs, or FQHCLAs
1200-13-10-.03 Medicaid Cost Reporting
1200-13-10-.04 Standard Reimbursement for a New RHC, FQHC, or FQHCLA
1200-13-10-.05 Determination of a Reimbursable Visit
1200-13-10-.06 Determination of Reasonable Costs
1200-13-10-.07 Change in Scope and Final PPS or APM Rate Adjustment
1200-13-10-.08 Standard Reimbursement for an Existing RHC, FQHC, or FQHCLA
1200-13-10-.09 Alternative Payment Methodology for an RHC, FQHC, or FQHCLA
1200-13-10-.10 Auditing of Provider-Reported Data
1200-13-10-.11 PPS Rates Outside of Core Reimbursement Rate
1200-13-10-.12 Provider Appeals
1200-13-10-.13 Implementation of this Chapter

1200-13-10-.01 Definitions. The following definitions apply to Rural Health Clinic (RHC), Federally Qualified Health Center (FQHC), and Federally Qualified Health Center Look-Alike (FQHCLA) provider reimbursement.

(1) Administrative Costs. Expenses incurred in operating the clinic as a whole which are reasonable and that are related to the cost of administration and management of the clinic and are not directly associated with furnishing patient care. Administrative costs include but are not limited to: office salaries; office supplies; legal, accounting, or billing services; consulting services; insurance; telephone; fringe benefits; and, payroll taxes.

(2) Allowable Costs. Costs that are reasonable in amount and proper and necessary for the efficient delivery of RHC and FQHC services and that are incurred by a participating RHC, FQHC or FQHCLA.

(3) Base Year. The first full fiscal year following the effective date of a provider's registration with TennCare as an RHC, FQHC, or FQHCLA. The data collected during this fiscal year will provide the basis to determine the provider's PPS or APM rate. If a rate is rebased, the period of time on which the rebase is calculated becomes the new base year.

(4) Core Reimbursement Rate. The payment under an established PPS or APM rate for medically necessary primary health services and qualified preventive health services furnished by an RHC, FQHC, or FQHCLA to Medicaid enrollees. Note that additional services of dental, optometry, or pharmacy are reimbursed outside of the core reimbursement rate and a separate rate is calculated for each additional service.

(5) Core Visit. A reimbursable visit that counts toward the Core Reimbursement Rate.

(6) Employee. Any individual who, under the common law rules that apply in determining the employer-employee relationship as defined by § 3121(d)(2) of the Internal Revenue Code of 1986 (26 U.S.C. § 3121(d)(2)), is considered to be employed by, or an employee of, an entity. Application of these common law rules is discussed in 20 C.F.R. § 404.1007 and 26 C.F.R. § 31.3121(d)-1(c).

(7) Federally Qualified Health Center (FQHC). An entity that has been federally certified as an FQHC and meets one (1) of the three following criteria:

(a) Is registered with TennCare as an FQHC; and is receiving a grant under Section 330 of the Public Health Service (PHS) Act (42 U.S.C. § 254b) or is receiving funding from such a grant under a contract with the recipient of such a grant and meets the requirements to receive a grant under Section 330 of the PHS Act; and is determined by the Health Resources and Services Administration (HRSA) to meet the requirements for receiving such a grant; or

(b) Was treated by CMS, for purposes of Medicare Part B, as a comprehensive federally funded health center as of January 1, 1990; or

(c) Is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self–Determination Act or by an Urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(8) Federally Qualified Health Center Look-Alike (FQHCLA). A community-based health care provider that meets the requirements of the HRSA Health Center Program, but does not receive HRSA Health Center Program funding.

(9) Interim Rate. A rate established for new facilities after registration with TennCare as an RHC, FQHC, or FQHCLA and prior to the establishment of a final PPS or APM rate, as required by 42 U.S.C.A. §1396a(bb)(4).

(10) Medicare Cost Report. Form CMS-222 and Form CMS-224, the instructions for which are provided at CMS Publication 15-2, Sections 2908-2908.2, and CMS Publication 15-2, Sections 4404.1-4404.3; or their successor forms or publications.

(11) Non-Core Visit. A reimbursable visit that counts towards a rate established under rule .11.

(12) Non-Core Reimbursement Rate.. The payment under a rate established pursuant to rule .11 for additional services, including but not limited to, dentistry, optometry, or pharmacy services, that are reimbursed outside the Core Reimbursement Rate and where a separate rate is calculated for each additional service.

(13) Owner. A person, persons, or entities with an enforceable claim or title to the asset or property, and is recognized as such by law.

(14) Rebase. A new calculation of a provider's base rate utilizing cost data to determine a new reimbursement rate.

(15) Reimbursable Visit. A visit as defined in this rule and which also meets the requirements of rule .05.

(16) Related Parties. Any person, persons, or entities that are related to the owner, if applicable, either by familial relationship or by a business association other than the RHC, FQHC, or FQHCLA itself.

(17) Rural Health Clinic (RHC). A facility that has:

(a) Been determined by the Secretary of Health and Human Services to meet the requirements of § 1861(aa)(2) of the Social Security Act (42 U.S.C. § 1395x(aa)(2)) and 42 C.F.R. Part 491, concerning RHC services and conditions for approval; and

(b) Filed an agreement with CMS that meets the requirements in 42 C.F.R. § 405.2402 to provide RHC services under Medicare; and

(c) Has registered with TennCare as an RHC.

(18) TennCare. The state governmental agency administratively located within the Tennessee Department of Finance and Administration; includes references to the Division of TennCare, the Bureau of TennCare and to all employees and subdivisions of the agency.

(19) Visit. A medically-necessary face-to-face medical or mental health encounter or a qualified preventive health encounter between the patient and a physician, nurse practitioner (NP), physician's assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), clinical social worker (CSW), licensed professional counselor (LPC), or PharmD during which time one (1) or more qualified RHC, FQHC, or FQHCLA Medicaid covered services are furnished. In certain limited situations, an RHC, FQHC, or FQHCLA visit may also include a visit by a registered professional nurse or a licensed practical nurse to a homebound patient. For a provider that has an established Non-Core Reimbursement Rate, a Non-Core Visit will include a face-to-face encounter with a licensed professional for which the rate was established, during which time one (1) or more qualified Non-Core Visit covered services are furnished.

(20) Acronyms. Following is a list of acronyms used in this chapter:

(a) APM: Alternative Payment Method

(b) CMS: Centers for Medicare and Medicaid Services

(c) CPT: Current Procedural Terminology

(d) FQHC: Federally Qualified Health Center

(e) FQHCLA: Federally Qualified Health Center Look-Alike

(f) FTE: Full Time Equivalent

(g) HRSA: Health Resources and Services Administration

(h) MEI: Medicare Economic Index

(i) PHS: Public Health Service

(j) PPS: Prospective Payment System

(k) RHC: Rural Health Clinic

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.02 Determination of Reimbursable Costs for RHCs, FQHCs, or FQHCLAs.

(1) TennCare, in consultation with the Comptroller of the Treasury, establishes this chapter for the determination of the reimbursable per visit cost for services provided to Medicaid recipients who receive services at an RHC, FQHC, or FQHCLA. The Comptroller, pursuant to an agreement with TennCare, will review cost report and countable visit data submitted by providers to recommend a final PPS or APM rate.

(2) Only a facility registered with TennCare as an RHC, FQHC, or FQHCLA may participate in and be reimbursed as a provider under this chapter. TennCare shall notify the Comptroller of the Treasury when a provider enters the program and when its participation terminates.

(3) The specific items and services covered under the RHC, FQHC, or FQHCLA program shall be those defined and approved by TennCare. See rule .05. Other Medicaid services that are not RHC, FQHC, or FQHCLA services may be provided and billed outside of the PPS or APM payment structure, providing TennCare covers those services.

(4) When calculating an RHC's, FQHC's, or FQHCLA's PPS settlement, the Comptroller and TennCare will multiply the number of reimbursable visits, as determined in rule .05, times the established PPS or APM rate for that facility to calculate the total that should be received for services rendered under each

established Core or Non-Core Reimbursement Rate. From that total, the Comptroller and TennCare will subtract any claims-based reimbursement received for those services to calculate the settlement amount.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.03 Medicaid Cost Reporting.

(1) New and existing RHCs, FQHCs, or FQHCLAs shall, under the Medicare Cost Report Instructions, annually submit a Medicare Cost Report, located on the TennCare website, to the Comptroller by the due date imposed by Medicare. This cost report shall be for the RHC's, FQHC's, or FQHCLA's most recent fiscal year that ends at least six months before July 1.

(2) New and existing RHCs, FQHCs, or FQHCLAs shall annually submit a supplemental Medicaid Cost Report, which will be located on the TennCare website, to the Comptroller by the same due date for the Medicare Cost Report. This cost report shall be for the RHC's, FQHC's, or FQHCLA's most recent fiscal year that ends at least six months before July 1.

(3) Along with a Medicare Cost Report and supplemental Medicaid Cost Report, an RHC, FQHC, or FQHCLA shall submit to the Comptroller annually by the same due date imposed by Medicare for the Medicare Cost Report, a written statement of the RHC's, FQHC's, or FQHCLA's maximum hours per day, days per week, and weeks per year of operation, trial balance, detailed general ledger, depreciation schedule, schedule listing allocations, all management and consulting contracts, all billing NPI numbers, a listing of all related parties with which the provider does business, total visit log, schedule of owner's compensation, a schedule of all employee salaries by title, documentation for reclassification, and adjustments. If an RHC, FQHC, or FQHCLA does not submit this written statement, TennCare shall continue to pay the RHC, FQHC, or FQHCLA as it pays primary care centers that are not an RHC, FQHC, or FQHCLA.

(4) RHCs, FQHCs, or FQHCLAs that have just undergone an ownership change will continue to receive the same rate as before the ownership change. The new owner may formally request the setting of a new rate from TennCare. TennCare will consult with the Comptroller and evaluate the request and determine whether to issue a new rate.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.04 Standard Reimbursement for a New RHC, FQHC, or FQHCLA.

(1) New RHCs, FQHCs, or FQHCLAs are those providers which meet the definition for the provider type in rule .01 but did not register with TennCare prior to the implementation of the moratorium on the registration of new facilities approved by CMS on October 25, 2017 and have not had a final PPS or APM rate established by the Comptroller. New providers shall be reimbursed using an interim rate based on the average rate of similar entities (other FQHCs for an FQHC, or other RHCs for an RHC) in the same Grand Division, or in the entire state if there are not enough similar entities in the same Grand Division.

(2) Upon receipt of a Medicare Cost Report and supplemental Medicaid Cost Report submitted by an RHC, FQHC, or FQHCLA to the Comptroller as required by rule .03, the Comptroller shall:

(a) Review the Medicare Cost Report and supplemental Medicaid Cost Report; and

(b) Notify the RHC, FQHC, or FQHCLA if additional documentation is necessary.

(c) 1. If additional documentation is necessary to establish a final PPS rate or APM rate, the RHC, FQHC, or FQHCLA shall:

(i) Provide the additional documentation to the Comptroller within thirty (30) days of the notification of need for additional documentation; or

(ii) Request an extension beyond thirty (30) days to provide the additional documentation.

2. The Comptroller has full discretion on whether to grant the extension.

3. An extension shall not exceed thirty (30) days.

(d) 1. If the Comptroller requests additional documentation from the RHC, FQHC, or FQHCLA but does not receive additional documentation or an extension request within thirty (30) days, TennCare shall reimburse the RHC, FQHC, or FQHCLA as it reimburses primary care centers that are not an RHC, FQHC, or FQHCLA until:

(i) The additional documentation has been received by the Comptroller; and

(ii) The Comptroller has established a final PPS or APM rate.

2. If an RHC, FQHC, or FQHCLA does not submit both a Medicare Cost Report and supplemental Medicaid Cost Report to the Comptroller, TennCare shall reimburse the RHC, FQHC, or FQHCLA as it reimburses primary care centers that are not an RHC, FQHC, or FQHCLA until the RHC, FQHC, or FQHCLA submits both a Medicare Cost Report and supplemental Medicaid Cost Report to the Comptroller.

(e) The Comptroller may review an RHC's, FQHC's, or FQHCLA's paid claims listing for the period of time corresponding to the submitted cost report.

(f) When an RHC, FQHC, or FQHCLA has submitted all necessary information to the Comptroller, within one hundred twenty (120) days, the Comptroller shall:

1. Establish a final PPS rate for the RHC, FQHC, or FQHCLA; and

2. Notify the RHC, FQHC, or FQHCLA in writing of the RHC's, FQHC's, or FQHCLA's Final PPS or APM rate.

(g) Upon setting the final rate, TennCare shall reconcile all quarterly settlements made under the interim rate to the final rate, adjusting payments upward or downward as necessary.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.05 Determination of a Reimbursable Visit.

(1) RHCs, FQHCs, or FQHCLAs shall only be reimbursed for visits paid by a TennCare managed care contractor (MCC). This applies to both the PPS and APM methodologies. Claims for visits denied by an MCC that met all filing requirements of all state and federal laws and regulations, as well as the applicable MCC provider agreement, may be submitted to TennCare to be considered a reimbursable visit. Reimbursement determinations will be made at the discretion of TennCare upon consultation with the Comptroller. If TennCare determines a visit shall not be counted as a reimbursable visit based on the denied claim, the provider may appeal the determination pursuant to rule .12.

(2) TennCare shall adopt or amend a list of CPT codes that will be published on the TennCare website. The list of CPT codes will be presumed reimbursable visits for both the PPS and APM methodologies and may be periodically updated with additions, deletions, or modifications. TennCare will post any amendments to the list on its website at least thirty (30) days prior to making any changes. When amendments to the CPT codes list become effective, any changes in payments to providers will also become effective on the same date.

(3) If an encounter between an RHC, FQHC, or FQHCLA provider and a TennCare enrollee involves a CPT code that is not on the TennCare CPT codes list, the RHC, FQHC, or FQHCLA may request reimbursement for the CPT code. Requests for inclusion of a CPT code not on the TennCare codes list shall be made via the visit report and the decision regarding inclusion will be at the discretion of TennCare upon consultation with the Comptroller. If TennCare determines a requested CPT code will not be included for reimbursement, the provider may appeal the determination pursuant to rule .12.

(4) An encounter for the sole purpose of medication therapy management, whether provided by a pharmacist or other provider, shall not be considered a reimbursable visit, as payment for this service is made outside of the PPS or APM methodology.

(5) An encounter or service related to patient-centered medical home payments, including the activity payments, practice transformation payments, and outcome payments, shall not be considered a reimbursable visit, as payment for this service is made outside of the PPS or APM methodology.

(6) An encounter or service related to Tennessee Health Link payments, including activity payments and outcome payments, shall not be considered a reimbursable visit, as payment for this service is made outside of the PPS or APM methodology.

(7) An encounter or service related to any other types of payment reform initiatives that may be implemented by TennCare, structured as per member per month case rates or outcome payments based on established performance criteria, shall not be considered a reimbursable visit, as payment for this service is made outside of the PPS or APM methodology.

(8) If an encounter includes both a medical visit and a mental health visit, the RHC, FQHC, or FQHCLA shall report it as two separate visits. This applies to both the PPS and APM methodologies. In addition, the RHC, FQHC, or FQHCLA shall be allowed to submit both a core visit and a non-core visit for the same patient on the same day.

(9) An RHC, FQHC, or FQHCLA shall not report multiple CPT codes that comprised one (1) visit as multiple visits in a submission to the Comptroller, except when a minor child receives both a well-child visit and a sick visit at the same time, each visit may be billed separately for a maximum of two (2) allowable paid TennCare visits. This applies to both the PPS and APM methodologies.

(10) Medicare Crossover claims are ineligible for being counted as visits in either the PPS or APM methodologies.

(11) Each billed item for patient care must include an invoice date and at least one (1) CPT code for the visit to be considered a reimbursable visit in either the PPS or APM methodologies.

(12) For both PPS and APM purposes, the RHC, FQHC, or FQHCLA must submit visits to the Comptroller using the template that will be posted at the TennCare website, in order for the visits to be reimbursed. All data elements on the template must be complete and in the requested format for a claim to be considered as a visit. TennCare may change the template after providing at least thirty (30) days prior notice.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.06 Determination of Reasonable Costs.

(1) Only reasonable costs will be reimbursed under this chapter. It is within the Comptroller's discretion to determine what is a reasonable cost and if it may be reimbursed in accordance with this chapter.

(2) The following factors will be considered in determining reasonable costs:

(a) Fees paid by an RHC, FQHC, or FQHCLA pursuant to any contract to pay contingency fees for consulting, accounting, bookkeeping or similar services, or any contract to pay the vendor a percentage of the fees recovered from TennCare, will be presumed unreasonable and will not be reimbursed.

(b) Imputed salaries will be presumed unreasonable. All salary amounts must be reported on an IRS Form W-2 or an IRS Form 1099 to be considered for reasonableness.

(c) Salaried or contracted costs shall be accompanied by an FTE calculation.

(d) Owner's compensation and compensation to any related parties claiming salary or wages from the RHC, FQHC, or FQHCLA will be indexed to the Tennessee Occupational Employment and Wage Rates or other sources as determined by the Comptroller and will be paid only in circumstances as described in this rule. Compensation exceeding the indexed amount will be presumed unreasonable.

(e) For any employee or owner whose job functions include responsibilities other than direct patient care, the RHC, FQHC, or FQHCLA will be required to report the total number of hours the employee or owner spent performing functions that were not direct patient care.

(f) Administrative costs will be capped at thirty percent (30%) of the total costs, with imputed costs excluded. Total administrative costs exceeding 30% will be presumed unreasonable. Actual administrative costs must be established by each facility.

(3) For reimbursement purposes, a reasonable allowance or compensation for services of an owner shall be subject to the following:

(a) The services provided by the owner must be a necessary function, meaning that had the owner not rendered the services, the facility would have been required to employ another person to perform them. The services must be related to patient care or pertinent to the operation and sound management of the facility. TennCare shall be responsible for determining which services are related to patient care and pertinent to the operation and sound management of the facility, upon consultation with the Comptroller.

(b) Total compensation to owners must be listed on the Medicare Cost Report. Where these amounts include items other than salaries, a schedule must be attached that identifies the amounts and the method of assigning values to these benefits.

(c) The Comptroller's Office will review these amounts and compare them with allowable compensation ranges and make necessary adjustments. The Comptroller will consider the duties, responsibilities, and managerial authority of the owner as well as the services performed for other facilities and his engagements in other occupations. Only one-and-one-half (1.5) full-time positions, or the equivalent, will be allowed for each owner. Individual owner(s) and related party(ies) will be allowed no more than one (1.0) full-time position each, or the equivalent, for hours performing administrative functions. The duties performed, time spent, and compensation received by the owner must be substantiated by appropriate records.

(4) The Comptroller may review any item in the cost report for reasonableness and to determine whether it should be an allowable cost.

(5) This rule applies to both the standard PPS and APM methodologies.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.07 Change in Scope and Final PPS or APM Rate Adjustment.

(1) (a) If an RHC, FQHC, or FQHCLA changes its scope of services after the base year rate is established, the Comptroller shall adjust its final PPS or APM rate if the change in scope qualifies for an adjustment under this rule, upon review and approval of the change in scope.

(b) An adjustment to a final PPS or APM rate resulting from a change in scope that occurred after an RHC's, FQHC's, or FQHCLA's base year rate is established shall be effective from the beginning of the quarter that the change in scope request was submitted.

(2) A change in scope of service shall be restricted to:

(a) A change in type: adding or deleting a Medicaid-covered ambulatory service; or

(b) A change in intensity: a change in the type or quality of services offered in an average visit such that the average patient receives a different array of services than the service mix patients received when the PPS or APM rate was last set. Examples include changes caused by new statutory or regulatory requirements or the introduction or expansion of specialty care; or

(c) A change in duration: a change in the average length of time it takes RHC, FQHC, or FQHCLA providers to complete an average patient visit due to changing circumstances such as the introduction of a health care delivery system transformation program or patient-centered care, or a

change in patient demographics including, but not limited to, populations with HIV or AIDS or other chronic diseases, homeless, elderly, migrant, or other special populations; or

(d) A Change in amount: an increase or decrease in the quantity of services that an average patient receives in an average Medicaid-covered visit such as improvements to technology or facilities that result in increased services to the RHC's, FQHC's, or FQHCLA's patients; or

(e) A statutory or regulatory change that materially impacts the costs or visits of an RHC, FQHC, or FQHCLA.

(3) The following items individually shall not constitute a change in scope:

(a) A general increase or decrease in the costs of existing services;

(b) A reduction or an expansion of hours per day, days per week, or weeks per year;

(c) A wage increase;

(d) A renovation or other capital expenditure;

(e) A change in ownership; or

(f) An addition of a service that is not a TennCare covered service.

(4) (a) The addition of a new category of service shall be restricted to the addition of a licensed professional staff member who can perform a Medicaid covered service that is not currently being performed within the RHC, FQHC, or FQHCLA by a licensed professional employed or contracted by the facility.

(b) The deletion of a category of service shall be restricted to the deletion of a licensed professional staff member who performed a Medicaid covered service that was being performed within the RHC, FQHC, or FQHCLA by the licensed professional staff member.

(5) The Comptroller shall consider a change in scope request due to a statutory or regulatory change that materially impacts the costs of visits at an RHC, FQHC, or FQHCLA if:

(a) A government entity imposes a mandatory minimum wage increase and the increase was:

1. Not included in the calculation of the final PPS or APM rate; or

2. Not subsequently included in the MEI applied yearly; or

(b) A new licensure requirement or modification of an existing requirement by the state results in a change that affects all facilities within the class. A provider shall document that an increase or decrease in the cost of a visit occurred as a result of a licensure requirement or policy modification; or

(c) The state imposes new requirements on its managed care plans that are then passed down as obligations to the RHCs, FQHCs, or FQHCLAs, if the obligations result in an increase in clinic costs of at least five percent (5%).

(6) A requested change in scope shall:

(a) Increase or decrease the existing final PPS or APM rate by at least five percent (5%);

(b) Remain in effect at least twelve (12) months; and

(c) Be submitted to the Comptroller as a written detailed description including documentation of the service change.

1. For the addition of a service: the description must include the service the RHC or FQHC is adding, the location(s) offering the service, the date the RHC or FQHC began providing the

service, and a brief description of how the new service will benefit the patient population.

2. For a change in intensity, duration, or amount: the description must include the service change, the location(s) where the change has occurred, a description of how the average visit has changed from when the RHC's or FQHC's rate was set, along with relevant supporting documentation, and how the change has benefitted the patient population.

(7) (a) An RHC, FQHC, or FQHCLA that requests a change in scope shall submit the following documents to the Comptroller within twelve (12) months of the requested effective date of a change in scope:

1. A narrative describing the change in scope;

2. A Medicare Cost Report for the affected fiscal year; and

3. Relevant documentation including a trial balance, depreciation schedule, detailed general ledger, schedule listing allocations, total visit log, schedule of owner's compensation, a schedule of all employee's salaries by title, a list of related parties, documentation for reclassification, and adjustments.

(b) If the Comptroller requests information from the provider and does not receive the required documentation within ninety (90) days, the change in scope shall be denied.

(c) 1. The Comptroller shall:

(i) Review the documentation listed in this rule; and

(ii) Notify the RHC, FQHC, or FQHCLA in writing of the:

(I) Approval or denial of the request for change in scope within ninety (90) days from the date the Comptroller received the request; or

(II) Need for additional documentation from the RHC, FQHC, or FQHCLA to establish a final PPS or APM rate associated with the change in scope.

2. If the Comptroller requests additional documentation to calculate the final PPS or APM rate for a change in scope, the RHC, FQHC, or FQHCLA shall:

(i) Provide the additional documentation to the Comptroller within thirty (30) days of the request for additional documentation; or

(ii) Request an extension beyond thirty (30) days to provide the additional documentation.

3. (i) An extension shall not exceed thirty (30) days.

(ii) The Comptroller shall have complete discretion regarding whether to grant or deny an extension.

4. If the Comptroller approves the request for a change in scope and receives all of the necessary documentation from an RHC, FQHC, or FQHCLA within the timelines established in this rule, the facility shall begin receiving the current PPS or APM rate for any newly approved service associated with the change in scope until a final rate can be set.

5. If an RHC, FQHC, or FQHCLA has submitted all necessary information to the Comptroller, within one hundred twenty (120) days, the Comptroller shall:

(i) Establish a final PPS or APM rate for the RHC, FQHC, or FQHCLA; and

(ii) Notify the RHC, FQHC, or FQHCLA in writing of the RHC's, FQHC's, or FQHCLA's Final PPS or APM rate.

(8) If an RHC, FQHC, or FQHCLA requests a change in scope and it is granted, all of the rates, including the Core Reimbursement Rate and other rates outside the Core Reimbursement Rate, will be rebased.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.08 Standard Reimbursement for an Existing RHC, FQHC, or FQHCLA.

(1) Existing RHCs, FQHCs, or FQHCLAs are those providers which meet the definition for the provider type in rule .01 and either registered with TennCare prior to implementation of the moratorium on the registration of new facilities approved by CMS on October 25, 2017 or have a final PPS or APM rate established by the Comptroller.

(2) For existing providers, for a visit by a recipient who is a TennCare enrollee, TennCare shall reimburse:

(a) An RHC, FQHC, or FQHCLA: a quarterly settlement based on the final PPS or APM rate as required by 42 U.S.C. 1396a(bb); or

(b) A satellite facility of an RHC, FQHC or FQHCLA: a quarterly settlement based on the final PPS or APM rate.

(3) The Comptroller shall calculate a final PPS or APM rate for a new RHC, FQHC, or FQHCLA under rule .04.

(4) The Comptroller shall adjust a final PPS or APM rate:

(a) By the percentage increase in the MEI applicable to RHC services on July 1 of each year; or

(b) By the market basket measure for FQHC and FQHCLA services; and

(c) As permitted by rule .07:

1. Upon request and documentation by an RHC, FQHC, or FQHCLA that there has been a change in scope of services; or

2. Upon review and determination by the Comptroller that there has been a change in scope of services; or

3. If necessary as a result of a desk review or audit.

(5) A final PPS or APM rate established under this rule shall not be subject to an end of the year cost settlement.

(6) Upon both this chapter becoming effective and TennCare's corresponding State Plan Amendment being approved by CMS, the Comptroller will review all PPS rates using the cost data used to set those rates if available, or if not, using the newest available cost data of at least 12 months, in order to determine if the included costs are allowable costs according to the requirements in this chapter. If it is determined that some of the costs are not allowable costs according to this chapter, the RHC, FQHC, or FQHCLA will be offered the opportunity to change to an APM methodology and either:

(a) Accept an APM methodology where the APM rate will equal the previous final rate established for the facility prior to the Comptroller's review. This APM rate will receive no annual inflationary adjustment until it is determined that the revised PPS rate plus annual inflationary adjustments has surpassed this APM rate. At that point, the APM rate will equal the PPS rate and receive annual inflationary adjustments as described in this rule; or

(b) Accept the revised PPS rate established pursuant to the Comptroller's review under this paragraph.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.09 Alternative Payment Methodology for an RHC, FQHC, or FQHCLA.

(1) TennCare may offer to an RHC, FQHC, or FQHCLA, for which a final PPS rate exists, an alternative payment methodology. The RHC, FQHC, or FQHCLA, at the RHC, FQHC, or FQHCLA's election, may receive the alternative payment methodology rate if it notifies TennCare in writing that it elects to receive the alternate reimbursement.

(2) Establishment of base years and periodic rebasing.

(a) If the RHC, FQHC, or FQHCLA elects to use the alternative payment methodology, it will undergo establishment of a new base year. The Comptroller shall collect and review Medicare Cost Report data from the previous two (2) fiscal years, or if the provider has been in existence for fewer than two (2) years, then for as many months as are available, and use this data to compute a new PPS rate, which will be called the APM rate. A minimum of twelve (12) months data must be available in order to set an APM rate, and the rate must be rebased as soon as there are twenty-four (24) months of available cost report data.

(b) Following that rebase year, the APM rate for an RHC, FQHC, or FQHCLA shall be adjusted by the market basket measure applicable to FQHC and FQHCLA services on July 1 of each year.

(c) The factors included in rule .06 will be calculated into the APM rate.

(d) The Comptroller may perform a rebase of all RHCs, FQHCs, or FQHCLAs no more than one (1) time per fiscal year and no less than one (1) time every five (5) fiscal years, without prior notice and using the previous two (2) fiscal years of Medicare Cost Report data.

(e) The Comptroller may not offer, and an RHC, FQHC, or FQHCLA may not collect, the APM rate unless the APM rate is equal to or higher than the Standard PPS Rate, as calculated according to this chapter. When an APM rate is first implemented, or when it is rebased, TennCare will ensure that the APM rate is equal to or greater than the Standard PPS Rate as calculated according to the provisions in this chapter.

(f) The offer of the APM is valid for only the year in which the payment is offered. Entities that do not choose the APM in the year it is offered will be required to wait until APM is offered again. This will be a minimum of five (5) years.

(3) If a facility elects to use the APM, it must use the APM for all rates, including the Core Reimbursement Rate and those rates outside of the Core Reimbursement Rate.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.10 Auditing of Provider-Reported Data.

(1) The cost reports and visit reports filed under this chapter by an RHC, FQHC, or FQHCLA, and all pertinent provider records shall be subject to audit by the Comptroller of the Treasury or his agents based on the criteria in this chapter or the Medicare regulations, as applicable.

(2) The cost reports filed under this chapter must provide adequate cost and statistical data. This data must be:

(a) Based on and traceable to the provider's financial and statistical records; and

(b) Adequate, accurate and in sufficient detail to support payment made for services rendered to enrollees; and

(c) Available for and capable of verification by the Comptroller of the Treasury or his agents.

(3) The provider shall permit the Comptroller or his agents to examine any records and documents necessary to ascertain information pertinent to the determination of the proper amount of program payments due.

(4) Data reflected on the cost report which cannot be substantiated may be disallowed with reimbursement being required of the provider.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.11 PPS Rates Outside of Core Reimbursement Rate.

RHCs, FQHCs, or FQHCLAs are permitted to establish Non-Core Reimbursement Rates for services outside of the Core Reimbursement Rate, including but not limited to, dental, pharmacy, and optometry. In order to do this, a request must be submitted to the Comptroller to set these rates. All provisions in this rule apply to Non-Core Reimbursement Rates in the same way that they apply to Core Reimbursement Rates.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109 and 71-5-130.

1200-13-10-.12 Provider Appeals.

Information contained in a provider's cost and visit reports or supplemental filings required to be submitted to the Comptroller by this chapter is utilized by the Comptroller to determine reimbursement. Reimbursement rate determinations made by the Comptroller and implemented by the Bureau shall be appealable as set out in Chapter 1200-13-18. A provider may request review of Reimbursable Visit determinations pursuant to rule .05 paragraphs (1) and (3). A denial following review by TennCare shall be appealable pursuant to Chapter 1200-13-18.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109, 71-5-118 and 71-5-130.

1200-13-10-.13 Implementation of this Chapter.

It is the intention of TennCare that this Chapter 1200-13-10 shall become effective the later of the date of effectiveness assigned by the Secretary of State or the date the corresponding State Plan Amendment is approved by CMS.

Statutory Authority: T.C.A. §§ 4-5-202, 71-5-105, 71-5-107, 71-5-109, 71-5-118 and 71-5-130.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Division of TennCare on 01/24/2019 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 09/26/18

Rulemaking Hearing(s) Conducted on: (add more dates). 11/27/18

Date: 1/24/19

Signature:

Name of Officer: John G. Roberts

Title of Officer: Director, Division of TennCare
Tennessee Department of Finance and Administration

VICKI L JOHNSON
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SUMNER
MY COMMISSION EXPIRES: MAY 17, 2021

Subscribed and sworn to before me on: 1/24/19

Notary Public Signature: Vicki L Johnson

My commission expires on: May 17, 2021

Agency/Board/Commission: Division of TennCare

Rule Chapter Number(s): 1200-13-10

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

1/25/2019
Date

Department of State Use Only

2019 JAN 29 PM 5:21
SECRETARY OF STATE

Filed with the Department of State on: 1/29/19

Effective on: 4/29/19

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Middle Tennessee State University
SUBJECT:	Public Records – Inspecting and Copying
STATUTORY AUTHORITY:	Tennessee Code Annotated, § 10-7-503(g)(2), requires state government entities to promulgate rules regarding public records that meet the requirements of § 10-7-503(g)(1).
EFFECTIVE DATES:	June 2, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	Previously, MTSU adopted and followed the Comptroller's Office of the Open Records model policy related to responding to requests for public records. The proposed rule does not materially change MTSU's previous policy or processes for responding to such requests.

Regulatory Flexibility Addendum

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

This rule is not anticipated to have an impact on small businesses.

Impact on Local Governments

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

This rule is not anticipated to have an impact on local government.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Previously, MTSU adopted and followed the Comptroller's Office of the Open Records model policy related to responding to requests for public records. The proposed rule does not materially change MTSU's previous policy or processes for responding to such requests.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 10-7-503(g)(2) requires state government entities to promulgate rules regarding public records that meet the requirements of T.C.A. § 10-7-503(g)(1).

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The MTSU Board of Trustees urges adoption. Individuals/entities that wish to review public records of the State of Tennessee are directly affected by this rule. MTSU believes the rule is consistent with the intent of the law, namely to create transparency in its operations, but does not know whether interested individuals/entities would urge adoption or rejection of this rule.

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

None known.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

None

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

Heidi Zimmerman, MTSU University Counsel

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

Heidi Zimmerman, MTSU University Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Heidi Zimmerman

MTSU University Counsel
1301 E. Main Street, CAB 209
Murfreesboro, TN 37132
615-898-2025
Heidi.zimmerman@mtsu.edu

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

On April 2, 2019, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 2, 2019. See page 16.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 01-10-19
Rule ID(s): 8050
File Date: 1/3/19
Effective Date: 4/3/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission: Middle Tennessee State University
Division:
Contact Person: Heidi Zimmerman, University Counsel
Address: 1301 E. Main Street, CAB 209, Murfreesboro, TN
Zip: 37132
Phone: 615-898-2025
Email: Heidi.zimmerman@mtsu.edu

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0240-07-01	Public Records – Inspecting and Copying
Rule Number	**Rule Title**
0240-07-01-.01	Purpose
0240-07-01-.02	Definitions
0240-07-01-.03	Procedures to Access Public Records
0240-07-01-.04	Copying of Public Records
0240-07-01-.05	Aggregation of Frequent and Multiple Requests

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
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Sequence Number: 04-03-19
Rule ID(s): NA
File Date: 4/2/2019
Effective Date: 4/2/2019

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission: Middle Tennessee State University
Division:
Contact Person: Doug Garrett
Address: 425 5th Avenue North, Suite 922; Nashville, TN
Zip: 37243
Phone: (615) 741-9532
Email: doug.garrett@capitol.tn.gov

Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/03/19*
Rule Original Effective Date: *04/03/19*
Length of Stay (not to exceed 75 days): 60 days
New Effective Date of Rule Filing: *06/02/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/RuleTitle per row)

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0240-07-01-.03	Procedures to Access Public Records
0240-07-01-.04	Copying of Public Records
0240-07-01-.05	Aggregation of Frequent and Multiple Requests

Date: 04/02/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 2, 2019

Notary Public Signature: Franklin Lee Whitmore

My commission expires on: 8/20/2019

My Commission Expires 8/20/2019

Department of State Use Only

Filed with the Department of State on: 4/2/2019

Tre Hargett
Secretary of State

2019 APR -2 PM 1:07
SECRETARY OF STATE

Rules
of
Middle Tennessee State University, Murfreesboro
Chapter 0240-07-01
Public Records – Inspecting and Copying

New

Table of Contents is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

Table of Contents

0240-07-01-.01 Purpose
0240-07-01-.02 Definitions
0240-07-01-.03 Procedures to Access Public Records
0240-07-01-.04 Copying of Public Records
0240-07-01-.05 Aggregation of Frequent and Multiple Requests

0240-07-01-.01 Purpose is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

0240-07-01-.01 Purpose

(1) This rule establishes the process under Tennessee's Public Records Act for making and responding to requests to inspect and/or copy records, including redaction practices; the fees charged for copies of public records; the procedures for billing and payment; and the name or title and contact information of the public records request coordinator.

Authority: T.C.A. § 10-7-503.

0240-07-01-.02 Definitions is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

0240-07-01-.02 Definitions

(1) Records Custodian. The MTSU office(s) or employee(s) lawfully responsible for the direct custody and care of a public record.

(2) Public Records. All documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, electronic mail messages, films, sound recordings, or other material regardless of physical form or characteristics, made or received pursuant to law or in connection with the transaction of official University business and required to be open to inspection under the provisions of Tennessee law.

(3) Public Records Request Coordinator (Coordinator). The individual (or designee) responsible for ensuring that public records requests are routed to the appropriate records custodian and that requests are fulfilled in accordance with the Public Records Act.

(4) Requestor. A person seeking access to a public record, whether it is for inspection or duplication.

Authority: T.C.A. § 10-7-503.

0240-07-01-.03 Procedures to Access Public Records is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

0240-07-01-.03 Procedures to Access Public Records

(1) Generally.

(a) Except for confidential records as prescribed by law, public records will be open for inspection by citizens of Tennessee during business hours which shall be the business hours of the University's administrative offices.

(b) Requests for inspection only may be made orally and cannot be required to be made in writing. Requests for copies, or requests for inspection and copies, must be made in writing. The Request to Inspect or Copy Public Records form may be used, but a written request in any form or format will be acceptable. Requests may be made to the Coordinator

(c) Persons requesting to inspect or copy records must show proof of Tennessee citizenship with a government-issued photo identification card including the person's address (i.e., driver's license, voter's registration, etc.).

(2) Public Records Request Coordinator.

(a) MTSU will publish the name, telephone number, email address and office location of the Coordinator .

(b) The Coordinator shall review public record requests and make an initial determination of the following:

1. if the requestor provided evidence of Tennessee citizenship;

2. if the records requested are described with sufficient specificity to identify them; and

3. if MTSU is the custodian of the records.

(c) The Coordinator shall acknowledge receipt of the request and take any of the following appropriate action(s):

1. Advise the requestor of determinations made regarding:

(i) proof of Tennessee citizenship;

(ii) form(s) required for copies;

(iii) fees and charges, including labor and programming costs;

(iv) aggregation of multiple or frequent requests.

2. Provide the records.

3. Deny the request in writing using the Public Records Request Response, which shall indicate the basis for the specific legal denial, including, but not limited to:

(i) the requestor is not, or has not presented evidence of being, a Tennessee citizen;

(ii) the request lacks specificity;

(iii) an exemption makes the record not subject to disclosure;

(iv) the University is not the custodian of the requested records;

(v) the records do not exist.

4. If appropriate, contact the requestor to see if the request can be narrowed or the scope of the request clarified.

5. Forward the records request to the appropriate records custodian.

6. If the Coordinator knows that the requested records are in the custody of a different governmental entity, advise the requestor of the correct governmental entity and the coordinator for that entity, if known.

(3) The University is not required to sort through files to compile information, create records, or recreate records that do not exist.

(4) Form or Format of Record to be Inspected/Copied. Actual records will be produced or used for viewing and/or copying. The nature of certain records and applicable confidentiality requirements, however, may result in providing the requested record/information in a form or format other than the original records form or format. In such cases, the records custodian may coordinate with the requestor to find an alternate form or means of providing access to the same desired record or information as available under the open records laws.

(5) Redaction.

(a) With the exception of records which are confidential in their entirety (for example, student education records protected by FERPA), if a record contains confidential information or information that is not open for public inspection, the records custodian shall prepare a redacted copy prior to providing the records for inspection or copies of the records.

(b) Whenever a redacted record is provided, the records custodian should provide the requestor with the basis for redaction. The basis given shall be general in nature and not disclose confidential information.

(6) Inspection of Records. If the request is to inspect records, the records custodian will arrange a location for the requestor to do so and may, under reasonable circumstances, require an appointment for inspection. Inspection must be made in the presence of the records custodian. Custody of the original record is not to be relinquished.

(7) Time Required to Produce Records. All efforts will be made to provide the records within a reasonable period of time. If the record cannot be produced within seven (7) business days (i.e., time is needed to determine if the records exist; additional time is needed to search for, retrieve, or otherwise gain access to records; or it will take additional time to redact confidential information from the record), the requestor shall be advised when the record(s) will be available using a Public Records Request Response. If the request will be denied, a Public Records Request Response must be sent within seven (7) business days.

Authority: T.C.A. § 10-7-503.

0240-07-01-.04 Copying of Public Records is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

0240-07-01-.04 Copying of Public Records

(1) The records custodian will make copies, or arrange for copies to be made, as well as determine copy fees and charges in the most economic and efficient manner practicable. An itemized estimate of the charges to be assessed for copies and labor should be provided to the requestor using the Request to Inspect or Copy Public Records form prior to producing the requested copies. Payment of fees and charges are to be made in advance. A requestor will be allowed to make copies of records with a camera or a cell phone if the number of pages to be copied is twenty-five (25) pages or less.

(2) Copy Format

(a) Notwithstanding the form of the records, reproduction or copying of records shall be made in a form as best determined by the records custodian.

(b) Electronic data and documents will be produced in a read-only format.

(c) If the requested records exist electronically, but not in the format requested, or a new or modified computer program or application is necessary to put the records in a readable and reproducible format; or it is necessary to access backup files, the records custodian shall charge the requestor the actual costs incurred in producing the records in the format requested, or in creating or modifying a computer program or application necessary to put the records in a readable and reproducible format, or in accessing backup files.

(d) Records should be produced electronically whenever feasible as a means of utilizing the most cost effective method of producing records.

(3) If a records custodian reasonably determines that production of records should be segmented because the records request is for a large volume of records, or additional time is necessary to prepare the records for access, the records custodian shall notify the requestor by using the Public Records Request Response form that production of the records will be in segments and that a records production schedule will be provided as expeditiously as practicable.

(4) If a records custodian discovers records responsive to a records request were omitted, the requestor should be contacted concerning the omission and the records produced as quickly as possible.

(5) Copies will be available for pickup at a location specified by the records custodian. At the requestor's request, and upon payment of postage, copies will be mailed to the requestor via USPS first-class mail.

(6) Fees and Charges.

(a) No fees or charges may be imposed for inspection of records, even if copies of records were required to be made to allow for redaction of confidential information.

(b) An itemized estimate of the fees and charges should be provided to the requestor. Payment of this amount must occur prior to copies being made. Payment in full of the actual costs must be made prior to release of the requested copies. Both the estimated charges and the actual charges may be included on the Request to Inspect or Copy Public Records form.

(c) MTSU will publish the per page copy charges and a schedule of any other costs. Labor charges will be calculated and imposed as allowed by the Office of Open Records Counsel.

(7) If the total amount of fees, labor/programming charges, and postage is less than twenty dollars ($20.00), the cost will be waived.

Authority: T.C.A. § 10-7-503.

0240-07-01-.05 Aggregation of Frequent and Multiple Requests is added to Chapter 0240-07-01 Public Records – Inspecting and Copying and shall read as follows:

0240-07-01-.05 Aggregation of Frequent and Multiple Requests

(1) MTSU will aggregate record requests in accordance with the Frequent and Multiple Request Policy promulgated by the Office of Open Records Counsel when more than four (4) requests are received within a calendar month either from a single individual or a group of individuals deemed working in concert.

(2) The level at which records requests will be aggregated is by office.

(3) The Coordinator is responsible for making the determination that a group of individuals are working in concert. The Coordinator or records custodian must inform the individuals of this determination and that they have the right to appeal the decision to the Office of Open Records Counsel.

Authority: T.C.A. § 10-7-503.

* 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)
Andy Adams	X				
J.B. Baker	X				
Pete DeLay	X				
Darrell Freeman, Sr.	X				
Joey Jacobs	X				
Christine Karbowiak				X	
Stephen B. Smith	X				
Pamela Wright				X	
Tony Johnston	X				

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Board on 12/11/2018, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: 12-12-18

Signature: Heidi Zimmerman

Name of Officer: Heidi Zimmerman

Title of Officer: University Counsel

Subscribed and sworn to before me on: 12/12/18

Notary Public Signature: Sherry Preston

My commission expires on: 3/23/21

SHERRY PRESTON
STATE OF TENNESSEE NOTARY PUBLIC
RUTHERFORD COUNTY
MY COMMISSION EXPIRES 3-23-2021

Agency/Board/Commission: Middle Tennessee State University

Rule Chapter Number(s): Chapter 0240-07-01

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

12/21/2018
Date

Department of State Use Only

Filed with the Department of State on: 1/3/19

Effective on: 4/3/19

Tre Hargett
Secretary of State

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2019 JAN -3 PM 1:57
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PUBLICATIONS

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Safety and Homeland Security
DIVISION:	Driver License Issuance
SUBJECT:	Classified and Commercial Driver Licenses and Temporary Driver Licenses
STATUTORY AUTHORITY:	The Real ID Act of 2005, Pub.L. 109-13, 119 Stat. 302, enacted May 11, 2005.
EFFECTIVE DATES:	June 30, 2019, through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rulemaking hearing rule sets forth the requirements and procedure for issuing Federally Compliant Licenses, pursuant to the Real ID Act of 2005.

Public Hearing Comments

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

On December 17, 2018, the Department of Safety and Homeland Security held a rulemaking hearing regarding the proposed Rules and Regulations for Federally Compliant Licenses, Rule 1340-03-13.

At the hearing, there was no one in attendance and no public comments were presented. The record was held open for an additional two (2) weeks for further written comments to be submitted. No written comments were received during the comment period or the additional two week period.

Regulatory Flexibility Addendum

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

This rule will not affect small businesses.

Impact on Local Governments

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

This rule will have no impact on local government.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule set forth the requirements and procedure for issuing Federally Compliant Licenses. This is being done pursuant to the Real ID Act of 2005.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The Real ID Act of 2005, Pub.L. 109–13, 119 Stat. 302, enacted May 11, 2005.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee citizens that would like to fly domestic, commercial flights, enter nuclear plants or federal buildings will be most impacted by this rule.

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

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

This will have minimal impact on the state revenues and expenditures.

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

Liz Hale, Deputy General Counsel
Elizabeth Stroecker, Assistant General Counsel
Lori Bullard, Assistant Commissioner of Driver Services
Michael Hogan, Director of Driver License Issuance

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

Liz Hale, Deputy General Counsel
Elizabeth Stroecker, Assistant General Counsel
Lori Bullard, Assistant Commissioner of Driver Services
Michael Hogan, Director of Driver License Issuance

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

312 Rosa L. Parks Avenue, 25th Floor, Nashville, TN 37243;
Lizabeth.Hale@tn.gov, 615-251-5349;
Elizabeth.Stroecker@tn.gov, 615-251-5199
1150 Foster Ave
Nashville, TN 37243
Lori.Bullard@tn.gov, 615-251-5106;

Michael.Hogan@tn.gov , 615-251-5140

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

On April 3, 2019, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 30, 2019. See page 16.

Department of State
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For Department of State Use Only

Sequence Number: 01-29-19
Rule ID(s): 8549
File Date: 1/31/19
Effective Date: 5/1/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Department of Safety & Homeland Security
Division:	Driver License Issuance
Contact Person:	Elizabeth Stroecker
Address:	312 Rosa L. Parks Ave, 25th Floor, Nashville TN
Zip:	37243
Phone:	615-251-5199
Email:	Elizabeth.stroecker@tn.gov

Revision Type (check all that apply):

X Amendment
___ New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1340-01-13	Classified and Commercial Drivers Licenses and Temporary Driver Licenses
Rule Number	**Rule Title**
1340-01-13-.24	Federally Compliant Licenses

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Nashville, TN 37243
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Sequence Number: 04-08-19
Rule ID(s): N/A
File Date: 4/3/19
Effective Date: 4/3/19

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission:	Department of Safety & Homeland Security
Division:	Driver License Issuance
Contact Person:	Doug Garrett
Address:	425 5th Ave North, Suite 922, Nashville, TN
Zip:	37243
Phone:	(615)741-9532
Email:	doug.garrett@capitol.tn.gov

Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/31/19*
Rule Original Effective Date: *05/01/19*
Length of Stay (not to exceed 75 days): 60 days
New Effective Date of Rule Filing: *06/30/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1340-01-13	Classified and Commercial Drivers Licenses and Temporary Driver Licenses
Rule Number	**Rule Title**
1340-01-13-.24	Federally Complaint Licenses

Date: 04/03/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 3, 2019

Notary Public Signature: Jamika Lee Whitmore

My commission expires on: 8/20/2019

My Commission 8/20/2019

Department of State Use Only

Filed with the Department of State on: 4/3/19

Tre Hargett
Secretary of State

2019 APR -3 PM 3:13
SECRETARY OF STATE

Amendments:

RULES
OF
TENNESSEE DEPARTMENT OF SAFETY
DIVISION OF DRIVER LICENSE ISSUANCE
CHAPTER 1340-01-13
CLASSIFIED AND COMMERCIAL DRIVERS LICENSES
AND TEMPORARY DRIVER LICENSES

1340-01-13-.24 FEDERALLY COMPLIANT LICENSES

(1) As used in this section:

(a) "Federally Compliant License" means a driver license or photo identification license, including a temporary driver license or temporary photo identification license, that complies with the Rules and Regulations of the United States Department of Homeland Security, 6 C.F.R. Part 37, in addition to the requirements of state law and regulations.

(b) "DHS" means the United States Department of Homeland Security.

(c) "Official purposes" means accessing Federal facilities, boarding Federally-regulated commercial aircraft, and entered nuclear power plants.

(d) "USCIS" means the United States Customs and Immigration Services.

(2) An applicant who applies for a Federally Compliant License shall be required to comply with the document and verification requirements of this section 1340-01-13-.24.

(3) The Driver License Examiner will require positive proof of identity, date of birth, citizenship, lawful permanent residency, and Tennessee residency of any person applying for any class of Federally Compliant License.

(4) The Department reserves the right to require primary proof of identity on other transactions as determined by the Department.

(5) Primary Identity Documents

(a) For applicants seeking to obtain a Federally Compliant License the acceptable primary identity documents are limited to those approved by DHS pursuant to 6 C.F.R Part 37 that include original or certified documents with applicant's full legal name and date of birth. Acceptable documents are:

1. Certified Birth Certificate registered with the applicant's State Office of Vital Statistics or equivalent agency in the individual's State of birth;

2. Valid, unexpired U.S. passport;

3. Consular Report of Birth Abroad (CRBA) issued by the U.S. Department of State (DS-1350 or FS-545) or Report of Birth Abroad (FS-240);

4. Valid, unexpired Permanent Resident Card (Form I-551) issued by DHS or INS;

5. Unexpired employment authorization document (EAD) issued by DHS, (I-766 or

I-688B);

6. Unexpired foreign passport with a valid, unexpired U.S. visa affixed and accompanied by the approved I-94 form documenting the applicant's most recent admittance into the United States;

7. Certificate of Naturalization issued by DHS (N-550 or N-570);

8. Certificate of Citizenship issued by DHS (N-560 or N-561);

9. Federally compliant driver license or identification card issued in compliance with the standards established by 6 C.F.R. Part 37; and

10. Such other documents as DHS may designate by notice published in the Federal Register.

(6) Social Security Number

(a) In addition to providing primary identification, an applicant must provide proof of their Social Security Number, which shall be verified by the Department, for issuance of a Federally Compliant License or Federally Compliant CDL. Acceptable proof includes the following items as authorized by 6 C.F.R. Part 37:

1. Social Security Card (does not include metal or plastic replicas);

2. IRS Forms (W-2; SSA-1099); Non-SSA 1099 forms may also be accepted such as those issued for gambling winnings or other non-work compensation that may be on local jurisdiction 1099 forms;

3. Computerized Paycheck Stubs with the applicant's name and SSN printed on it; and

4. Such other documents as DHS may designate by notice published in the Federal Register.

(b) Individuals presenting the unexpired foreign passport (1340-01-13-.24(5)(f)) as primary identity document must present a verified SSN or demonstrate non-work authorized status through DHS or USCIS.

(c) The SSN will be verified through a Social Security Administration verification process that is compliant with 6 C.F.R § 37.13(b)(2).

(7) Citizenship, Permanent Residence, or Lawful Presence

(a) Applicants applying for a Federally Compliant License shall present proof acceptable to the Department that such applicant is a United States citizen or a lawful permanent resident of the United States. Such proof is limited to the following items as authorized by 6 C.F.R. Part 37:

1. Certified Birth Certificate issued by a U.S. state, jurisdiction or territory (Puerto Rico, U.S. Virgin Islands, Northern Mariana Islands, American Samoa, Guam);

2. U.S. Consular Report of Birth Abroad (DS-1350 or FS-545);

3. Report of Birth Abroad of a Citizen of the U.S. (FS-240);

4. Valid, unexpired U.S. Passport;

5. Certificate of Naturalization (N550, N570 or N578);

6. Valid, unexpired Permanent Resident Card (I-551);

7. Valid, unexpired Conditional Resident Card (I-551);

8. Form I-94 Record of Arrival and Departure stamped Refugee, Asylee or Asylum; however, applicants who present the Refugee/Asylee I-94 must also present another USCIS document as supporting evidence such as:

(i) Valid employment authorization document (I688B or I766);

(ii) Notice of Action (I-797 or I-797C) indicating USCIS receipt of a pending or approved application for lawful permanent residency or adjustment of status (I-485) or application for employment authorization (I-765).

9. Such other documents as DHS may designate by notice published in the Federal Register.

(b) Applicants applying for a Federally Compliant License who are not US Citizens or Lawful Permanent Residents shall present proof acceptable to the Department that such applicant lawfully present in the United States.

1. An applicant who has submitted the following identity documents will not need to provide additional proof of lawful presence:

(i) Certified Birth Certificate issued by a U.S. state, jurisdiction or territory (Puerto Rico, U.S. Virgin Islands, Northern Mariana Islands, American Samoa, Guam);

(ii) U.S. Consular Report of Birth Abroad (DS-1350 or FS-545);

(iii) Report of Birth Abroad of a Citizen of the U.S. (FS-240);

(iv) Valid, unexpired U.S. Passport;

(v) Certificate of Naturalization issued by DHS, Form N-550 or Form N-570.

(vi) Certificate of Citizenship, Form N-560 or Form N-561, issued by DHS.

2. An applicant who has submitted any other approved identity document will also need to present a second identity document or documentation issued by DHS or other Federal agencies demonstrating lawful status as determined by USCIS.

(8) Renewals and Duplicates

(a) Persons holding a Federally Compliant License shall be required to renew their license or obtain a duplicate in person if the previous renewal or duplicate was not obtained in person.

(b) Persons holding temporary Federally Compliant Licenses shall be required to renew in person to present updated lawful presence documents.

(c) The Department shall take an updated photograph of the applicant at any in person

transaction.

(d) The Department shall re-verify the renewal applicant's SSN and lawful status, if applicable, prior to renewing the Federally Compliant License.

(e) Any material change of name or other personally identifiable information shall require a person to renew or obtain a duplicate in person, and the person shall present acceptable documentation of the change.

(9) Federally Compliant License Documents

(a) Any Federally Compliant License card shall conform to the requirements of 6 C.F.R. Part 37.

(b) Any driver license or photo identification license, including temporary driver license or temporary photo identification license that is not Federally Compliant shall clearly state on the face of the card that it is not acceptable for official purposes and shall be distinguishable from Federally Compliant Licenses.

(10) The Tennessee Department of Safety, Division of Driver License Issuance hereby adopts the REAL ID Driver Licenses and Identification Cards regulations, and all subsequent amendments thereto, promulgated, approved, and adopted by the United States Department of Homeland Security and contained in Title 6 of the C.F.R. Part 37.

Authority: T.C.A. §§ 4-3-2009, 55-50-202, 55-50-321, 55-50-331.

* 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)

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Department of Safety and Homeland Security on January 2, 2019, 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: *10/26/18*

Rulemaking Hearing(s) Conducted on: (add more dates). *12/17/18*

Date: 1/2/2019

Signature: [signature]

Name of Officer: Elizabeth Stroecker

Title of Officer: Assistant General Counsel, Legal Division

LORETTA MARIE BALTZ STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY, TENN.

Subscribed and sworn to before me on: January 2, 2019

Notary Public Signature: Loretta Marie Baltz

My commission expires on: March 3, 2020

Agency/Board/Commission: Tennessee Department of Safety and Homeland Security

Rule Chapter Number(s): 1340-03-13

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]
Herbert H. Slatery III
Attorney General and Reporter

1/31/2019
Date

Department of State Use Only

Filed with the Department of State on: 1/31/19

Effective on: 5/1/19

[signature]
Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Human Services
DIVISION:	Community and Social Services
SUBJECT:	Registration of Family Day Care Homes
STATUTORY AUTHORITY:	Not Available
EFFECTIVE DATES:	June 7, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	This rule deletes the voluntary registration of family daycare homes as this rule is no longer utilized.

NOTE: Rule not submitted in redline form.

Regulatory Flexibility Addendum

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

This rule will have no impact on small businesses.

Impact on Local Governments

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

This rule will have no impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule deletes the voluntary registration of family daycare homes as this rule is no longer utilized.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

N/A

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

N/A

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

N/A

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

N/A

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

Rebekah Baker, Deputy General Counsel, Department of Human Services

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

Rebekah Baker, Deputy General Counsel, Department of Human Services

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Rebekah Baker, Deputy General Counsel, Department of Human Services, 400 Deaderick Street, Nashville, TN 37243, (615) 350-4153, Rebekah.A.Baker@tn.gov

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

N/A

On April 3, 2019, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 7, 2019. See page 7.

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Sequence Number: 01-13-19
Rule ID(s): 8161
File Date: 1/8/19
Effective Date: 4/8/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission:	Department of Human Services
Division:	Community and Social Services
Contact Person:	Jude White, Assistant Commissioner, Community and Social Services
Address:	One Citizen's Plaza Bldg., 8th Floor, 400 Deaderick St., Nashville, TN
Zip:	37243
Phone:	(615)837-5092
Email:	Jude.White@tn.gov

Revision Type (check all that apply):

___ Amendment
___ New
X Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1240-04-12	Registration of Family Day Care Homes
Rule Number	**Rule Title**
1240-04-12-.01	Scope and Purpose
1240-04-12-.02	Definitions
1240-04-12-.03	Responsibilities of Department
1240-04-12-.04	Sponsoring Organization's Authority
1240-04-12-.05	Standards for Registered Family Day Care Providers

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For Department of State Use Only

Sequence Number: 04-07-19
Rule ID(s): N/A
File Date: 4/3/19
Effective Date: 4/3/19

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission:	Department of Human Services
Division:	Community and Social Services
Contact Person:	Doug Garrett
Address:	425 5th Ave North, Suite 922, Nashville, TN
Zip:	37243
Phone:	(615)741-9532
Email:	doug.garrett@capitol.tn.gov

Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/08/19*
Rule Original Effective Date: *04/08/19*
Length of Stay (not to exceed 75 days): 60 days
New Effective Date of Rule Filing: *06/07/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1240-04-12	Registration of Family Day Care Homes
Rule Number	**Rule Title**
1240-04-12-.01	Scope and Purpose
1240-04-12-.02	Definitions
1240-04-12-.03	Responsibilities of Department
1240-04-12-.04	Sponsoring Organization's Authority
1240-04-12-.05	Standards for Registered Family Day Care Providers

Date: 04/03/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 3, 2019

Notary Public Signature: Jamelia Lee Whitmore

My commission expires on: 8/20/2019

8/20/2019

Department of State Use Only

Filed with the Department of State on: 4/3/19

Tre Hargett
Secretary of State

2019 APR -3 PM 3:13
SECRETARY OF STATE

Chapter 1240-04-12
Registration of Family Day Care Homes

Repeal

Chapter 1240-04-12 Registration of Family Day Care Homes is repealed in its entirety, and the title is amended by deleting the previous title of the chapter and substituting instead the word "Repealed."

Authority: T.C.A. 4-5-201 et seq.; 71-3-501 et seq.

* 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)

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Department of Human Services on October 31, 2018, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: October 31, 2018

Signature: Cherrell Campbell-Street

Name of Officer: Cherrell Campbell-Street

Title of Officer: Deputy, Programs and Services

Subscribed and sworn to before me on: October 31, 2018

Notary Public Signature: Jacqueline Griffin

My commission expires on:

JACQUELINE GRIFFIN STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY My Commission Expires SEPT. 7, 2021

Agency/Board/Commission: Department of Human Services

Rule Chapter Number(s): 1240-04-12

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

12/19/2018
Date

Department of State Use Only

Filed with the Department of State on: 1/8/19

Effective on: 4/8/19

Tre Hargett
Secretary of State

RECEIVED
2019 JAN -8 PM 3:53
SECRETARY OF STATE
PUBLIC DIVISION

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Labor and Workforce Development
DIVISION:	Bureau of Workers' Compensation
SUBJECT:	Uninsured Employers Fund Benefits
STATUTORY AUTHORITY:	Tennessee Code Annotated, § 50-6-801 et seq. establishes uninsured employers fund benefits to be paid by the bureau of workers' compensation to workers who are injured but their employer has no compensation coverage.
EFFECTIVE DATES:	April 2, 2019 through June 30, 2020
FISCAL IMPACT:	The overall effect will have little fiscal impact upon state or local government.
STAFF RULE ABSTRACT:	These rulemaking hearing rules establish the rules for uninsured employers fund benefits for workers' compensation claims in Tennessee. NOTE: Rule not submitted in redline form.

Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

PUBLIC COMMENTS AND RESPONSES:

No public comments were received.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rulemaking 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 amended rules should not affect small employers that fall under the Tennessee Workers' Compensation Laws, which would be employers with at least five employees, or for those in the construction industry at least one employee. There should be no additional costs associated with these rule changes.

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: There is no additional record keeping requirement or administrative cost associated with these rule changes.

3. A statement of the probable effect on impacted small businesses and consumers: These rules should not have a negative impact on consumers or small businesses.

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: There are no less burdensome methods to achieve the purposes and objectives of these rules.

5. Comparison of the proposed rule with any federal or state counterparts: None.

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: Exempting small businesses could frustrate the small business owners' access to the services provided by the Bureau of Workers' Compensation and timely medical treatment for injured workers, which would be counter-productive.

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 proposed rules will have little, if any, impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules establish the rules for uninsured employers fund benefits for workers' compensation claims in Tennessee.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 50-6-801 et seq. establishes uninsured employers fund benefits to be paid by the bureau of workers' compensation to workers' who are injured but their employer has no compensation coverage.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Injured workers and employers who have no workers' compensation insurance coverage may be affected by the adoption or rejection of these rules.

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

None

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The overall effect will have little fiscal impact upon state or local government.

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

Troy Haley, Director of Administrative Legal Services

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

Troy Haley, Director of Administrative Legal Services

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees:

Tennessee Bureau of Workers' Compensation 220 French Landing Drive, Floor 1-B Nashville, TN 37243 (615) 532-0179 troy.haley@tn.gov

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

None

Department of State
Division of Publications
312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615.741.2650
Email: publications.information@tn.gov

For Department of State Use Only
Sequence Number: 01-02-19
Rule ID(s): 8026
File Date: 1/2/19
Effective Date: 4/2/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Department of Labor and Workforce Development
Division:	Bureau of Workers' Compensation
Contact Person:	Troy Haley
Address:	220 French Landing Drive 1-B, Nashville, TN 37243
Phone:	615-532-0179
Email:	troy.haley@tn.gov

(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)

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
0800-02-30	Uninsured Employers Fund Benefits
Rule Number	**Rule Title**
0800-02-30-.01	Purpose and Scope of Rules
0800-02-30-.02	Definitions
0800-02-30-.03	General Requirements
0800-02-30-.04	Available Benefits
0800-02-30-.05	Requirements for Payment of Benefits
0800-02-30-.06	Investigation
0800-02-30-.07	Mediation
0800-02-30-.08	Court of Workers' Compensation Claims Processes
0800-02-30-.09	Payments from the Fund
0800-02-30-.10	Recovery from Employer

Rules of the
Bureau of Workers' Compensation

Chapter 0800-02-30
Uninsured Employers Fund Benefits
New Rules

0800-2-30-.01 Purpose and Scope of Rules

(1) The purpose of these rules is to establish the processes and procedures for administering the Uninsured Employers Fund in T.C.A. § 50-6-801 et seq.

(2) These procedures apply to all claims by eligible employees submitted to the Bureau of Workers' Compensation in accordance with T.C.A. § 50-6-801 et seq. The provisions of this chapter apply to all employers, adjusters and providers of services related to claims in the State of Tennessee subject to the Workers' Compensation Law.

Authority: T.C.A. §§ 50-6-801, 802, and 803.

0800-2-30.02 Definitions

(1) "Act": Tennessee Code Annotated, Title 50, Chapter 6.

(2) "Administrator": The same definition as in T.C.A § 50-6-102.

(3) "Bureau": The Tennessee Bureau of Workers' Compensation as defined in T.C.A. § 50-6-102, an autonomous unit attached to the Department of Labor and Workforce Development for administrative matters only under T.C.A. § 4-3-1409.

(4) "Claim": A demand for something as due; or an assertion of a right or an alleged right.

(5) "Claimant": An individual who is claiming benefits under the Tennessee workers' compensation law.

(6) "Court": The Court of Workers' Compensation Claims.

(7) "Employee": The same definition as in T.C.A. § 50-6-102.

(8) "Employer": The same definition as in T.C.A. § 50-6-102.

(9) "Fund" and "UEF": The Uninsured Employers Fund established in T.C.A. § 50-6-801.

(10) "Mediator": A Bureau of Workers' Compensation employee who has received training in alternative dispute resolution, as described in T.C.A. § 50-6-236.

(11) "Ombudsman": A Bureau of Workers' Compensation employee who assists injured workers in resolving disputes and obtaining information available under the Tennessee workers' compensation law, as described in T.C.A. § 50-6-216.

(12) "Third Party Administrator": An organization that has contracted with the Bureau to handle administrative claims for benefits under the Uninsured Employers Fund benefit program.

Authority: T.C.A. §§ 4-3-1409, 50-6-102, 216, 236, 801, 802, 803.

0800-2-30-.03 General Requirements

An employee is eligible, subject to approval by the Bureau of Workers' Compensation Administrator, within the meaning provided by this section if: (1) The employee was employed by an uninsured employer; (2) The employee suffered an injury on or after July 1, 2015, arising primarily out of and in the course and scope of employment at a time when the employer was uninsured; (3) The employee was a Tennessee resident on the date of injury; (4) The employee notified the bureau of the injury and the employer's lack of insurance coverage no more than sixty (60)

days after the date of the injury; and (5) except as provided in § 50-6-802(d) and (e), the employee secured a judgment for workers' compensation benefits against the employer.

Authority: T.C.A. §§ 50-6-801, 802, 803.

0800-2-30-.04 Available Benefits

(1) The following benefits are available to an eligible employee: temporary disability benefits up to $20,000.00; and medical benefits up to $20,000.00, to include a medical causation evaluation and mileage reimbursement if ordered by the Court of Workers' Compensation Claims.

(2) The maximum benefit is $40,000.00, including applicable mileage reimbursement and any medical causation evaluation.

(3) The cost of a medical causation evaluation may be paid by the Fund without an order from the Court of Workers' Compensation Claims.

(4) Reasonable mileage reimbursement may be paid to an eligible employee subject to applicable state employee maximums.

(5) All medical costs must be paid under the Medical Fee Schedule pursuant to Rules 0800-2-17, 0800-2-18 and 0800-2-19. The bureau shall have the authority to waive this requirement when necessary to provide treatment for an injured employee, as provided in T.C.A. § 50-6-204.

Authority: T.C.A. §§ 50-6-204, 205, 50-6-801, 802, 803.

0800-2-30-.05 Requirements for Payment of Benefits

(1) An Expedited Request for Investigation may be filed to confirm eligibility for benefits from the Uninsured Employers Fund.

(2) The Notice to the Uninsured Employer must be included on the petition for benefit determination and the cover letters to the dispute certification notices. The notice language informs the employer that benefits may be paid by the bureau and that the bureau will seek to collect the amount expended by the state from the employer under T.C.A. § 50-6-803.

(3) The Uninsured Employers Fund claims manager is the designated bureau employee who will interact between the bureau and the third-party administrator. A third-party administrator will be contracted to provide services and access to medical networks and to monitor billing compliance.

(4) The referral of the injured worker to obtain a medical causation opinion will take place in consultation with the Uninsured Employers Fund Benefits claims manager.

(5) Benefits will not be paid without a court order to support a lien against the employer.

Authority: T.C.A. §§ 50-6-801, 802, 803.

0800-2-30.06 Investigation

(1) If the bureau receives information about a work injury involving an uninsured employer, an Expedited Request for Investigation is required.

(2) The bureau employee notified about the work injury and lack of insurance coverage will submit a completed Expedited Request for Investigation to uef.compliance@tn.gov and, if applicable, refer the injured worker to an ombudsman.

(3) The assigned Uninsured Employer's Fund compliance investigator will gather facts relating to eligibility in addition to conducting a standard investigation, and the compliance investigator will conduct and complete a report within ten (10) business days. The report must contain the four (4) major eligibility requirements.

(4) The investigation will use the same protocol as other investigations to work in conjunction with the mediator.

Authority: T.C.A. §§ 50-6-801, 802, 803.

0800-2-30-.07 Mediation

(1) Upon assignment of a petition for benefit determination for an Uninsured Employers Fund claim, the bureau mediator will attempt to contact the employer and employee for voluntary mediation and will notify the Uninsured Employers Fund claims manager who will determine if the circumstances suggest a need for a medical causation opinion.

(2) If an alleged employer is unwilling to mediate or fails to respond to requests to mediate, the mediator must issue a dispute certification notice. The dispute certification notice must indicate the issues, the employee's eligibility for Uninsured Employers Fund benefits, temporary disability benefits and medical benefits. Under T.C.A. § 50-6-236, a dispute certification notice will also note an alleged employer who fails to cooperate with scheduling mediation.

(3) On agreement, the mediator must complete the Uninsured Employers Fund settlement agreement as prescribed by the Administrator and arrange for court approval of the agreement and the issuance of an agreed order with a judge in the proper jurisdiction.

(4) In the event of an impasse, the employee's eligibility for Uninsured Employers Fund benefits must be included as an issue on the dispute certification notice. In addition, the cover letter to the first and second dispute certification notices must include the petition for benefit determination notice language.

(5) The mediator must send the dispute certification notice or settlement agreement to the Uninsured Employers Fund benefit claim manager.

Authority: T.C.A. §§50-6-216, 236, 801, 802, 803.

0800-2-30-.08 Court of Workers' Compensation Claims Processes

(1) The Court of Workers' Compensation Claims will follow statutory guidelines, existing hearing procedures and protocol for expedited hearings and compensation hearings.

(2) The Court of Workers' Compensation Claims will consider the investigator's report and if applicable the medical causation report.

(3) The Court of Workers' Compensation Claims will make additional findings consistent with T.C.A. § 50-6-801(d) and include specific language in the order.

(4) If settled through mediation, the Court will conduct an approval hearing for the proposed settlement of interlocutory temporary disability and medical benefit issues. The Court may approve or deny the proposed settlement agreement.

(5) The UEF claims manager will receive the order and transmit it to the third-party administrator for servicing if approved by the Court of Workers' Compensation Claims.

Authority: T.C.A. §§ 50-6-239; 50-6-801, 802, 803.

0800-02-30-.09 Payments from the Fund

(1) Annually the bureau will contract with a third-party claim administrator to administer UEF claims. The third-party claim administrator will request, receive, and review medical records and medical bills and will submit recommendations to pay temporary disability benefits and medical benefits via a voucher to the claim administrator.

(2) Payments for temporary disability benefits and medical benefits will not be issued unless the bureau has on file: IRS form W-9 "Request for Taxpayer Identification Number and Certification;" an expedited hearing order; and a voucher from the claim administrator recommending payment to medical providers or injured workers or payment of attorney's fees, and child support liens.

(3) The bureau will establish the injured worker and each medical provider as a vendor in the state system for payments.

(4) The bureau will maintain financial records to document payments for contract services, total medical payments made per each injured worker, total disability benefits, monthly benefit payments and payments per fiscal year.

(5) Any costs associated with a third party administrator, along with any other administrative costs, shall be paid by the bureau administrator from the Fund.

Authority: T.C.A. §§ 50-6-801, 802, 803.

0800-02-30-.10 Recovery from Employer

(1)The bureau administrator may pay from the Fund reasonable expenses of collection and enforcement, including filing fees and collection expenses incurred by the bureau. The administrator may recover these fees and expenses from employer.

(2)The bureau shall assume the rights of a creditor against an employer for money paid by the bureau administrator pursuant to statute or rule, and may place a lien on the assets of the employer by filing a notice of claim with the register of deeds of any county where the employer has assets. Upon filing the notice of claim with the appropriate official, the bureau shall be a secured creditor.

Authority: T.C.A. §§ 50-6-801, 802, 803.

* 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)

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Bureau of Workers' Compensation on 11/2/18 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 August 21, 2018.

Rulemaking Hearing Conducted on October 16, 2018.

Date: 11/2/18

Signature: Abbie Hudgens

Name of Officer: Abbie Hudgens

Title of Officer: Administrator, Bureau of Workers' Compensation

JANIE L. DORRIS
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 3-8-2022

Subscribed and sworn to before me on: 11/2/18

Notary Public Signature: Janie L. Dorris

My commission expires on: March 8, 2022

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

12/19/2018
Date

Department of State Use Only

2019 JAN -2 AM 11:52
SECRETARY OF STATE
PUBLIC CHAPTERS

Filed with the Department of State on: 1/2/19

Effective on: 4/2/19

Tre Hargett
Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Alcoholic Beverage Commission
SUBJECT:	Rules for the Sale of Liquor by the Drink, Local Option Liquor Rules, Intra-Industry Conduct and Regulations
STATUTORY AUTHORITY:	The current are similar to federal law in various aspects, but the only federal law, to the knowledge of TABC, used as a guideline for the adoption of the proposed rules in 27 CFR 6.94, which allows an industry member to provide "nominal hospitality" as part of an educational seminar.
EFFECTIVE DATES:	June 24, 2019 through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rulemaking hearing rule makes various changes regarding retailers and suppliers and makes certain technical changes. The revisions to the rules were proposed by the relevant industry members and the final rules were adopted with the ongoing support and coordination with such industry members. The proposed rule: (1) Eliminates the requirement that retail package stores publish notice of their application in a local newspaper at least 3 times before any local hearing for the certificate of compliance; (2) Provides more latitude in the in industry members providing certain routine business entertainment to retailers, including increasing the maximum amount that can be provided for certain activities from $100 to $300; (3) Increases and clarifies the manner in which licensees can advertise, including reducing current restrictions on direct communications to consumers while still providing protection to consumers against unwanted communications; (4) Removes advance approval requirements for consumer education seminars and requires only 2 days

advance notice to the T ABC and clarifies that any T ABC permit holder may serve alcoholic beverages at a consumer education seminar;

(5) Specifies certain circumstances in which a supplier of alcoholic beverages may also own an establishment selling alcoholic beverages at retail for on premise consumption while otherwise maintaining the three tier system in the state;

(6) Limits and reduces the times in which a manufacturer representative permit would be required.

(7) Eases the manner in which a manufacturer can add a noncontiguous premises for storage of spirits by requiring only notice of such additional storage instead of Commission approval;

(8) Clarifies when a private event not requiring any license can be held;

(9) Clarifies that distilled spirits may be imported in bulk for manufacturing, rectifying, or blending alcoholic beverages and clarifies what the term "rectifying" means.

(10) Allows industry members to award prizes to retail employees as part of nationwide contests with the prior written approval of the T ABC;

(11) Allows industry members to participate in trade shows and conventions for retailer or industry associations;

(12) Increases the ability of industry members to provides free samples of alcoholic beverages to retailers; and

(13) Increases the type of items that an industry member can provide to a retailer for their own use or for further dissemination to consumers and makes other beneficial revisions regarding the offering of contents, items, and services by industry members.

Public Hearing Comments

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

Comments to the proposed rules are attached to this filing.

Regulatory Flexibility Addendum

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

Beginning in August, 2016, the Tennessee Alcoholic Beverage Commission (TABC) requested suggestions for changes to the TABC rules and regulations effecting retail package stores, retail food stores, and manufacturers of alcoholic beverages. The proposed rules are the result from this industry feedback after multiple periods of revisions and continued work with the industry, especially including working with several organizations that represented business interests in the state, including the interests of small businesses. As a result, the proposed rules benefits small business retail package stores, retail food stores, and manufacturers throughout the state. This rule benefits small businesses by doing the following:

(1) Eliminates the requirement that retail package stores publish notice of their application in a local newspaper at least 3 times before any local hearing for the certificate of compliance. This removal removes a significant burden on applicant retail package store;
(2) Provides more latitude in the in industry members providing certain routine business entertainment to retailers, including increasing the maximum amount that can be provided for certain activities from $100 to $300;
(3) Increases and clarifies the manner in which licensees, including small businesses, can advertise, including reducing current restrictions on direct communications to consumers while still providing protection to consumers against unwanted communications;
(4) Removes the requirement that retail package stores obtain approval for a consumer education seminar at least 4 days before the event and instead requires only that notice be given at least 2 days before the event and makes other revisions regarding these events to the benefit of retail package stores and small businesses;
(5) Specifies certain circumstances in which a supplier of alcoholic beverages may also own an establishment selling alcoholic beverages at retail for on-premise consumption while otherwise maintaining the three tier system in the state;
(6) Limits and reduces the times in which a manufacturer representative permit would be required. This is very beneficial to small businesses as many small businesses use certain persons to promote alcoholic beverages while not soliciting orders and this rule specifies that such persons would not need this permit;
(7) Eases the manner in which a manufacturer can add a noncontiguous premises for storage of spirits by requiring only notice of such additional storage instead of Commission approval;
(8) Clarifies when a private event not requiring any license can be held;
(9) Increases the ability of industry members to provides free samples of alcoholic beverages to retailers; and
(10) Increases the type of items that an industry member can provide to a retailer for their own use or for further dissemination to consumers and makes other beneficial revisions regarding the offering of contents, items, and services by industry members.

In addition, several additional changes to update the rules to be consistent with current law, as well as several technical corrections, had been made providing additional clarity on the law to the benefit of small businesses. An exact number of such small businesses affected is impossible to estimate at this time, but is expected to be substantial and significant. There are no state or federal counterparts for which this rule can be effectively compared to. The exemption of small businesses from this rule would be detrimental to the small businesses of this state and in certain cases may be contrary to statute.

Impact on Local Governments

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

Proposed rule does not have any expected impact on local government.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This proposed rule makes various changes regarding retailers and suppliers and makes certain technical changes. The revisions to the rules were proposed by the relevant industry members and the final rules were adopted with the ongoing support and coordination with such industry members. The proposed rule:

(1) Eliminates the requirement that retail package stores publish notice of their application in a local newspaper at least 3 times before any local hearing for the certificate of compliance;
(2) Provides more latitude in the in industry members providing certain routine business entertainment to retailers, including increasing the maximum amount that can be provided for certain activities from $100 to $300;
(3) Increases and clarifies the manner in which licensees can advertise, including reducing current restrictions on direct communications to consumers while still providing protection to consumers against unwanted communications;
(4) Removes advance approval requirements for consumer education seminars and requires only 2 days advance notice to the TABC and clarifies that any TABC permit holder may serve alcoholic beverages at a consumer education seminar;
(5) Specifies certain circumstances in which a supplier of alcoholic beverages may also own an establishment selling alcoholic beverages at retail for on-premise consumption while otherwise maintaining the three tier system in the state;
(6) Limits and reduces the times in which a manufacturer representative permit would be required.
(7) Eases the manner in which a manufacturer can add a noncontiguous premises for storage of spirits by requiring only notice of such additional storage instead of Commission approval;
(8) Clarifies when a private event not requiring any license can be held;
(9) Clarifies that distilled spirits may be imported in bulk for manufacturing, rectifying, or blending alcoholic beverages and clarifies what the term "rectifying" means.
(10) Allows industry members to award prizes to retail employees as part of nationwide contests with the prior written approval of the TABC;
(11) Allows industry members to participate in trade shows and conventions for retailer or industry associations;
(12) Increases the ability of industry members to provides free samples of alcoholic beverages to retailers; and
(13) Increases the type of items that an industry member can provide to a retailer for their own use or for further dissemination to consumers and makes other beneficial revisions regarding the offering of contents, items, and services by industry members.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

The current are similar to federal law in various aspects, but the only federal law, to the knowledge of TABC, used as a guideline for the adoption of the proposed rules is 27 CFR 6.94 which allows an industry member to provide "nominal hospitality" as part of an educational seminar.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules primarily impact licensed retailers and suppliers with some impact on licensed wholesalers. These rules were created in coordination with and with the support of the Tennessee Wine and Spirits Retailers Association, the Distilled Spirits Counsel, the Tennessee Distiller's Guild, The Wine Institute, and Wine and Spirits Wholesalers of Tennessee.

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

There are none.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The fiscal impact is minimal.

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

Clay Byrd, Director; Zack Blair, Assistant Director

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

Clay Byrd, Director

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

500 James Robertson Pkwy, 3rd Floor, Nashville, TN 37243
615-741-7620
Clay.Byrd@tn.gov

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

There is no such additional information.

TN Tennessee State Government

MEMO

From: Clayton Byrd, Executive Director

Re: TABC Response to Public Hearing Comments

Date: October 20, 2017 and updated on September 11, 2018

On December 9, 2016, a rulemaking hearing was held in accordance with the Uniform Administrative Procedures Act. At the hearing, various comments were made regarding proposed revisions to Chapters 3 and 6 of the proposed rules of the Tennessee Alcoholic Beverage Commission (TABC). The TABC also accepted written comments after the hearing. Below please find the TABC's response to the verbal and written comments. In addition, further comments were made at the Commission's meeting held on August 22, 2017, in which the Commission took up these rules, and from those comments additional revisions to the rules were made prior to their adoption by the Commission at its meeting held on September 26, 2017. In September of 2018 further revisions were made after passage of legislation by the Tennessee General Assembly. The final adoption of these rules by the Commission occurred on September 27, 2018.

(1) BULK TRANSPORT OF WINE - Rule 0100-03-.12(2) - A request was made that this rule be removed or revised to be consistent with the statutes on this subject and Chapter 7 of the TABC's rules. The TABC agrees with this proposed change and this paragraph has been removed due to the updated statute.

(2) DEFINITION OF IMPORTER – Rule 0100-03-.16(1) – Comments were made to include "non-resident sellers" and "non-manufacturer non-resident sellers" in the title of the rule because both constitute "importers" under state law. The TABC agrees. Pursuant to Tenn. Code Ann. 57-3-101(9) an "importer" includes both a "non-manufacturer non-resident seller" and a "non-resident seller". The title/rules have been revised to clarify this issue.

(3) TRUST - Rule 0100-03-.16(1)(b) - A request was made that this rule specify that only blind trusts could be used for the purposes of this rule to avoid a dual interest conflict. Pursuant to Public Chapter 371, the General Assembly authorized, for a two year period, manufacturers to hold an interest in a on premise retailer, as long as, the interest is held in an irrevocable trust by an

independent trustee. The TABC interprets this statute to allow for beneficiaries to hold an interest in both license types in the trust arrangement; provided, that the beneficiaries do not exercise control over the trust property. In other words, state law requires the trustee to be independent; however, it does not require independent beneficiaries. This rule clarifies that issue in the context of the new public chapter.

(4) INDIRECT INTERESTS - Rule 0100-03-.16(1)(b) - A request was made to clarify that the minimal ownership requirement applies to both a five percent (5%) interest in a manufacturer and a five percent (5%) interest in an on-premise establishment. The TABC agrees that the five percent threshold applies to both license types. This minimum ownership requirement is consistent with the minimum disclosure requirement in Tenn. Code Ann. 57-4-201(b)(2).

(5) INTERESTS IN WHOLESALERS - Rule 0100-03-.16(1)(c) - A request was made to clarify that an importer, non-resident seller, or non-manufacturer non-resident seller could have a direct or indirect interest in a wholesaler. The TABC agrees with this request and added language making such clarification as a new Rule 0100-03-.16(1)(c).

(6) TAXES ON DONATED ALCOHOLIC BEVERAGES - Rule 0100-03-.20 - Comments were made about revising the rule to clarify which taxes were required to be paid by the donating manufacturer when donating alcoholic beverages to a non-profit. The TABC does not believe that any further clarification is required because it is the responsibility of the donating entity to determine which taxes must be paid.

(7) PRIVATE PARTIES - Rule 0100-03-.22(1)(e) - Comments were made requesting that (1) the requirement that a private party not have any "commercial purpose" be removed, revised, or clarified, such that the rule would not be overly broad, and that (2) the rule be clarified by specifically prohibiting manufacturers and importers from donating alcoholic beverages to private parties. The TABC agrees. The revised rule clarifies that the prohibited commercial purpose means a commercial purpose related to the sale, marketing, and promotion of alcoholic beverages. Moreover, the revised rule provides that a licensee may not donate alcoholic beverages to a private event, which eliminates a loop hole in existing TABC rules.

(8) ADVERTISING SERVICES - Rule 0100-06-.03(4) - A request was made that the requirement that industry members list all licensed retailers selling their

brand that are within the geographic area covered by the advertisement, if the industry members wishes to advertise a list of retailers where their products may be sold. The proposed revision would allow an industry member to select certain retailers to advertise the availability of product. Authorizing this method would be to provide certain retailers with something of value to the exclusion of other retailers. Therefore, the TABC will not incorporate this suggestion due to discrimination concerns.

(9) SAMPLES TO RETAILERS - Rule 0100-06-.03(10) - Various comments were provided regarding whether or not there should be additional limitations on the provision of samples to retailers. The TABC considered this suggestion previously and determined the existing proposed rule serves as a reasonable accommodation to multiple stakeholder interests.

(10) DELIVERY BY RETAIL PACKAGE STORES - A request was made that the rules be revised to authorize any agent of a retail package store to deliver alcoholic beverages under the license of the retail package store, instead of only such store's employees. State law prohibits a third party agent of a retail package store from delivering alcoholic beverages on behalf of the retail package store. After drafting of these proposed rules, Chapter 765 of the Public Acts of 2018 revised a number of statutes related to delivery. Therefore, it has been determined to remove the provisions of the rules concerning delivery in order to take those up in a separate rulemaking process.

(11) PROVISION OF STOCKING, ROTATING, PRICING AND OTHER SERVICES TO RETAILERS - Rule 0100-06-.03(13) - A request was made that the rule allow manufacturers and importers, in addition to wholesalers, to provide such services to retailers. The TABC maintains that this proposed rule would authorize industry members to perform activities that are traditionally reserved to wholesalers, and that a statutory change would be a more appropriate avenue to authorize these practices.

(12) DIGITAL REBATES - Rule 0100-06-.03(14) - A request was made that the rule allowing manufacturer and importer rebates be clarified to allow for such rebates to be scanned and emailed to the manufacturer or importer, instead of only being mailed. The TABC agrees and will include this change.

(13) PRODUCT DISPLAYS - Rule 0100-06-.03(2)(b) - A request was made to remove the allowance of industry members to list the name and address of retailers

on product displays. The TABC agrees with this request and has made this change.

(14) CONTESTS - Comments were made requesting the restriction of the proposed rule allowing retail employees to participate in certain contests. The TABC agrees that some restriction would be beneficial and has revised the proposed rule to require that any such contest receive prior written approval of the TABC.

(15) ROUTINE BUSINESS ENTERTAINMENT - Rule 0100-06-.03(7)(e) - A request was made to limit the expansion of the rules on routine business entertainment to where such business entertainment must be either within the state or within 100 miles of the state. The TABC agrees with this request and has made this change.

(16) FEDERAL LAW - Rule 0100-06 - Comments were made that certain rule revisions may be contrary to federal law. The TABC agrees that the portion of Rule 0100-06-.03(12) allowing the provision of reasonable meals and local ground transportation could potentially lead to a violation of federal rules, and the TABC has changed this to track such federal rule to instead allow "nominal hospitality". However, all other rule revisions referenced in the comment are compliant with federal and therefore have not been revised.

(17) BAR SPENDING - Rules 0100-06 - A request was made that a new rule be added to allow an industry member to purchase alcoholic beverages from a retailer in order to then give such alcoholic beverages away to customers located in such retailer. The TABC believes this practice would be providing something of value to another tier and therefore the rule will remain unchanged.

(18) DISPLAY ENHANCEMENTS - Rule 0100-06 - A request was made that a new rule be added to allow an industry member to give certain display enhancements worth up to $155 with the intent that such display enhancements be awarded to customers of the retailers after its use as a display has expired. The TABC maintains that this practice would authorize providing something of significant value to another tier, which could result in disparate treatment between separate retailers. As a result, the TABC will not include this proposal due to discrimination and inducement concerns.

(19) WHOLESALERS - Various comments were made requesting changes to the rules that specifically addressed wholesalers. The proposed rules were proposed to update the rules regarding retail package stores, manufacturers, and importers, and not any other license type. Changes to any other rules are considered to be outside of the scope of these proposed rules.

- Rule 0100-01-.03(12): Comments were made to include LBDs in this section. The proposed rule primarily deals with wholesalers and LBDs, which is beyond the scope of this particular rulemaking process.

- Rule 0100-01-.03(16): Comments were made to eliminate the TABC consent/notification requirement for a licensee's name change. This is beyond the scope of this particular rulemaking process, as it applies to all license types

- Rule 0100-01-.07(2)(b): Comments were made to clarify existing rules on special occasion permits and tax exempt status. This is beyond the scope of this particular rulemaking process, as it applies to special occasion permits.

- Rule 0100-03-.06(1): Comments were made to restrict the delivery of point of sale advertising materials to wholesalers. The TABC agrees with this request and has revised the rules to require that such materials be provided to the wholesaler who would then provide them to the retailer.

- Rule 0100-03-.09: Comments were made to a reference to the renewal process when a retailer fails to timely pay wholesalers in accordance with Rule 0100-06-.04. The TABC considers untimely payments as a part of a retailer's renewal application pursuant to statute, and therefore, no further rule/revision on this point is necessary.

- Rule 0100-03-.10(5): Comments were made suggesting that wholesalers be required to identify products that are provided through the wholesale tier for sampling or tastings be marked "not for resale". The TABC agrees with this proposed change and believes it would be appropriate to impose this obligation on all industry members due to tied house concerns over donated product.

- Rule 0100-03-.19(1): Comments were made to clarify instances where a manufacturer's permit would be required in performing solicitations, sales, marketing and other sales conduct. The TABC maintains that a manufacturer's representative permit is not required when an individual is promoting or marketing product, but that the permit would be required if the individual is soliciting orders or selling alcoholic beverages on behalf of a manufacturer.

Sincerely,

Clayton Byrd
Executive Director
Tennessee Alcoholic Beverage Commission

On April 3, 2019, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 24, 2019. See page 114.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 01-25-19
Rule ID(s): 8521-8523
File Date: 1/25/19
Effective Date: 4/25/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission: Tennessee Alcoholic Beverage Commission
Division:
Contact Person: Clay Byrd , Director; Zack Blair, Assistant Director
Address: 500 James Robertson Pkwy, 3rd Floor, Nashville, TN
Zip: 37243
Phone: 615-741-7620
Email: Clay.Byrd@tn.gov; Zack.Blair@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0100-01	Rules for the Sale of Liquor by the Drink
Rule Number	**Rule Title**
0100-01-.01	Advertising
0100-01-.02	Solicitation of Business and Services Restricted
0100-01-.03	Conduct of Business
0100-01-.04	Transfer of Locations
0100-01-.05	Applications by Private Clubs
0100-01-.06	Additional Rules Applicable to Caterers
0100-01-.07	Applications for Special Occasion Permits
0100-01-.08	Terminal Building of a Commercial Airport Carrier

Chapter Number	**Chapter Title**
0100-03	Local Option Liquor Rules
Rule Number	**Rule Title**
0100-03-.01	Advertising of Alcoholic Beverages Generally
0100-03-.02	Reserved
0100-03-.03	Advertising of Distilled Spirits and Wine by Direct Communications

0100-03-.04	Reserved
0100-03-.05	Advertising Alcoholic Beverages on Billboards and Outside Signs
0100-03-.06	Advertising Materials Within Retail Premises
0100-03-.07	Authorized Products and Services by Retailers
0100-03-.08	Advertising Approval Does Not Sanction Any Violation, Commission Discretion on Advertising
0100-03-.09	Licenses and Permits
0100-03-.10	Transporting and Delivery of Alcoholic Beverages
0100-03-.11	Solicitation of Business, Services Restricted
0100-03-.12	Containers and Sizes
0100-03-.13	Conduct of Business-Wholesaler and Retailer
0100-03-.14	Conduct of Business of Wholesalers
0100-03-.15	Restrictions on Premises, Conduct of Business of Retailers
0100-03-.16	Dual Interests Prohibited
0100-03-.17	Responsibility and Penalties for Violations
0100-03-.18	Transfer of Licenses
0100-03-.19	Manufacturer Representative Permits
0100-03-.20	Donations to Nonprofit Organizations
0100-03-.21	Noncontiguous Premises of Manufacturers
0100-03-.22	Private Events
0100-03-.23	Rectifying

Chapter Number	**Chapter Title**
0100-06	Intra-Industry Conduct and Regulations
Rule Number	**Rule Title**
0100-06-.01	Definitions
0100-06-.02	General Prohibitions
0100-06-.03	Exceptions to General Prohibitions
0100-06-.04	Limitations on Credit Sales
0100-06-.05	Dual Permits Prohibited
0100-06-.06	Wholesale Sales and Employee Permits
0100-06-.07	Retail Employee Permits
0100-06-.08	Non-Resident Seller Permits
0100-06-.09	Prohibition on Discrimination

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Sequence Number: 04-04-19
Rule ID(s): N/A
File Date: 4/3/19
Effective Date: 4/3/19

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission:	Tennessee Alcoholic Beverage Commission
Division:	
Contact Person:	Doug Garrett
Address:	425 5th Ave North, Suite 922, Nashville, TN
Zip:	37243
Phone:	(615)741-9532
Email:	doug.garrett@capitol.tn.gov

Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/25/19*
Rule Original Effective Date: *04/25/19*
Length of Stay (not to exceed 75 days): 60 days
New Effective Date of Rule Filing: *06/24/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

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0100-01-.04	Transfer of Locations
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0100-06-.07	Retail Employee Permits
0100-06-.08	Non-Resident Seller Permits
0100-06-.09	Prohibition on Discrimination

Date: 04/03/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 3, 2019

Notary Public Signature: Tamika Lee Whetmore

My commission expires on: 8/20/2019

8/20/2019

Department of State Use Only

Filed with the Department of State on: 4/3/19

Tre Hargett
Secretary of State

2019 APR -3 PM 3:15
SECRETARY OF STATE

Chapter 0100-01, Rules for the Sale of Liquor by the Drink, is amended by deleting the chapter in its entirety and by substituting instead the following language:

RULES OF TENNESSEE ALCOHOL BEVERAGE COMMISSION CHAPTER

0100-01 RULES FOR THE SALE OF LIQUOR BY THE DRINK

TABLE OF CONTENTS

0100-01-.01 Advertising
0100-01-.02 Solicitation of Business and Services Restricted
0100-01-.03 Conduct of Business
0100-01-.04 Transfer of Locations
0100-01-.05 Applications by Private Clubs
0100-01-.06 Additional Rules Applicable to Caterers
0100-01-.07 Applications for Special Occasion Permits
0100-01-.08 Terminal Building of a Commercial Air Carrier

0100-01-.01 Advertising.

(1) Billboards and Outside Signs.

(a) Alcoholic Beverages may be advertised on signs and billboards in those cities and counties that have legalized the sale of such beverages under the provisions of T.C.A. § 57-3-106.

(b) Advertising may bear trademarks, trade slogans, ~~trade slogans~~ or other distinctive designations associated with a particular brand while also bearing the name, or advertise the establishment, or refer to the services of any licensee. However, all advertising costs, direct or indirect, must be borne by the on-premise consumption licensee, except as permitted by Rule 0100-06-.03.

(2) Advertising Outside the Licensed Premises Relating to the Availability of Alcoholic Beverages.

(a) Advertising on Radio or Television Stations. The availability of alcoholic beverages may be advertised on radio or television stations in Tennessee subject to the following restrictions:

1. Restrictions. An advertisement shall not contain:

i. Any statement that is materially false or misleading ~~in any material particular~~.

ii. Any statement that is disparaging of a competitor's products.

iii. Any statement, design, device, or representation which is obscene or indecent.

iv. Any statement, design, device, or representation of or relating to analysis, standards, or tests, irrespective of falsity, which is likely to mislead the consumer.

v. Any statement that the product is produced, blended, made, bottled, packed, or sold under, or in accordance with, any authorization, law, or regulation of any municipality, county, or state, federal or foreign government unless such statement is required or specifically authorized by the laws or regulations of such government; and if a municipal, county, state, or federal permit number is stated, such permit number shall not be accompanied by any additional statement relating thereto.

(b) Statements Inconsistent with Labeling. No advertisement shall contain any statement concerning a brand or lot of ~~distilled spirits~~ alcoholic beverages that is inconsistent with any statement on the labeling thereof.

(c) Curative and Therapeutic Effects. No advertisement shall contain any statement, design, or device representing that the use of ~~distilled spirits~~ alcoholic beverages has curative or therapeutic effects, if such statement is untrue in any particular, or tends to create a misleading impression.

(d) Place of Origin. No advertisement shall represent that the ~~distilled spirits~~ alcoholic beverages were manufactured in, or imported from a place or country other than that of their actual origin, or were produced or processed by one who was not in fact the actual producer or processor.

(e) Flags, Seals, Coats of Arms, Crests, ~~and~~ Other Insignia. No advertisement shall contain any statement, design, devices, ~~or~~ pictorial representation of or relating to, or capable of being construed as relating to the armed forces of the United States, or of the American flag, any state flag, or of any emblem, seal, insignia, or decoration associated with any such flag or the armed forces of the United States; nor shall any advertisement contain any statement, device, design, or pictorial representation of or concerning any flag, seal, coat of arms, crest, or other insignia, likely to falsely lead the consumer to believe that the product has been endorsed, made, used by, produced for, under the supervision of, in accordance with the specifications of the government, organization, family, or individual with whom such flag, seal, coat of arms, crest, or insignia is associated.

(f) Brand and Establishment Advertisement Prohibited. No advertisement relating to the availability of any alcoholic beverages in any licensed premises shall carry any advertising associated with a particular brand of alcoholic beverages if the cost of such advertising is paid by the industry member, except as permitted by Rule 0100-06-.03.

Authority: T.C.A. §§ 57-1-209, ~~57-3-104~~, 57-4-201, ~~57-2-209 to implement §~~ and 57-3-106 ~~and Chapter 211, Public Acts of 1967, and 57-818 to implement §57-111 and Chapter 211, Public Acts of 1967~~.

0100-01-.02 Solicitation Of Business, And Services Restricted

(1) Manufacturer and Importer, Limited to Wholesale Solicitation.

(a) No manufacturer, importer or representative thereof shall solicit orders of alcoholic beverages or wine in any manner from anyone in this state except from those holding wholesale liquor licenses.

(b) No manufacturer, importer, or representative thereof shall perform or provide any service whatsoever for a licensee hereunder, or his employee in this state, whether on or away from the licensed premises. No manufacturer, importer, or

representative thereof shall enter the premises of any licensee hereunder, except as a bona fide customer.

(c) No manufacturer, importer, or representative thereof shall give anything of value whatsoever, including but not limited to alcoholic beverages and money, to any Tennessee retail licensee or his employee whether on or away from the retail premises. Furthermore, no manufacturer, importer, or representative thereof may take into any licensed premises hereunder any alcoholic beverages in any quantity.

~~(d) Notwithstanding the prohibitions contained herein, all conduct or services permitted by 0100-06 of these regulations are permitted.~~

Authority: T.C.A. §§ ~~57-818,~~ 57-1-209, 57-3-104, 57-3-202, and 57-3-405.

0100-01-.03 Conduct Of Business.

(1) Business Management Restricted.

(a) Every licensed business shall be managed by the holder of the license, if an individual, or by a partner or corporation officer or by a manager designated to the Commission in the event that the business is operated by a partnership or corporation (or by a manager in any case who has been designated to the Commission). The Alcoholic Beverage Commission is to be notified in writing, by certified mail, of any change in management within seven (7) days of the actual change.

(b) Each on-premise manager, assistant manager, and/or any individual working in such capacity, whether paid by salary or hourly and/or in training, and having duties which directly or indirectly impacts on the selling and dispensing of alcoholic beverages, must complete and submit to the Tennessee Alcoholic Beverage Commission a questionnaire within seven (7) days of assuming their managerial duties.

(c) Each on-premise manager, assistant manager, and/or any individual working in such capacity and having duties which directly or indirectly impacts on the selling and dispensing of alcoholic beverages must have a valid server permit subject to the provisions of T.C.A. § 57-3-707.

(2) Consumption on Licensed Premises. No licensee shall permit alcoholic or malt beverages to be consumed on the licensed premises between the hours of 3:00 a.m. and 8:00 a.m. on Monday through Saturday or between the hours of 3:00 a.m. and 10:00 a.m. on Sunday unless the local jurisdiction has opted out of the expanded hours. If such is the case, then the consumption and/or sale of alcoholic beverages may begin at 12:00 p.m. on Sunday.

(3) Free Access to Licensed Premises Without Warrant. Immediate access, without a warrant, to all parts of a licensed premise shall at all times be accorded agents of the Tennessee Alcoholic Beverage Commission.

(4) Refusal of Cooperation. Any licensee, his agent, or employee who refuses to open or disclose his records to, furnish information to, or who furnishes false and/or misleading information to an agent or representative of the Tennessee Alcoholic Beverage Commission upon any matter relating to or arising out of the conduct of the licensed premises shall subject the license to revocation or suspension.

(5) Licensees Not to Combine. No combination of licensees shall be permitted to purchase merchandise in the name of the licensee and subsequently distribute merchandise which they have purchased in combination with each other to any one of the combination, and no licensee shall be permitted to transfer goods from one to another. If any member of the combination is apprehended violating this regulation, every member shall likewise be guilty of a violation, and it shall also be a violation for the wholesale distributor to furnish merchandise to any combination of licensed dealers.

(6) Licensee Responsible For Law and Order on Licensed Premises. Each licensee shall maintain his establishment in a decent, orderly, and respectable manner in full compliance with all laws of Tennessee, Commission rules and regulations, federal statutes, and ordinances and laws of the municipality and/or county where licensed premises are located at all times. The renting or leasing of the licensed premises for an event to a non-licensed entity, person, or corporation is specifically deemed not to be a defense for a violation of this rule and does not diminish the licensee's responsibility to comply with this rule.

(7) Sanitary and Fire Standards. All licensed premises shall be kept in clean and proper sanitary condition, and in full compliance with the provisions and regulations of all duly authorized health authorities whether state, county, or city.

(8) On-Premise Sale By Bottle Restricted. On-premise licensees shall not sell or give away distilled spirits by the bottle or package, open or unopened. Licensees shall have the right to sell wines, champagnes, or malt beverages by the bottle or container for consumption on the premises only, and said bottle or container must be opened prior to its being served to the consumer, except as specifically provided in T.C.A. § 57-4-203.

(9) On-Premise Employees' Activities Restricted ("B-Girl" Activity). It shall be unlawful for any person who is an employee of an on-premise licensee or any other person on behalf of the on-premise licensee to solicit alcoholic beverages ~~or distilled spirits~~ for public consumption by the employee or any other person, and it shall be further unlawful to dispense or consume any beverage under the pretense that it is an alcoholic beverage ~~or distilled spirits~~ for public consumption but is not. However, nothing in this section shall preclude an industry member and/or its employees or representatives from promoting products as permitted under Rule 0100- 03-.11.

(10) Restriction As To Age Of Dispensing Employees. No person under the age of eighteen (18) years shall be permitted to dispense, serve, or sell alcoholic or malt beverages in any establishment licensed under the provisions of T.C.A. § 57-4-101, *et seq.*

(11) Dual Interests Prohibited. Except as provided in Rule 0100-03-.16:

(a) No licensee holding a license issued pursuant to T.C.A. § 57-4-101, *et seq.* and no person owning an interest, financial or otherwise, in a partnership or corporation holding such a license, shall have any interest, directly or indirectly, in any business licensed under the provisions of T.C.A. §§ 57-3-202, or 57-3-203~~, or 57-3-204~~.

(b) No person having any interest, financial or otherwise, directly or indirectly, in any business licensed under the provisions of T.C.A. §§ 57-3-202~~,~~ or 57-3-203 ~~or 57-3-204,~~ shall have any interest in any business licensed under T.C.A. § 57-4-101, *et seq.*

(12) Restrictions on License After Surrender or Revocation.

(a) No license will be issued to the spouse, child or children, son-in-law or daughter-in-law, employee, or other person having any interest in the business of a licensee whose license has been revoked, for the privilege of doing business at the same location or in close proximity to the location of the establishment whose license was revoked.

(b) The Commission may refuse to reissue a license to the same person, firm, or corporation whose license has been revoked for one (1) year from the date of said revocation.

(c) The Commission may treat a surrender of a license as a revocation under the restrictions contained in this paragraph.

(13) Licensee Must Surrender License If Business Discontinued. Whenever any licensee discontinues business for any reason, he shall immediately notify the Commission in writing and surrender his license.

(14) Prohibited Practices. No licensee, employee, or agent of a licensee shall give away any sealed package, or any drink, of wine or alcoholic beverages except as permitted by T.C.A. § 57-3-404 and Rules 0100-03-.11 and 0100-06-.03. "Give" for the purpose of this paragraph, shall include:

(a) Offering or delivering any free alcoholic beverage or wine to any person or group of persons;

(b) Offering or delivering unlimited drinks of wine or alcoholic beverages for a fixed price if the actual cost of all ingredients, including the alcohol and all applicable taxes, of the drinks actually served to a customer exceeds the fixed price charged; or

(c) Awarding any wine or alcoholic beverages as a prize or free drink or encouraging or conducting any game or contest which involves drinking or uses wine or alcohol as a prize or free drink.

(15) Happy Hour Restrictions. No licensee, employee, or agent of a licensee shall engage in any of the following promotional practices during the period beginning at 10:00 p.m., prevailing time, until the time set by law for closing of such licensed establishments:

(a) Serve two (2) or more drinks or containers of alcoholic beverages to a consumer at one time.

(b) Increase the volume of alcohol contained in any such drink during any calendar week without increasing proportionately the price regularly charged for such drink.

(16) Business Name Change. At least seven (7) calendar days prior to any change in its business name or "d/b/a" name, a licensee must submit the proposed change in writing to the Commission for approval. Upon approval, the Commission will amend the license to reflect the licensee's new business or "d/b/a" name.

(17) Display of License. Any person, partnership, corporation, or other legal entity holding an on-premise consumption liquor-by-the-drink license issued under Chapter 4 of Title 57 of Tennessee Code Annotated, shall prominently display and post, and keep displayed and posted, in the most conspicuous place in the licensed premises, the license so issued.

(18) Server Permits. On-premise consumption licensees should maintain and have available for review on the premises documentation of the date of hire for anyone working in a capacity to serve alcoholic beverages. Acceptable documentation shall include a dated application for employment or a dated W-4 form. If the licensee does not have acceptable documentation of the date of hire for the employee, then it will be deemed that the employee has worked at the licensed premises greater than sixty-one (61) days.

(19) Seating. All on-premise consumption licensees licensed as a restaurant shall maintain a minimum seating for forty (40) people at tables and all on-premise consumption licensees licensed as a hotel shall maintain a minimum seating for seventy-five (75) people at tables during business hours with the exception of wine-only restaurants as defined at T.C.A. § 57-4-101(c) ~~gourmet restaurants as defined at T.C.A. § 57-4-102(27)(e)~~, or any other statutory exception. Seasonal seating (i.e. outside patio seating) shall count toward total numbers, but not toward the minimum seating requirements at tables. Seats at bars will be counted toward the minimum number of seats at tables if the bar is at least twenty (20) inches in depth and meals may be served and are regularly served at the bar. Those bars containing less than twenty (20) inches in depth will be looked at on a case by case basis with such factors as the type of menu served, placement of the bar, and whether food is regularly served at that bar.

(20) Minors in Possession of Alcohol. All on-premise consumption licensees are required to insure that minors are not in possession of and/or are not allowed to consume any alcoholic beverage – including malt beverages or beer – on the licensed premises.

(21) Employer Responsible for Employee's Action.

(a) Licensees are at all times responsible for the conduct of their businesses and are at all times directly responsible for any act or conduct of any employee which is in violation of the state statues, the rules and regulations of the Commission, and/or any local ordinance or federal statute whether the licensee be present at any such time or not. This section is defined to mean that any unlawful, unauthorized, or prohibited act on the part of a licensee's agent or employee shall be construed as the act of the employer, and disciplinary actions will proceed as though he were present and had an active part in such unlawful, unauthorized, or prohibited act, and as if having been at the employer's direction and with his knowledge.

(b) In any disciplinary proceeding, it shall be no defense that an employee or agent of a licensee acted contrary to order, or that a licensee did not personally participate in the violating action or actions. However, disciplinary actions related to sales of alcoholic beverages to minors, intra-industry violations, and trade violations are subject to the provisions of Rule 0100-05-.07, the Responsible Licensee Program.

(22) Application Process for On-premise Consumption Licenses.

(a) Applications, in duplicate, shall be submitted to the nearest office of the ABC. In addition, the following documents must be submitted in support of an application for license to sell alcoholic beverages for consumption on premises:

1. Completed application;

2. Questionnaire for anyone having at least five percent (5%) ownership in the business, for any officers of a corporate applicant, and for any manager, assistant manager, and/or any individual working in such

capacity and having duties which directly or indirectly impacts on the selling and dispensing of alcoholic beverages;

3. Lease agreements, assignments, subleases, and/or deed to property;

4. Current Certificate of Occupancy;

5. Inspection by the Tennessee Alcoholic Beverage Commission;

6. Acknowledgment of the rules and regulations;

7. Menu;

8. Price Schedule of Drinks;

9. Proof that applicant entity, if a corporation, LLC, LP, etc., is registered with the Tennessee Secretary of State's office, and the submission by said applicant entity of a Certificate of Existence/Good Standing issued by the Tennessee Secretary of State's Office within thirty (30) days of applicant's application for a new license or renewal of an existing license. If the applicant entity was formed in another state or foreign jurisdiction, the applicant must submit a Certificate of Authorization issued by the Tennessee Secretary of State's Office within thirty (30) days of the applicant's application for a new license or renewal of an existing license.

10. Corporate charter/Articles of Organization;

11. List of Officers/Owners/Members/Partners;

12. Sales & Use Tax Certificate of Registration;

13. Bond Posted with the Department of Revenue;

14. Application fee;

15. Completed declaration of citizenship form to be submitted by owner(s), officer(s), and/or principal(s) of the applicant or others as required by ~~P.C 1061 (2012)~~ T.C.A. § 4-58-101, *et seq*.

16. Any other information that the Tennessee Alcoholic Beverage Commission may request.

(b) In addition, any of the following documents which exist must also be submitted:

1. Management agreements;

2. Bill of sale.

Authority: T.C.A. §§ 4-58-103, ~~57-1-207,~~ 57-3-104(c), ~~57-3-406~~57-1-209(b), 57-3-704, 57-3-710, 57-4-102~~(29), 57-4-104(c),~~ 57-4-201(a)(2), and 57-4-203, 57-7-223 and Chapter 371, Public Acts of 2017. ~~and 2008 Public Chapter 649.~~

0100-01-.04 Transfer Of Locations.

(1) The transfer of an on-premise consumption liquor license from one location to another shall be subject to the following provisions:

(a) The licensee must submit to the Commission prior to the actual move the following documents for approval:

1. Completed application;

2. Lease agreements, assignments, subleases, and/or deed to property;

3. Use and Occupancy permit;

4. Inspection by the Tennessee Alcoholic Beverage Commission;

5. Letter of explanation for the request; and

6. Any other information that the Tennessee Alcoholic Beverage Commission may request.

(b) Selling, consuming, and/or otherwise dispensing alcoholic beverages at the new location prior to the approval by the Commission is in violation of T.C.A. § 57-4-203(i).

Authority: T.C.A. §§ ~~57-3-205,~~ 57-1-207, ~~57-1-201,~~ 57-1-209, 57-3-104, 57-3-212, ~~and~~ 57-4-201 and 57-4-203.~~(a)(2).~~

0100-01-.05 Applications By Private Clubs.

(1) Public Notice. Each club, as defined by ~~Pursuant to~~ T.C.A. § 57-4-102~~(7)~~, ~~each club~~ applying for a license to sell alcoholic beverages for consumption on its premises shall place a notice in a newspaper of general circulation in the county or municipality to be served indicating the club's intention to apply for a license from the Alcoholic Beverage Commission. The notice shall contain the information prescribed in subsection (2) below and shall appear in at least three (3) consecutive issues preceding the date that the application is filed with the Commission. The application shall be accompanied by a copy of the published notice and the sworn statement of the applicant that the notice was published in accordance with this section.

(2) Format of Notice. Each private club applicant shall place the following notice in the newspaper as described above:

PRIVATE CLUB LIQUOR LICENSE NOTICE

Take notice that _____

(Name of Club)

intends to seek a license from the Tennessee Alcoholic Beverage Commission, ~~226 Capitol Boulevard Building~~ 500 James Robertson Parkway; 3rd Floor; Nashville, Tennessee 37243~~-0755~~, to sell alcoholic beverages to its members and guests for consumption on the club's premises at _____. The officers of

(Address of club's premises)

_____ are: _____

(Name of Club)

_____

(Name and address of officers)

The club currently has approximately _____ regular dues paying members.

_____

(Name/Address of Person Actually in Charge of Sale of Alcoholic Beverages)

will be in actual charge of the sale of alcoholic beverages at the club's premises and has

applied to _____
(City or County)
for a certificate of good moral character.

(3) Size of Notice. The title of the notice shall be all capital letters and at least ten (10) point type size. The text of the notice shall be at least eight (8) point type size and the size of the entire notice shall not be less than two (2) columns by two (2) inches of newspaper space.

(4) Change of Manager. Whenever there is a change in person or persons who are in actual charge of the sale of alcoholic beverages by a private club licensee, the licensee must submit to the Alcoholic Beverage Commission a certificate of good moral character for the new person or persons who will be in actual charge of the sale of alcoholic beverages within thirty (30) days of the change. Nothing in this rule should be interpreted to relieve a private club licensee from the obligation to inform the Commission of a change in management as set out in Rule 0100-01-.03(1).

(5) Application Process for New Private Club Licenses.

(a) Applications, in duplicate, shall be submitted to the nearest office of the ABC. In addition, the following documents must be submitted in support of an application by a private club for a license to sell alcoholic beverages for consumption on premises:

1. Application (in duplicate) (Form ABC-OPP);

2. Questionnaires - officers of club and managers in control of actual sale of alcoholic beverages;

3. List of club officers (names, addresses, date assumed office);

4. Charter, constitution, and any amendments thereto, if club is incorporated;

5. Lease, sublease, deed or other instrument indicating ownership and/or possession of physical premises;

6. Certificate of good moral character for person(s) in actual charge of sale of alcoholic beverages;

7. Newspaper notice accompanied by sworn statement as required by subsections (2) through (3) above;

8. Menu;

9. Department of Revenue Drink Price Schedule;

10. Employees work permit applications;

11. Answers to questions on ABC form - Questions For Private Club Applicants.

(b) In addition, any of the following documents which exist must be submitted:

1. Bylaws;

2. Minutes of membership or board meetings;

3. Management contract;

4. Loan or financing agreements;

5. Past tax returns (2 years);

6. Resolutions relative to changes in name, purpose, or location of club;

7. Financial statements;

8. Written approval of use and occupancy by appropriate local authorities, where applicable.

(c) Applicants should submit any other documents which indicate the club's compliance with licensing requirements. Such documentation may include items such as announcements of past activities, newsletters sent to members, ledgers reflecting payment of dues in past years and disbursement of funds, IRS recognition as tax-exempt nonprofit organization, sworn statements regarding the club's history and activities, etc. The applicant for a license has the burden of proving that it meets the requirement of the law and is, therefore, eligible to hold a license to sell alcoholic beverages. The fact that the applicant submits all the documents listed above does not automatically entitle the applicant to a license. Further, the applicant may be required to submit additional information or documentation if questions arise.

(d) A license for a private club to sell alcoholic beverages on its premises may only be granted by action of the Alcoholic Beverage Commission itself.

(6) License Renewal and Transfer of Location by Private Clubs.

(a) License Renewal. Each license issued is valid for one (1) year from the date of issuance and expires at midnight on the expiration date. Both the issuance date and the expiration date shall be clearly printed on the face of the license. Failure to timely and properly file the material required by this rule shall result in the expiration of the license.

1. On or before the expiration date of the license, the licensee shall submit an application for license renewal and the appropriate license fee to the nearest office of the Alcoholic Beverage Commission.

2. Applications for license renewal need not submit that material required by rule 0100-01-.05(5) of new applicants.

3. All financial records shall be maintained and available for inspection for a minimum of three (3) years.

(b) Transfer of Location. Licenses issued to private clubs may be transferred from one location to another only upon the following conditions:

1. Written request for approval of such a transfer with adequate explanation for the need of such a transfer.

2. Submittal of a satisfactory lease or deed to the proposed new location.

3. Written approval of the use and occupancy of the proposed new space by the appropriate local officials.

4. Inspection by the Tennessee Alcoholic Beverage Commission.

5. Submittal of a petition or resolution in favor of such a transfer which reflects that it was adopted by a quorum of the club's members at a membership meeting held pursuant to the club's charter and by-laws.

6. When the proposed transfer is into a new jurisdiction, the club shall publish a new notice in compliance with paragraphs (1) through (3) of this rule and supply copies of that notice along with required sworn statement to the ABC as well as a certificate of good moral character upon the person pursuant to T.C.A. § 57-4-201(c)(2).

7. No such transfer shall be approved unless the Commission, in its sole discretion, determines that the licensee continues to meet the requirements of these rules and Chapter 4 of Title 57, T.C.A.

(7) Definitions. For the purpose of this chapter, the following definitions shall be used:

(a) "Non-profit association" shall mean a legal entity which is not-for-profit and has at least the following characteristics:

1. Financial statements covering the immediately preceding years of the club's operations. Financial statements shall clearly indicate the amount and source of all club receipts and the amount and purpose of all club disbursements in specific categories consistent with standard accounting practices. In addition, the financial statements must show a balance sheet of the club's assets and liabilities at the end of the immediately preceding year. Copies of IRS Form W-2 for each employee shall be maintained and made available upon request.

2. Bylaws or rules of the association which provide membership application procedures. Those bylaws or rules shall provide for (a) at least one (1) week waiting period between application for membership and election to membership and (b) a committee composed of three (3) or more members of the club vested with the authority by charter, bylaws or regulations, to approve, reject, or make recommendations on membership applications.

3. An association shall have a written guest policy which reasonably limits access to club facilities by guests.

(b) "In existence and operating" shall mean for at least two (2) years prior to the application for a club license, the association shall have had at least an annual meeting of the membership with a quorum present, shall have taken actions toward the performance of their non-profit purposes, and shall have elected a governing body which meets periodically.

(c) "Regularly paying dues" shall mean that the members have paid dues on a regular schedule at least annually.

(d) "Salary" shall mean a fixed periodical compensation paid for services rendered. No salary may be paid which is based on the amount of liquor or malt beverages sold or on the profits made from such sales.

(e) "Suitable kitchen" shall mean that the kitchen is adequate to prepare regular meals. Said kitchen shall have sufficient cookware, tableware, and food preparation and storage equipment to actually store, prepare, and serve meals. These facilities shall be inspected and approved by appropriate local zoning and codes inspectors.

(8) Additional Rules for Private Clubs.

(a) Each club shall maintain a complete membership roster. The membership roster shall contain the names of all members, their addresses, and the date on which their dues are to be paid. Private club licensees shall maintain their membership records at the club premises and make them available to representatives of the Alcoholic Beverage Commission during hours when the club is open to its members. Since minimum membership is one hundred (100), failure to have ten (10) members at any annual meeting shall be prima-facie evidence of the non-existence of the association.

(b) All salaries, rents, or management fees paid by a private club to any person or legal entity must be reasonable and proper compensation under the circumstances.

(c) No private club shall dispense alcoholic beverage on the premises of the club to any person other than a bona fide member of the club or a bona fide guest of a member of the club. Alcoholic beverages should not be served in an area to which the general public is admitted. If the club's bar area is in a separate room from that to which the general public is admitted and admission to the bar is limited to members of the club and their guests, the bar may remain open. If, however, the bar is in the room to which the general public is admitted, no alcoholic beverages are to be served in that room during the time the general public is present.

(d) The Alcoholic Beverage Commission shall determine whether a club exists exclusively for non-profit purposes. No such license shall be issued where the ABC determines that the purpose is to make a profit.

(e) Violation of any of the rules set out herein may, in the judgment of the ABC, result in the suspension or revocation of the club's license or the imposition of a fine under the rules of the Commission. These rules are in addition to the other rules of the ABC and shall apply to club licensees only.

(f) Whenever membership in the club drops below one hundred (100), the club ceases to have facilities in which to serve its members or guests, or the club discontinues its operations, it shall surrender its license immediately.

(g) No private club licensed by the Commission shall utilize any name other than the name approved by the Commission and appearing on the club's license. Use of a d/b/a name is prohibited.

Authority: T.C.A. §§ 57-1-209, 57-3-104, 57-4-102 and 57-4-201; ~~1980 Tennessee Public Acts, Chapter 895~~.

0100-01-.06 Additional Rules Applicable To Caterers.

(1) Commission licensed caterers shall have available for inspection at catered events involving the sale or dispersion of alcoholic beverages by that caterer, its catering license or a copy as issued by the Commission.

(2) Only employees of a licensed caterer who are in possession of a valid server's permit may serve alcoholic beverages at any event, whether at the caterer's designated premises or a remote venue.

(3) Commission licensed caterers may only sell alcoholic beverages on a by-the-drink basis, collecting appropriate taxes, and only in cities, municipalities, and/or counties where such sales are authorized.

(4) No Commission licensed caterer may provide only alcohol without food items present and available for consumption at any catered event.

(5) Commission licensed caterers must provide and the Commission must receive at its Nashville office, a written and/or electronic notice of any catered event involving the sale or distribution of alcohol. Such notice must be provided by the caterer and received by the Commission at least two (2) full business days prior to the event during state working hours, prevailing time. Such notice shall include the date of the event, the address of the event, the host of the event, and the time of the event.

(6) If a Commission licensed caterer is providing and selling the alcohol at a catered event, then all proceeds generated from the sale of alcoholic beverages at the catered event shall be deposited into the caterer's monetary account(s). No third party shall receive any proceeds from the sale of alcoholic beverages at a catered event.

(7) Alcohol may be transported by the caterer to the premises of the catered event no earlier than 8:00 am. At the conclusion of the catered event, all alcohol must be removed from the premises no later than 12:00 p.m. of the following day. No one other than the licensed caterer or its employees may serve, sell, or otherwise dispense, and/or have access to any alcohol on the premises of the catered event.

(8) During the duration of the catered event, the licensed caterer is responsible and liable for full compliance with all laws of Tennessee, Commission rules and regulations, federal statutes, and ordinances and laws of the municipality and/or county where licensed premises are located at all times.

Authority: T.C.A. §§ 57-1-209, 57-3-104, 57-4-101, 57-4-102 and 57-4-201.

0100-01-.07 Applications For Special Occasion Permits.

(1) Special Occasion Permits are a one-day (1) permit allowing the sale, service, and/or otherwise dispensing of alcoholic beverages at specifically designated areas by certain qualified entities and are subject to the laws governing the consumption of alcoholic beverages. Special Occasion Permits are required if an entity does not otherwise hold an on-premise consumption liquor license, and/or if the entity is selling, serving, or otherwise dispensing alcoholic beverages to the general public. A special occasion permit is also required if the entity is selling alcoholic beverages to invited guests only.

(2) To obtain a special occasion permit, the following documents must be submitted to the Commission at least two (2) calendar weeks prior to the date of the event:

(a) A completed and notarized application;

(b) Certification of recognition of 501(c) status from the IRS, and/or financial records for two (2) years preceding the date of the application indicating that at least sixty percent (60%) of the gross revenues have been used exclusively for religious, educational, or charitable purposes;

(c) If the applicant is a bona fide political organization, then the applicant will submit documentation that it is either a political campaign committee as defined at T.C.A. § 2-10-102(a) or that it is a political party as defined at T.C.A. § 2-13-101;

(d) Proof that the applicant is registered with the Secretary of State's Office as a charitable, non-profit organization;

(e) Application fee;

(f) Letter of permission from the owner of the property where the event will be held granting permission to the applicant to sell or serve alcoholic beverages on its premises; and

(g) Any other documentation that the Commission may request.

(3) All proceeds generated from the sale of alcoholic beverages pursuant to the special occasion permit must be deposited into the special occasion permittee's monetary account(s).

(4) Special occasion permittees shall be responsible for complying with state statutes, rules and regulations related to the sale of alcoholic beverages to minors, the sale of alcoholic beverages to visibly intoxicated persons, and/or the sale of alcoholic beverages by the bottle.

Authority: T.C.A. §§ 57-1-209, 57-3-104, 57-4-101, 57-4-102 and 57-4-201.

0100-01-.08 TERMINAL BUILDING OF A COMMERCIAL AIR CARRIER.

(1) Hours of Sale. Notwithstanding subsection 0100-01-.03(2), any establishment that holds a license as a terminal building of a commercial air carrier airport under Tenn. Code Ann. §57- 4-102(36), any establishment that holds a license as a commercial airline travel club under Tenn. Code Ann. § 57-4-102(10), or a concessionaire that holds a liquor-by-the-drink license and is located in a terminal building of a commercial air carrier airport, shall be permitted to allow alcoholic or malt beverages to be consumed and/or sold on the licensed premises during the hours that the terminal building of the commercial carrier airport is open to the public, unless the local jurisdiction has opted out of these expanded hours.

(2) Privilege Tax. Establishment, as the term is used in Tenn. Code Ann. § 57-4-301(b)(1)(L), shall mean the license holder. Only one license fee or privilege tax shall be due from each holder of a license for a terminal building of a commercial air carrier airport, regardless of the number of points of sale the entity may operate under the license.

(3) Establishment.

(a) A terminal building of a commercial air carrier airport license may be issued either to the entity having contractual, jurisdictional or other such authority to operate the airport, or, in the entity's discretion, to another entity or entities as are contractually authorized to operate within the airport. All such entities shall be considered an establishment for purposes of Tenn. Code Ann. § 57-4-301(b)(1)(L) and shall file an addendum with each renewal application identifying each point of sale within the

airport.

(b) The holder of a license for a terminal building of a commercial air carrier airport may contractually authorize a separate entity to operate under the terminal building of a commercial air carrier airport license, and such contractually authorized entity shall not be required to obtain its own license; provided that prior notice and disclosures shall be given to the commission, on such forms or in such manner as may be prescribed by the commission. The license holder shall ultimately be responsible for any violation or sanction issued by the commission.

(4) Enforcement. The commission may, in its discretion, treat each point of sale at the terminal building of a commercial air carrier separately for enforcement purposes.

Authority: *T.C.A. §§ 57-3-204(i), 57-4-101, 57-4-102, 57-4-201, 57-4-203, and 57-4-301.*

DRAFT

Chapter 0100-03 Local Option Liquor Rules is amended by deleting the chapter in its entirety and by substituting instead the following language:

RULES OF TENNESSEE ALCOHOL BEVERAGE COMMISSION CHAPTER

CHAPTER 0100-03 LOCAL OPTION LIQUOR RULES

TABLE OF CONTENTS

0100-03-.01 Advertising of ~~Distilled Spirits in Newspapers, Magazines or Similar Publications~~ Alcoholic Beverages Generally
0100-03-.02 ~~Advertising of Wine in Newspapers, Magazines, or Similar Publications~~ Reserved
0100-03-.03 Advertising of Distilled Spirits and Wine by Direct Mail Communications
0100-03-.04 ~~Advertising of Distilled Spirits and Wine on Radio or Television~~ Reserved
0100-03-.05 Advertising ~~Distilled Spirits and Wine~~ Alcoholic Beverages on Billboards and Outside Signs
0100-03-.06 Advertising Materials Within Retail Premises
0100-03-.07 ~~Advertising Novelties and Specialties~~ Authorized Products and Services by Retailers
0100-03-.08 Advertising Approval Does Not Sanction Any Violation, Commission Discretion on Advertising
0100-03-.09 Licenses and Permits
0100-03-.10 Transporting and Delivery of Alcoholic Beverages
0100-03-.11 Solicitation of Business, Services Restricted
0100-03-.12 Containers and Sizes
0100-03-.13 Conduct of Business-Wholesaler and Retailer
0100-03-.14 Conduct of Business of Wholesalers
0100-03-.15 Restrictions on Premises, Conduct of Business of Retailers
0100-03-.16 Dual Interests Prohibited
0100-03-.17 Responsibility and Penalties for Violations
0100-03-.18 Transfer of Licenses
0100-03-.19 ~~Repealed~~ Manufacturer Representative Permits
0100-03-.20 ~~Repealed~~ Donations to Nonprofit Organizations
0100-03-.21 ~~Repealed~~ Noncontiguous Premises of Manufacturers
0100-03-.22 Private Events
0100-03-.23 Rectifying

0100-03-.01 Advertising of ~~Distilled Spirits in Newspapers, Magazines, or Similar Publications~~ Alcoholic Beverages Generally.

(1) Statements Prohibited in Advertisements of ~~Distilled Spirits in Newspapers, Magazines, or Other Publications~~ Alcoholic Beverages.

(a) Restrictions. An advertisement shall not contain:

1. Any statement that is materially false or misleading ~~in any material particular~~.

2. Any statement that is disparaging of a competitor's products.

3. Any statement, design, device, or representation which is obscene or indecent.

4. Any statement, design, device, or representation of or relating to analysis, standards, or tests, irrespective of falsity, which is likely to mislead the consumer.

5. Any statement, design, device, or representation of or relating to any guaranty, irrespective of falsity, which is likely to mislead the consumer.

6. Any statement that the product is produced, blended, made, bottled, packed, or sold under, or in accordance with, any authorization, law, or regulation of any municipality, county, or state, federal or foreign government unless such statement is required or specifically authorized by the laws or regulations of such government; and if a municipal, county, state, or federal permit number is stated, such permit number shall not be accompanied by any additional statement relating thereto.

(b) Statements Inconsistent with Labeling. No advertisement shall contain any statement concerning a brand or lot of ~~distilled spirits~~ alcoholic beverages that is inconsistent with any statement on the labeling thereof.

(c) Curative and Therapeutic Effects. No advertisement shall contain any statement, design, or device representing that the use of ~~distilled spirits~~ alcoholic beverages has curative or therapeutic effects, if such statement is untrue in any particular, or tends to create a misleading impression.

(d) Place of Origin. No advertisement shall represent that the ~~distilled spirits~~ alcoholic beverages were manufactured in, or imported from a place or country other than that of their actual origin, or were produced or processed by one who was not in fact the actual producer or processor.

(e) Flags, Seals, Coats of Arms, Crests, and Other Insignia. No advertisement shall contain:

1. ~~any~~ Any statement, design, devices, or pictorial representation of or relating to, or capable of being construed as relating to the armed forces of the United States, or of the American flag, any state flag, or of any emblem, seal, insignia, or decoration associated with any such flag or the armed forces of the United States if including such statement, design, devices, or pictorial representation is likely to falsely lead the consumer to believe that the product has been endorsed, made, used by, produced for, under the supervision of, or in accordance with the specifications of the government or armed forces; ~~nor shall any advertisement contain~~ or

2. ~~any~~ Any statement, device, design, or pictorial representation of or concerning any flag, seal, coat of arms, crest, or other insignia, if including such flag, emblem, seal, coat of arms, crest, insignia, or decoration is likely to falsely lead the consumer to believe that the product has been endorsed, made, used by, produced for, under the supervision of, or in accordance with the specifications of the government, organization, family, or individual with whom such flag, seal, coat of arms, crest, or insignia is associated.

(2) Prior Approval. Advertisements conforming to the foregoing provisions need not have prior approval of the Commission before publication.

(3) Advertising by Licensees and Permittees.

(a) Advertising by ~~a person or other legal entity licensed as a wholesaler or retailer~~ any licensee or permittee shall be allowed on the internet, or any other computer-accessed communication; however, such advertisement shall be subject to ~~TABC Rules 0100-03-.01 and 0100-03-.02~~ Rule 0100-03-.01 and Rule 0100-03-.03.

(b) ~~Wholesalers and retailers~~ Any licensee or permittee under Title 57 of Tennessee Code Annotated may develop e-mail or other computer-access communication mailing lists, and may respond by electronic mail or other computerized communication (including, but

not limited to, mobile devices and electronic communications via social media) to any party making inquiry by providing information regarding an alcoholic beverages or any other products or services which may be sold or provided in accordance with laws, rules, and regulations of the State of Tennessee. ~~No retailer shall authorize or send any unsolicited electronic mail to a consumer.~~

(c) Manufacturers, importers, non-resident sellers, non-manufacturer non-resident sellers, wholesalers, or any representative thereof, may place posts or messages on social media to identify to consumers the retail locations where the industry member's product may be purchased at retail in the manner specified in Rule 0100-06-.03(4).

~~(c)~~(d) Licensees and permittees engaged in internet advertising ~~may~~ shall not directly or indirectly falsely identify ~~itself~~ themselves in any advertising or in domain addresses. ~~Further, such licensee must submit to the Commission the exact "web site" or domain address it intends to use prior to beginning the advertising.~~

Authority: T.C.A. §§ ~~57-818, and 57-1-203,~~ 57-3-104, and 57-4-201.

0100-03-.02 Reserved ~~Advertising of Wine in Newspapers, Magazines or Similar Publications.~~

~~(1)~~ ~~Prohibited Statements.~~

~~(a)~~ ~~Restrictions. An advertisement shall not contain:~~

~~1.~~ ~~Any statement that is false or misleading in any material particular.~~

~~2.~~ ~~Any statement that is disparaging of a competitor's products.~~

~~3.~~ ~~Any statement, design, device, or representation which is obscene or indecent.~~

~~4.~~ ~~Any statement, design, device, or representation of or relating to analyses, standards, or tests, irrespective of falsity, which is likely to mislead the consumer.~~

~~5.~~ ~~Any statement, design, device, or representation of or relating to any guaranty, irrespective of falsity, which is likely to mislead the consumer.~~

~~6.~~ ~~Any statement that the product is produced blended, made, bottled, packed, or sold under, or in accordance with, any authorization, law or regulations of any municipality, county, or State, Federal, or foreign government unless such statement is required or specifically authorized by the laws or regulations of such government; and if a municipal, county, State, or Federal permit number is stated, such permit number shall not be accompanied by any additional statement relating thereto.~~

~~(b)~~ ~~Statements Inconsistent with Labeling. No advertisement shall contain any statement concerning brand or lot of wine that is inconsistent with any statement on the labeling thereof.~~

~~(c)~~ ~~Curative and Therapeutic Effects. No advertisement shall contain any statement, design or device representing that the use of any wine has curative or therapeutic effects, if such statement is untrue in any particular, or tends to create a misleading impression.~~

~~(d)~~ ~~Place or Origin. No advertisement shall represent that the wine was manufactured in, or imported from, a place or country other than that of the actual origin, or was produced or processed by one who was not in fact and actual producer or processor.~~

~~(e) Flags, Seals, Coats of Arms, Crests, and other Insignia. No advertisement shall contain any statement, design, device, or pictorial representation of or relating to, or capable of being construed as relating to, the armed forces of the United States, or of the American flag, any State flag, or of any emblem, seal, insignia, or decoration associated with any such flag or the armed forces of the United States; nor shall any advertisement contain any statement, device design, or pictorial representation of or concerning any flag, seal, coat of arms, crests, or other insignia, likely to falsely lead the consumer to believe that the product has been endorsed, made, or used by, or produced for, or under the supervision of, or in accordance with the specifications of the government, organization, family, or individual with whom such flag, seal, code of arms, crest or insignia is associated.~~

~~(2) Prior Approval. Advertisements conforming to the foregoing provisions need not have prior approval by the Commission before publication.~~

~~Authority: T.C.A. § 57-1-209.~~

0100-03-.03 Advertising of ~~Distilled Spirits~~ Alcholic Beverages and Wine by Direct ~~Mail~~ Communications.

(1) Brands ~~Only~~. Manufacturers, importers, non-resident sellers, non-manufacturer non-resident sellers, and Tennessee licensed wholesalers of ~~distilled spirits~~ alcoholic beverages ~~and wines~~, or any representative thereof whose brands have been approved for distribution in Tennessee ~~and Tennessee licensed wholesalers~~ may advertise brands ~~only~~ directly to consumers by ~~direct~~ mail and/or e-mail, internet, or any other computer-accessed communication (including, but not limited to, mobile devices and communications via social media); provided, however, measures are taken to prevent such communications from targeting individuals under the age of twenty-one (21).

(2) Restrictions. Direct ~~mail~~ communications advertising must conform substantially, where applicable, with the provisions of Rule 0100-03-.01 ~~or 0100-03-.02~~ and in addition must not contain the name, address, or telephone number of any Tennessee-licensed wholesaler, retail food store, or retailer, other than the individual wholesaler, retail food store, or retailer that is directly responsible for sending the direct communication, and this extends to the return address on the envelope. ~~The prohibition of 0100-03-.07(1) is also applicable.~~

(3) Retailer Advertising. Subject to the restrictions of ~~subsection~~ paragraphs (2) and (4) of this rule, a retailer licensed under T.C.A. § 57-3-204 may advertise ~~consumer education seminars, distilled spirits, wines and alcoholic beverages by direct mail to consumers in the form of a newsletter, catalogue or similar communications~~ any and all services and products the retailer is authorized to sell or provide under Title 57 of Tennessee Code Annotated or any rules and regulations adopted by the Commission in accordance therewith.

(4) Restrictions on Direct ~~Mail~~ Communications.

(a) A retailer package store or retail food store may send a communication directly ~~mail or email a newsletter, catalogue, or similar communication only~~ to a consumer ~~who has requested to receive such communication in writing or via email~~, unless a consumer has made a request to the licensee to not receive such communication in writing or via e-mail.

~~(b) The written request or email of a consumer must be maintained in hard copy, scanned, or electronic format by the retailer to whom it is addressed and is valid until such written notification is received by the retailer from the consumer requesting withdrawal of his/her name from the direct mail listing.~~

~~(c) Each written request by a consumer must state the retailer to whom it is addressed and must include the date upon which it is signed by the consumer.~~

~~(d)~~(b) No ~~industry member~~ manufacturers, importers, non-resident sellers, non-manufacturer non-resident sellers, and Tennessee licensed wholesalers of alcoholic beverages may subsidize, contribute, or otherwise compensate a retailer, wholesaler, or retail food store for ~~such~~ any direct ~~mailing~~ communication advertising or otherwise assist, directly or indirectly, with the cost or preparation of any direct communication advertisement.

~~(e)~~(c) A retailer shall not be deemed to be in violation of this section unless it can be established that a consumer has made ~~at least one requests~~ a request to be removed from the mailing, ~~or~~ e-mail list, or other direct communication and such consumer continued to receive ~~mailings or e-mail~~ such communications after ~~thirty~~ fourteen (14) days following ~~the second~~ such a request.

(d) For any direct communications, measures must be taken to prevent such communications from targeting individuals under the age of twenty-one (21). Any direct communications must afford the consumer the ability to opt out of the communications.

(e) Each violation of this rule may result in suspension or revocation of a license or a fine not to exceed the statutory maximum.

Authority: T.C.A. §§ 57-1-209, ~~and~~ 57-3-104~~(c)(4)~~, and ~~57-4-201~~.

0100-03-.04 Reserved ~~Advertising of Distilled Spirits and Wine on Radio or Television by Manufacturers, Importers and wholesalers.~~

~~(1) Radio or Television Advertising. Manufacturers and importers of distilled spirits and wine and Tennessee licensed wholesalers and retailers may advertise via the radio or television.~~

~~(2) Restrictions. Such advertisements must comply with the provisions of 0100-03-.01(1) and 0100-03-.02(1).~~

~~(3) Wine Permitted But Restricted.~~

~~(a) Such advertisements must comply with the provisions of 0100-03-.02(1).~~

~~(b) Such advertisements must not give the name, address or telephone number of a Tennessee licensed wholesaler or retailer.~~

~~Authority: T.C.A. §§ 57-1-209, 57-3-104(c)(4) and 57-3-104(c)(9).~~

0100-03-.05 Advertising ~~Distilled Spirits and Wine~~ Alcoholic Beverages on Billboards and Outside Signs.

(1) Limited to Local Option Counties. Alcoholic beverages may be advertised on signs and billboards only in those counties which have legalized the off-premise or on-premise retail sale of such beverages under the provisions of T.C.A. § 57-3-106.

(2) Restrictions on Billboard and Outside Sign Advertising.

(a) No such sign or billboard shall contain the statements prohibited by Rule 0100-03-.01(1) ~~and 0100-03-02(1)~~.

(b) No such sign or billboard which bears a trademark, trade name, trade slogan, or a facsimile of a product, container, or display associated with a particular brand shall also bear the name or advertise the establishment or refer to the services of any wholesale or retail licensee of this state.

(c) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof, may directly or indirectly give, loan, or supply any retail licensee a sign of any nature bearing the name of the retail establishment or referring to its services in any manner, nor shall they cause such signs to be painted on exterior walls of the retail premises.

(d) Signs advertising brands ~~only~~ painted on the exterior walls of a retail licensee's establishment and paid for directly or indirectly by a manufacturer, importer, wholesaler, or representative thereof ~~shall not extend more than 18 inches beyond the body of the sign and no other painting of the exterior shall be furnished the retail licensee~~ are permitted.

(e) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof, shall directly or indirectly (through a sign company or advertising agency) pay, credit, or otherwise offer inducement of any nature to a retail licensee for the display of any sign or billboard or for the use of space involved therein, nor shall they reimburse the retailer for any expense incidental thereto. ~~No~~ A billboard or other structure for which a retail licensee is paid a rental or offered any inducement may not be used ~~as a billboard~~ for advertising alcoholic beverages.

(3) Local Control. Signs and billboards approved herein are subject to reasonable rules and regulations duly adopted by proper governing bodies in the county and city wherein located.

Authority: T.C.A. §§ ~~57-111, 57-818,~~ 57-1-209, ~~and~~ 57-3-104, 57-3-106 and 57-4-201.

0100-03-.06 Advertising Materials Within Retail Premises.

(1) Who May Supply and Install. Subject to the provisions of Rule 0100-06-.03 ~~of these regulations~~, manufacturers, ~~and~~ importers, non-resident sellers, and non-manufacturer non-resident sellers, or any representative thereof may give, rent, loan or sell to Tennessee licensed wholesalers, but to no other person, signs, posters, placards, decorations, employee clothing, devices, statuettes or geographic displays – printed, painted or electric – for point-of-sale brand advertising, provided such items include branding or advertising of products or brands directly controlled by the manufacturers, importers, non-resident sellers, non-manufacturer non-resident sellers, providing such items. Wholesalers may install or set up such materials in the windows or elsewhere in the interior of a retail establishment. Retailers may not give, rent, loan, or sell such material referenced above to a consumer.

(2) Restrictions on Advertising Within a Retail Premises.

(a) All advertising materials provided under paragraph (1) of this Rule ~~0100-03-.06(1)~~ must conform to Rule 0100-03-.01(1) ~~and Rule 0100-03-.02(1)~~, with the only exception being that such material may contain specific prices and statements of pecuniary appeal.

b) All such material must have the primary value to the retailer of brand advertising only. Brand advertisements must be an integral and not easily separable part of any material that has a secondary or utility value (such as change mats, calendars, thermometers, ash trays, lamps, bottle racks, etc.).

(3) Prohibitions.

(a) The practice of painting the interior of retail licensed premises under the guise of advertising is prohibited. Decorating with crepe paper, "Corabuff" matting, or similar material as a background or setting for advertising material only is permitted but such decoration is limited to a twenty (20) square foot area, per manufacturer, importer, non-

resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof.

(b) Except as permitted by the provisions of Rule 0100-06-.03, no manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof, shall give, rent, loan, or sell a retail license any fixtures, furnishings, or equipment of a permanent nature under the guise of advertising except as permitted by Rule 0100-06-.01, *et seq*.

(c) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof, shall directly or indirectly through an agent pay, credit, or otherwise offer any inducement whatsoever to the retailer for displaying such materials as authorized herein for any expenses incidental thereto.

~~(d) No manufacturer, importer, wholesaler or representative thereof, shall directly or indirectly through an agent pay, credit, otherwise offer any inducement whatsoever to the retailer for displaying such materials as authorized herein for any expenses incidental thereto.~~

Authority: T.C.A. §§ ~~57-818, and~~ 57-1-209, 57-3-104, and 57-4-201.

0100-03-.07 ~~Advertising Novelties and Specialties.~~ Authorized Products and Services by Retailers

(1) ~~Off-premise retailers licensed under T.C.A. § 57-3-204 may distribute to consumers only alcoholic beverages and those types of items specifically authorized under chapter 0100-06 of these regulations.~~ A retail licensee is permitted to advertise or sell at retail items related to or incidental to the use, consumption, dispensing, or storage of alcoholic beverages, together with merchandise and supplies related to special events or parties.

(2) The list of items a retail licensee may sell, contained in T.C.A. § 57-3-404(e)(4), is illustrative in nature and non-exclusive. The Commission shall have the right to specifically enumerate additional items it deems to be within the intent of the statute.

(3) A retail licensee may conduct demonstrations at any time of nonalcoholic products, both within the licensed premises and at locations outside of the licensed premises, without any restrictions and is not subject to any advertising restrictions of such demonstrations or other events occurring upon its premises or away from its premises, except as expressly set forth in Rules 0100-03-.01 through 0100-03-.08.

Authority: T.C.A. §§ ~~57-818, 57-1-201, and 57-1-209,~~ 57-3-104, 57-3-202, and 57-3-404.

0100-03-.08 Advertising Approval Does Not Sanction Any Violation, Commission Discretion on Advertising.

(1) No Advertising Shall Indicate Any Violation Permitted. No advertising permitted herein shall imply sanction in any manner of any violation of the Tennessee Code, rules and regulations of the Commission, or valid ordinance of a duly constituted authority.

(2) Commission May Compel Discontinuance. The Commission reserves the right to instruct the discontinuance and withdrawal of any advertisement in any medium whatsoever which in its discretion, is determined to be inconsistent with the public interest.

Authority: T.C.A. §§ ~~57-818, and~~ 57-1-209, 57-3-104, and 57-4-201.

0100-03-.09 Licenses and Permits.

(1) Full-time Municipal Law Enforcement Department Required. No retail liquor license shall be granted for a location which is not situated within the jurisdiction of a regular full-time municipal law enforcement department or within a jurisdiction that has contracted with a regular full-time law enforcement department to provide services to the jurisdiction.

(2) Financial Disclosure.

(a) Applicants for retail liquor licenses shall submit, in conjunction with their application, proof of financial responsibility. Specifically required with each application are the following:

1. Financial statements containing financial information as requested by the Commission;

2. Loan agreements related to the licensed premises, the retail liquor operation, or any other interests in other liquor-related businesses owned by the applicant;

3. Gifts related to the licensed premises, the retail liquor operation, or any other interest in other liquor-related businesses owned by the applicant; and

4. Any other information requested by the Commission.

(b) The Commission may refuse to grant a retail liquor license to any applicant who fails to demonstrate, by a preponderance of the evidence, the financial ability and responsibility to reasonably conduct business.

(c) Upon renewal of an existing license the applicant for renewal need submit only the financial information as specifically requested by the Commission.

(3) Limit on Wholesalers' Licenses. No person, partnership, or corporation will be issued a wholesaler's license in more than one (1) municipality in the same county.

(4) Restriction on License After Surrender or Revocation.

(a) No ~~wholesale or retail~~ license will be issued to the spouse, child or children, son-in-law, daughter-in-law, or other person having any interest in the business of a licensee whose license has been revoked, for the privilege of doing business at the same location or in close proximity to the location of the establishment whose license was revoked for a period of one (1) year after said revocation. The Commission may, in its discretion, waive this prohibition.

(b) The Commission may refuse to reissue a license to the same person, firm, or corporation whose license has been revoked for one (1) year from the date of said revocation.

(c) The Commission may treat a surrender of a license as a revocation under the restrictions contained in this paragraph.

(5) Must Surrender License If Business Discontinued. Whenever any licensee discontinues business for any reason, he shall immediately notify the Commission in writing and surrender his license.

(6) Time Requirement to Commence Business. Approval, by the Commission, of the issuance of a new wholesaler's or retailer's license or the transfer of such a license to a different entity, shall automatically expire ninety (90) calendar days after such approval if the new license has not opened for business, unless a written request is received by the Commission for an extension of approval.

(7) Licensees Not Required To Have Permits. Persons whose names are listed on a ~~wholesale or~~

~~retail~~ license issued by the Commission are not required to obtain permits~~, and no such persons shall hold any permit issued by the Alcoholic Beverage Commission~~.

(8) Retail Licensees Not To Hold Federal Wholesale Stamp. No licensed retail liquor dealer shall purchase or have issued to him, nor may he possess, any federal liquor license, stamp, or permit without the corresponding state liquor license. Possession by any licensed retail liquor dealer of any such federal license, stamp, or permit without the corresponding state liquor license will be grounds for the revocation of his retail liquor license.

(9) Procedure for Off-Premise Retail License Application. Whenever any person has applied to the Alcoholic Beverage Commission for a license pursuant to T.C.A. § 57-3-204, except for an application for license renewal, the Commission may, at its discretion, conduct a hearing pursuant to the provisions of T.C.A. § 4-5-101 *et seq.* to determine whether the license shall be issued. The hearing may be held unless the applicant, municipality, or civil district wherein the applicant intends to conduct business and the Commission have stipulated in writing that no such hearing is necessary. However, when the municipality or civil district wherein the applicant intends to conduct business fails to grant or deny the certificate required by T.C.A. § 57-3-208 within sixty (60) days of the written application, the certificate is deemed to be granted, and further, the municipality or civil district is deemed to have stipulated that the hearing regarding the issuance of a license is not necessary.

~~(10) Public Notice. The Commission shall require each applicant for a new retail liquor license, pursuant to Chapter 3 of Title 57 of the Tennessee Code Annotated, to place a notice in a newspaper of general circulation in the area proposed to be served concerning the applicant's intent to seek a license from the Commission. The notice shall contain such information as is prescribed in Section (11) below and shall appear for at least three (3) consecutive issues immediately preceding the date that the applicant applies to the city or county for a certificate of compliance. The application shall be accompanied by a copy of the public notice and the sworn statement of the applicant that the notice was published in.~~

~~(11) Format of Notice.~~

~~(a) Anyone applying for a Tennessee retail liquor license shall place the following notice in a newspaper of general circulation:~~

~~RETAIL LIQUOR LICENSE NOTICE~~

~~Take notice that _____ (Name and address of applicant) has~~

~~applied to _____ (City or County) _____ for a certificate of compliance~~

~~and has or will apply to the Tennessee Alcoholic Beverage Commission at Nashville for a retail liquor license for a store to be named~~
~~_____ and to be located at~~
~~(Name of Store)~~

~~_____ and owned by~~
~~(Address of Store)~~

~~_____~~
~~_____~~
~~(List whether individual, partnership, or corporation. List individual owners except if corporation.~~

~~list officers and manager.)~~

~~All persons wishing to be heard on the certificate of compliance may personally or through counsel appear or submit their views in writing at~~

~~_____~~

~~(Name of City or Government to issue certificate and address)~~

~~on _____ at _____ The Tennessee Alcoholic Beverage~~
~~(Date) (Time)~~

~~Commission will consider the application at a later date to be set by the Tennessee Alcoholic Beverage Commission in Nashville, Tennessee. Interested persons may personally or through counsel submit their views in writing by the hearing date to be scheduled by the TABC. (Rule 0100-03-.09, continued) Anyone with questions concerning this application or the laws relating to it may call or write the Alcoholic Beverage Commission at~~

~~_____~~

~~(Address) (Phone)~~

~~(b) The title of the notice shall be all capital letters and at least 10 point size. The text of the notice shall be at least eight point size type, and the size of the entire notice shall be not less than two columns by two inches of newspaper space. Such newspaper notice shall be published prior to the issuance of the Certificate of Compliance.~~

Authority: T.C.A. §§ 57-1-201, 57-1-209, 57-3-104~~(c)(4), and~~ 57-3-208~~(e)~~, 57-4-201, ~~and~~ 57-3-203 and 57-3-204.

0100-03-.10 Transportation and Delivery of Alcoholic Beverages.

(1) Requirement For All Transporters. Any person transporting alcoholic beverages within, into, through, or from the State of Tennessee must comply with the provisions of T.C.A. § 57-3-403, ~~Tennessee Code Annotated~~ and shall, when requested by any representative of the Commission, or person having police authority, exhibit to such person the required bill of lading or other memorandum of shipment covering the cargo of the vehicle.

(2) Requirements for Tennessee-Licensed Wholesalers.

(a) Trucks and other motor vehicles owned or operated by wholesalers, when transporting alcoholic beverages, are forbidden to carry any other commodities of any nature, except those items specifically authorized by statute or Chapter 0100-06 of these Regulations Rules.

(b) All trucks and other motor vehicles owned or leased and operated by any Tennessee licenseed wholesaler, and used to transport, haul, deliver, or carry alcoholic beverages, shall have the name and address of such licensee printed on each side and on the rear of said truck or motor vehicle in legible letters of a minimum height as hereinafter prescribed. The name of the licensee shall be in letters not less than four (4) inches in height, the address of such licensee shall appear in letters of not less than two and one half (2 ½) inches in height and the license number shall appear in letters not less than one and one half (1 ½) inches in height. The following words, but no others, may be abbreviated: Tennessee (Tenn.), Company (Co.), and Incorporated (Inc.).

(c) Irrespective of any provision to the contrary contained within this regulation, a licensed wholesaler, a salesperson employed by a licensed wholesaler, or an employee of a wholesaler who has an active employee permit issued by the Commission, may transport and make deliveries of beverage alcohol in amounts less than twenty (20) cases in

vehicles which may or may not be owned or leased by the licensed wholesaler so long as the wholesaler, salesman, or employee possesses written documentation identifying the seller, purchaser, and the quantity and identity of products being delivered and so long as such delivery and transportation complies with the other transportation and delivery provisions of this regulation. Any wholesaler who authorizes such individual to transport in such a fashion shall be responsible for that individual's compliance with these rules.

(3) Wholesaler Must Deliver Off Premises. All alcoholic beverages sold by a wholesaler must be delivered away from his premises and then only to another licensed wholesaler, to a retailer or his employee at the retailer's licensed premises, to a retail food store or any employee of the retail food store at the retail food store's licensed premises, or to a Department of Defense Installation after compliance with T.C.A. § 57-3-110. Delivery to a wholesaler in another county must be by common carrier.

(4) Pickup By Retailer Prohibited. No retailer or his employees shall accept any alcoholic beverages at the wholesaler's premises or elsewhere other than at the licensed premises of the retailer.

(5) Transportation of Alcoholic Beverages by ~~Retailers~~ Retail Package Stores

~~(a)~~ ~~The sales of all alcoholic beverages by a retailer shall be made within the licensed premises; provided, that deliveries of alcoholic beverages sold within the premises may be made by the retailer only to a vehicle of the purchaser parked on the lot or lots upon which said licensed premises are situated or at the curb immediately adjacent to the lot or lots upon which said licensed premises are situated, and not elsewhere.~~

~~(b)~~ Where alcoholic beverages are desired to be transported for consumer educational seminars authorized by Rule 0100-03-.11(5), such transportation may be conducted by the wholesaler or retailer in accordance with the following provisions of this ~~section~~ subparagraph:

~~1.~~(a) The wholesaler or retailer shall transport alcoholic beverages directly to the location of the consumer educational seminar no more than twenty-four (24) hours prior to the time reported to the Commission for the start of the consumer educational seminar.

~~2.~~(b) All unsealed or otherwise opened containers of alcoholic beverages not consumed during the registered time of a consumer educational seminar shall be disposed of by removing opened container(s) and returning the product to the retail or wholesale premises. Such product, if returned to the retail licensee's premises, shall be documented as to its source and may only be used for employee training purposes. No sealed or unsealed containers of alcoholic beverages shall be given, sold, or otherwise transferred to persons attending a consumer educational seminar, to an on-premises consumption licensee, or to any other person.

~~3.~~(c) The wholesaler or retailer shall transport any unopened containers directly back to the licensed retail location within twenty-four (24) hours of the conclusion of the consumer educational seminar if the retailer purchased the alcohol. However, if the wholesaler donated the alcohol, then the wholesaler may, at its option, return such alcohol to its inventory or provide such alcohol to the retailer for use in employee training and not for resale.

~~4.~~(d) There shall accompany such alcoholic beverages at all times during transportation by the wholesaler or retailer as authorized herein, a copy of the written notification to the Commission regarding the consumer educational

seminar and a copy of the invoice. Further, any retailer transporting the alcohol to the approved seminar shall take a reasonably direct route from the location where the alcohol is obtained (either the wholesaler's licensed premises or the retailer's licensed premises) to the address of the consumer educational seminar approved by the Commission.

(6) Metric Net Contents.

(a) Distilled Spirits. The authorized standards of fill for distilled spirits shall be those container sizes authorized by 27 CFR § 5.47a.

(b) Wine. The authorized standards of fill for wine, as defined in 27 CFR § 24.10, shall be those container sizes authorized by 27 CFR § 4.72.

Authority: T.C.A. §§ ~~57-132, 57-136, 57-151, 57-818, 57-1-201,~~ 57-1-209, 57-3-104, ~~57-3-301, 57-3-303, 57-3-307, 57-3-110, 67-101 and 67-1-102,~~57-3-203, 57-3-218, 57-3-402, and 57-3-403.

0100-03-.11 Solicitation of Business, Services Restricted.

(1) Manufacturers and Importers Limited to Wholesale Solicitation.

(a) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or any representative thereof shall solicit orders in any manner for alcoholic beverages from anyone in the state except those holding wholesale licenses. The marketing, advertising, or promoting, or the encouraging of the public to purchase the manufacturer's, non-resident seller's, or non-manufacturer non-resident seller's product, does not constitute soliciting an order and does not require a permit.

(b) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or any representative thereof shall perform or provide any service whatsoever for a retail on-premise or off-premise licensee or his employee in the state, and no on-premise or off-premise licensee shall accept any service whatsoever, whether on or away from the retail premises—except as specifically authorized under Rules 0100-03-.06 and 0100-06-.03. ~~No manufacturer, importer or representative shall enter the premises of any retailer except in the main salesroom of said establishment.~~

(c) No manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or any representative thereof shall give anything of value whatsoever, including but not limited to alcoholic beverages and money, to any Tennessee retail on-premise or off-premise licensee or his employee, and no on-premise or off-premise licensee shall accept anything of value whether on or away from the retail premises except as specifically authorized under Rules 0100-03-.06 and 0100-06-.03.

(d) ~~Notwithstanding the restrictions contained herein, a~~ A manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative thereof may enter ~~the public and non-storage related areas~~ the premises of a retail licensee for the purpose of promoting the products manufactured, imported, or represented by the manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative, surveying or examining the retail and marketing operations of such on-premise or off-premise retail licensee or examining the advertising displays within the premises of such on-premise or off-premise retail licensee. Such manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative may also provide, orally or in writing, information related to such products to any licensee or employee of such licensee on the on-premise or off-premise retail licensee's premises as well as customers of the retail package store licensee in relation to tastings held under T.C.A. § 57-3-404(h)(2).

(e) ~~Notwithstanding the restrictions contained herein, a~~ A manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative thereof may, with the consent of the ~~retailer~~ retail package store, "face up" or dress a display of those products (and only those products) manufactured, imported, or represented by such person which displays are already established at such retail licensee premises and may arrange or rearrange those products manufactured, imported, or represented by such person which have been placed on display on the retail premises but is limited to "pulling forward" inventory already in the showroom and no restocking may occur from any area off the showroom floor. While providing such service, such person may not move, disturb, relocate, or re-shelve any product other than the products manufactured, imported, or represented by such person. No services of this kind may be provided to any retail food store licensee on or off their premises.

(2) Wholesale Sales Limited to Retailers.

(a) No wholesaler, salesman, or employee thereof shall solicit orders in any manner for alcoholic beverages from anyone in this state except those holding retail licenses.

(b) No wholesaler, salesman, or employee thereof shall provide any service whatsoever for a retail licensee or his employee whether within or away from the retail premises with the following exceptions:

1. Delivering alcoholic beverages or any item permitted under Chapter 0100-06 to the licensed premises.

2. Arranging stock delivered by his company in retail ~~establishments~~ package stores.

3. Setting up advertising signs or displays at retail package stores as set forth in Rules 0100-03-.05 and 0100-03-.06.

4. Assisting in the conduct of any retailer sponsored consumer educational seminar held in accordance with Rule 0100-03-.11(5).

5. Providing the services to retail food store licensees authorized by Chapter 443 of the Public Acts of 2017.

(c) No wholesaler, his salesman, or employee shall give anything of value whatsoever including, but not limited to, money and alcoholic beverages to any retail licensee or his employee except as otherwise permitted in these rules. No Tennessee retail licensee or his employee shall accept any alcoholic beverages, money, or other things of value except as allowed or provided for by the applicable regulations as set forth at Chapter 0100-06.

(d) Wholesalers are prohibited from accepting an order for alcoholic beverages from one retailer and delivering and invoicing part of the order to one retailer and the remainder of the order to another licensee. Retailers are prohibited from placing an order for one licensee, and having part of the order delivered to another licensee.

(e) Notwithstanding the limitations contained herein, a wholesaler, its salesman or its employees may solicit orders from any entity that has submitted to the Commission an application for license under T.C.A. §§ 57-3-204 or 57-4-101, but the wholesaler may not deliver any alcoholic beverages until the Commission has approved and issued such license.

(3) Complimentary Alcohol from Retailers ~~Shall Not Solicit at Residence or Place of Business of Consumer.~~

~~(a) No retail licensee or his employee shall solicit orders for alcoholic beverages by any method directed at the residence or place of business of a consumer any place in this State, other than as permitted by 0100-03-.03 or 0100-03-.04.~~

~~(b)~~ No retail package store licensee or his employee shall give any consumer ~~anything of value whatsoever except as provided in 0100-03-.07(2), and then only within the licensed premises or as may be permitted in Rule 0100-03-.11(5). Nothing herein shall prohibit a retail licensee from making withdrawals from inventory for donations to any organization that has been recognized as exempt from federal taxes under § 501(c) of the Internal Revenue Code (26 U.S.C. § 501(c)). Upon request, retailers shall present documentation to the Commission agent or representative of such withdrawals~~ any complimentary alcohol except as provided in T.C.A. § 57-3-404 or this rule.

(4) Tax Laws Unaffected. No provision of this rule is intended to restrict or otherwise affect the deductions available to manufacturers, importers, wholesalers or retailers for purposes of calculating taxes due to the United States.

(5) Retailer Retail Package Store Sponsored ~~Tastings~~ Consumer Educational Seminars. A ~~retailer~~ retail package store licensed under T.C.A. § 57-3-204 may conduct consumer educational seminars, which may include providing alcoholic beverages and wine directly to consumers for tasting purposes. A retailer must provide to the Commission written notification on forms prescribed by the Commission if the licensee or its representative or employee is present to discuss the product being sampled, if the licensee is sponsoring or co-sponsoring the event, if the licensee has provided the product to be sampled, and/or if the licensee is soliciting orders at the event.

(a) No consumer educational seminar which includes the consumption of alcoholic beverages or wine by a consumer may occur at a premises licensed by the Tennessee Alcoholic Beverage Commission pursuant to T.C.A. § 57-3-204. (See T.C.A. § 57-3-406(f)). Further, consumer educational seminars must occur within the boundaries of a political subdivision wherein the sale of alcoholic beverages at retail has been approved pursuant to T.C.A. §§ 57-3-106 and 57-4-103.

(b) Any retailer desiring to conduct a consumer educational seminar which involves the consumption of alcoholic beverages must provide written notification to the Commission disclosing the following information:

1. The date, time, and exact location of the consumer educational seminar;

2. The sponsors of such consumer educational seminar and any supplier or wholesaler involved, either directly or indirectly, with such consumer educational seminar;

3. Whether any fee or cost is assessed to the attendees in order to attend the consumer educational seminar, and if so, the amount of such fee; and

4. Any other relevant information as may be required by the Commission.

(c) Written or electronic notifications must be submitted to the Commission not less than ~~four (4)~~ two (2) calendar days prior to the date of the consumer educational seminar. Proof of such written notification shall be available for inspection at the event. ~~Upon approval, the Commission will issue a letter of permission to the retailer which will be valid for no longer than one 24-hour period, subject to the hours set forth in T.C.A. § 57-4-203(d)(1). Such~~

~~letter of permission must be available for inspection at the event.~~

~~(d)~~ ~~Failure to comply with the sub-paragraphs (b) and (c) above may result in a violation of this section.~~

~~(e)~~(d) No manufacturer, ~~or~~ non-resident seller, or non-manufacturer non-resident seller may directly supply any product to a retailer for use at a consumer educational seminar. Nothing herein shall prohibit a wholesaler licensed pursuant to T.C.A. § 57-3-203 from providing product to the retailer for use at a consumer educational seminar, nor shall this provision preclude a manufacturer or nonresident seller from providing product to a wholesaler with the intent that such product be used at a consumer educational seminar. A wholesaler who provides such product for an event should make a reasonable effort to provide a sufficient quantity of alcohol, but not in excess of the amount needed to conduct the consumer educational seminar. Any unopened salable product remaining at the conclusion of the seminar shall be returned to the wholesaler who provided the product if the product was donated for the event, pursuant to T.C.A. § 57-3-403 and Rules 0100-03-.14(1)~~(a)~~ and 0100-03-.10(5).

~~(f)~~(e) Any consumer educational seminar conducted under this ~~section~~ rule shall be conducted in accordance with the hour limitations set forth at T.C.A. § 57-4-203(d)(1).

~~(g)~~(f) A manufacturer, non-resident seller, non-manufacturer non-resident seller, retailer, wholesaler, or representative thereof whose products are to be tasted may advertise, in accordance with all other applicable regulations of the Commission, the date, time, location, sponsors, speakers, products to be tasted, food to be served, charge for attendance, and such other information as may be appropriate to inform the consumers of the consumer educational seminar. A retail location of a consumer educational seminar included in an industry member advertisement shall be relatively inconspicuous in relation to the advertisement as a whole.

(g) A manufacturer, non-resident seller, non-manufacturer non-resident seller, wholesaler, or representative thereof whose products are to be tasted may furnish consumer advertising specialties permitted under the rules directly to consumers, or to a retailer for distribution to consumers, at the consumer educational seminar.

(h) A consumer educational seminar conducted under this ~~section~~ rule may be conducted at any premises licensed pursuant to T.C.A. § 57-4-101. If so, a retailer may impose a reasonable charge for attendance at a the consumer educational seminar, and may solicit orders from consumers at the ~~tasting~~ seminars, provided that final sales of wines and alcoholic beverages must be completed within the licensed premises of the retailer package store or delivered pursuant to Rule 100-03-.10(5)(a).

(i) ~~On-premise consumption licensee employees shall not serve, sell, or otherwise dispense any alcoholic beverages not owned outright by such licensee. Any retailer employee and/or representative serving, selling, or otherwise dispensing alcoholic beverages at a consumer education seminar must first obtain a server's permit and such permit must be available for inspection while the consumer education seminar is being conducted.~~ Individuals holding any permit issued by the Commission or certified clerks employed by retail package stores may serve or dispense alcoholic beverages. Nothing in this paragraph authorizes an on-premise consumption licensee to purchase and resell alcoholic beverages from any entity other than a licensed wholesaler. In addition, an individual listed as licensee or manager on the license application or in the records of the Commission may serve or dispense alcoholic beverages at such educational seminar.

(j) If a consumer educational seminar is to be conducted at a premises not licensed pursuant to T.C.A. § 57-4-101, the following additional conditions shall apply:

1. No food, goods or services may be purchased or sold and no solicitation of orders may occur.

2. No person may attend such consumer educational seminar unless such person has received a written invitation, addressed to the invitee.

3. No charge may be imposed upon such invitee for attendance or for any food or product consumed.

(k) The retail licensee shall be responsible for compliance with all statutes, rules, and regulations, including but not limited to the prohibitions of selling to a minor or to an intoxicated individual. Violations of any statutes, rules, or regulations may result in disciplinary action against the appropriate licensee.

Authority: T.C.A. §§ ~~57-818, and~~ 57-1-209, 57-3-104, 57-3-202, 57-3-203, 57-3-210, 57-3-404, 57-3-405, 57-3-604, and 57-3-815

0100-03-.12 Containers and Sizes.

(1) Original Retail Containers Required.

No licensee shall import into Tennessee or sell in Tennessee any alcoholic beverages, except wine as provided by T.C.A. § 57-3-404(e)(4)(E) or § ~~57-4~~-108, not in original retail containers.

~~(2) Wine May Be Imported In Bulk.~~

~~Tennessee-licensed wineries and wholesalers may import wine in bulk for the purpose of bottling only. When wine is imported hereunder, it shall be stored on the licensed premises only, in containers approved by the Commission which shall have the right in its discretion to seal such containers and require them to be opened only after notice to the Commission and with its consent.~~

~~(3)~~(2) Standards of Fill for Wine.

All wine bottled in, sold in, and shipped into this state shall be in containers specified in the Standards of Fill for Wine prescribed by the Department of the Treasury of the United States for wine shipped in interstate commerce; and, said Federal Regulations relating to Standards of Fill for Wine are hereby adopted and incorporated by reference herein. See Rule 0100-03-.10(6).

~~(4)~~(3) Distilled Spirits May Be Imported In Bulk

Tennessee-licensed manufacturers may import distilled spirits in bulk for the purpose of manufacturing, rectifying, or blending, except that distilled spirits imported in bulk from outside of the State of Tennessee shall not be used in the manufacturing, rectifying, or blending of Tennessee whiskeys as defined in T.C.A. § 57-2-106. Such bulk shipments shall only be permitted in compliance with the rules and requirements of the Tobacco Tax and Trade Bureau ("TTB"). and T.C.A. § 57-3-202(f).

~~(5)~~(4) Standards of Fill for Distilled Spirits

All distilled spirits bottled in, sold in, and shipped into this state shall be in containers specified in the Standards of Fill for Distilled Spirits prescribed by the TTB for shipments of distilled spirits; and, said Federal Regulations relating to Standards of Fill for Distilled Spirits are hereby adopted and incorporated by reference herein. See Rule 0100-03-.10(6).

Authority: T.C.A. §§ ~~57-818, 57-1-201,~~ 57-1-209, 57-3-104, ~~57-1-209,~~ 57-3-202, 57-3-203, 57-3-207, ~~57-3-30~~57-3-218, 57-3-404, 57-4-201, and 57-4-108. ~~67-1-102, 57-3-303, 57-3-307 and 57-1-201~~.

0100-03-.13 Conduct of Business – Wholesaler and Retailer.

~~(1)~~ ~~Retail Licensees to Sell Nothing Except Alcoholic Beverages. No retailer or employee thereof shall store, sell or offer for sale on his licensed premises any article or commodity whatsoever except alcoholic beverages or otherwise provided by statute. However, a wholesaler may store, sell or offer for sale those items specifically authorized under T.C.A. §57-3-404 and Chapter 0100-06 of these regulations, and a retailer may store, display and distribute those items authorized under Chapter 0100-06 of these regulations.~~

~~(2)~~(1) All Licensees Must Keep Records Available Three (3) Years. Each licensee shall keep, for at least three (3) years, all purchase orders, invoices, and all other records of all purchases and sales of alcoholic beverages made by such licensee. All such orders, invoices, and all other books and records pertaining to the licensee's operation shall be open for inspection to any authorized representative of the Alcoholic Beverage Commission or Department of Revenue during business hours and failure to make such available shall be deemed cause for revocation of his license. For the purposes of this paragraph, electronic records are sufficient if they are readily available and easily accessible.

~~(3)~~(2) Business Management Restricted. Every licensed wholesale or retail business shall be managed by the holder of the license, if an individual, or by a partner or corporate officer, in the event that the business is operated by a partnership or corporation. In every case where alcoholic beverages at wholesale or retail are sold by a partnership or corporation, the managing partner or corporation officer in active control and management of the business shall be designated to the Commission.

~~(4)~~(3) Hours Licensees May Remain Open. Wholesalers and Retailers may remain open for business between the hours of 8:00 a.m. and 11:00 p.m. by the time zone and system in effect in the city where the store is located.

~~(5)~~(4) Storage Limited to Ground Floor of Licensed Premises. No wholesaler or retailer shall store alcoholic beverages at any place other than the ground floor constituting his licensed premises without written permission of the Commission.

~~(6)~~(5) No Wholesaler May Store for Retailer. No wholesaler shall store alcoholic beverages for a retail dealer without written approval of the Commission.

~~(7)~~(6) No Retailer May Store for Another Retailer. No retailer shall store alcoholic beverages belonging to another retail licensee.

~~(8)~~ ~~"Lugs" Prohibited-Pre-Sacking Restricted.~~

~~(a)~~ ~~No bottles of alcoholic beverages shall be removed from the delivery case and wrapped into packages for the purposes of resale commonly known as "lugs" on the premises of a licensed wholesaler or retailer, except a packaged "less than case" order delivered by a wholesaler to a retailer will not be construed as a "lug" if accompanied by an invoice. Retailers shall not sell alcoholic beverages to or pre-package alcoholic beverages for bootleggers.~~

~~(b)~~ ~~Any such "lug" found on the premises of a retailer or wholesaler shall be prima facie evidence of a violation of this regulation.~~

~~(c)~~ ~~No licensed retailer shall have on hand, in stock or stored in his possession, any alcoholic beverages that have been pre-sacked prior to the actual receipt by such retailer~~

~~of a specific order therefore. However, notwithstanding the provisions of this paragraph, nothing shall preclude a retailer from pre-sacking an order for personal consumption after being requested to do so by a consumer.~~

(7) A retailer shall not sell alcoholic beverages to an individual whom the retailer should reasonably believe is reselling such alcoholic beverages not permitted by law.

~~(9)~~(8) Contests Involving Alcoholic Beverages Prohibited. No manufacturer, wholesaler, non-resident seller, non-manufacturer non-resident seller, retailer, or representative or employee thereof may:

(a) Sponsor or conduct a contest in which alcoholic beverages are offered as prizes, premiums, or rewards;

(b) Offer as a prize, premium, or reward any alcoholic beverages; or

(c) Directly or indirectly aid or assist in the promotion of a contest involving alcoholic beverages which is conducted or sponsored by any person not a licensee.

(d) Notwithstanding the foregoing, a manufacturer, wholesaler, non-resident seller, non-manufacturer non-resident seller, or retailer may sponsor or conduct a contest in which alcoholic beverages are offered as prizes, premiums, or rewards for their own employees.

~~(10)~~(9) Gift Certificates. Tennessee-licensed retailers may sell gift certificates or gift cards to consumers. ~~However, no gift certificate shall be honored, accepted, or sold to anyone under the age of twenty-one or to anyone visibly intoxicated. If a gift certificate is honored, accepted, or sold to anyone under the age of twenty-one (21) or to anyone visibly intoxicated, then such practice will be deemed to be the equivalent of selling alcohol to a minor or selling alcohol to a person visibly intoxicated.~~ No gift card shall be honored, accepted, or sold to anyone visibly intoxicated. No gift card shall be honored or accepted from anyone under the age of twenty-one (21) for the purchase of alcoholic beverages or beer. Such practices will be deemed to be a violation.

~~(11)~~(10) Refusal of Cooperation. Any licensee who refuses to open or disclose records to, or furnish information to, or who furnishes false and/or misleading information to an agent of the Tennessee Alcoholic Beverage Commission upon any matter relating to or arising out of the conduct of the licensed premises shall subject the license to revocation or suspension.

~~(12)~~(11) Open Access to Licensed Premises Without Warrant. Immediate access, without a warrant, to all parts of a licensed premise shall at all times be accorded agents or representatives of the Tennessee Alcoholic Beverage Commission.

~~(13)~~(12) Licensee Responsible For Law and Order On Licensed Premises. Each licensee shall maintain his establishment in a decent, orderly, and respectable manner in full compliance with all laws of Tennessee and ordinances and laws of the municipality and/or county where licensed premises are located at all times.

~~(14)~~(13) Not withstanding any provisions herein, a retailer may accept a tentative order for alcoholic beverages from consumers by telephone, e-mail, facsimile transmission, or other electronic means, provided, however~~:~~

~~(a)~~ ,t~~T~~he retailer maintains a record, written or electronic, of the items tentatively ordered for a period of thirty (30) days following the actual purchase of the items~~; and~~.

~~(b) The sale and delivery of any such tentative order shall occur on the license premises in a face-to-face purchase~~

(14) A retail package store may sell or deliver alcoholic beverages or supply, deliver, and install products authorized to be sold by the retailer pursuant to T.C.A. § 57-3-406(j).

(15) Any government-issued document that has expired shall not be deemed to be "valid" for purposes of T.C.A. § 57-3-406(d), and as such, a retailer may not sell alcoholic beverages to a person who has not provided an unexpired government-issued document that meets the requirements of T.C.A. § 57-3-406(d).

Authority: T.C.A. §§ ~~57-109(g), (1) and (3), 57-818(2), 67-101, 57-132, 57-136, 57-1-201,~~ 57-1-209, 57-3-104~~(c)(4),~~ 57-3-202, 57-3-203, 57-3-404, 57-4-108, and 57-3-406~~(d)~~.

0100-03-.14 Conduct of Business of Wholesalers.

(1) Wholesaler Accountable for Inventory; Methods of Disposition of Alcoholic Beverage Limited. A wholesaler is strictly accountable for his inventory which he may deplete in the following manners only:

(a) Sales to a licensed retailer and to no other person and each sale and delivery must be covered by an invoice.

(b) Wholesalers may deplete inventories for personal or training use, for purposes of contributing to a charitable organization, for marketing, or for use at educational seminars held pursuant to Rule 0100-03-.11 or held for the benefit of retailer customers of the wholesaler. The wholesaler shall retain records of all such withdrawals showing the amount of inventory withdrawn, the purpose of the withdrawal and the employee responsible for such withdrawal. These records shall be retained in accordance with Rule 0100-03-.13(12).

(c) Broken and deteriorated merchandise (method of handling set forth in Rule 0100-03-.~~1415~~(3)).

(d) Courtesy sales from one wholesaler to another within the state.

(e) Returned merchandise to the manufacturer or importer.

(2) Consignment and Returns.

(a) No wholesaler shall sell and no retailer shall accept any alcoholic beverage on consignment, or upon condition, or with the privilege of return, or on any condition other than a bona fide sale, except as may be permitted pursuant to Chapter 0100-06.

(b) Novelty containers, commonly known as Christmas decanters, must be accepted back upon request in exchange for similar quantity of alcoholic beverages of the same brand and proof in conventional containers by the wholesaler from the retailer and by the manufacturer from the wholesaler. Such requests shall not be submitted before January 15 next after the Christmas season for which such decanters were delivered.

(3) Breakage and Deteriorated Merchandise.

The following procedure shall be followed in handling and accounting for broken or deteriorated merchandise:

(a) Wholesalers shall return broken bottles or deteriorated merchandise from the retailer involved to his warehouse before replacing same with the retailer.

(b) Replacement shall be listed on the wholesaler's standard invoice and designated whether

breakage or deteriorated merchandise.

(c) The wholesaler shall prepare a standard invoice covering the breakage or deteriorated merchandise within his own stock on the date it is broken or the deteriorated merchandise is removed from his inventory.

(d) No later than the fifth (5th) day of the month each wholesaler shall prepare from invoices of the previous month a complete list of breakage and deteriorated merchandise. The list shall be prepared in triplicate and shall include the invoice number, retail license number (or wholesaler's license number), brand, and size.

(e) An agent of the Tennessee Alcoholic Beverage Commission shall use this list in checking and destroying broken bottles, and checking the deteriorated merchandise which he shall mark as unsaleable. The agent will certify all three (3) copies of the list and forward one (1) copy to the Commission. The wholesaler shall mail another copy to the Miscellaneous Tax Division of the Department of Revenue and retain the third (3rd) as a part of its records.

(f) After checking and marking, the wholesaler may dispose of the deteriorated merchandise without regard to the limitation established in Rule 0100-03-.16(1)(b) provided, however, the wholesaler will incur tax liability at the same time all such unsaleable alcoholic beverages are removed from inventory and not destroyed.

(4) Wholesaler Assistance at Special Occasion Events. A wholesaler or employee thereof may participate in, assist, and serve alcoholic beverages on behalf of a holder of special occasion permits issued pursuant to T.C.A. § 57-4-101(g).

Authority: T.C.A. §§ 57-1-209, 57-3-104(c)(4),~~67-1-102~~, ~~57-3-303~~57-3-203, ~~57-3-307~~, and 57-3-404~~Public Acts of 1974, Chapter 707, § 1~~.

0100-03-.15 Restrictions on Premises, Conduct of Business of Retailers.

(1) Retailers Not to Combine. No combination of retailers shall be permitted to purchase merchandise in the name of one (1) retailer and subsequently distribute merchandise which they have purchased in combination with each other to any one of the combination and no retailer shall be permitted to transfer goods from one to another. If any member of the combination is found to have violated this regulation, every member shall likewise be deemed to have violated this regulation, and it shall also be a violation for the wholesale distributor to furnish merchandise to any combination of retail dealers.

(2) Living Quarters Prohibited. No part of the licensed premises occupied by a liquor store shall be used as living quarters by any person.

~~(3) No Commodity Except Alcoholic Beverages May Be Stored. No part of a licensed premises occupied by a liquor store shall be used as a storeroom for any commodity having no relation to the sale of alcoholic beverages.~~

~~(4) Services Restricted. No retailer within or on his licensed premises shall offer by sign or otherwise to perform any service whatsoever for a consumer except the sale of alcoholic beverages.~~

~~(5)~~(3) Drinking In or On Premises Prohibited. No retail licensee or his employee shall consume alcoholic beverages or permit alcoholic beverages to be consumed within publicly accessible areas of the retail establishment. Employee-only tastings are authorized to be conducted on the retail premises as authorized by T.C.A. § 57-3-404(h). Alcoholic beverages used for employee-only tastings/education must be properly identified as such and proper documentation from the wholesaler must be maintained on the premises. Notwithstanding this provision, all open alcohol

being used for employee tastings/education must be removed within seven (7) days of the wholesaler documentation. No licensee or his employee shall engage in the sale of alcoholic beverages on the licensed premises while under the influence of intoxicants or drugs.

(4) Notwithstanding paragraph (3) of this rule, a retail package store may conduct tastings pursuant to T.C.A. § 57-3-404(h).

(6)(5) Operation of a Licensee. Every retail licensee shall register and designate on its application one or more persons as managers of the retail operation. All managers of retail licensees shall submit to the Alcoholic Beverage Commission a completed questionnaire within one (1) week of assuming such duties. Such person may be the licensee, if the licensee is an individual. The designated manager or managers of the licensee shall be either the owner or a full-time employee of the licensee and shall not be an employee of any other licensee nor shall such be a consultant, advisor, or provide any services to any other licensee. Only the licensee, if an individual, or the designated manager or managers may engage in any of the following activities:

(a) Select, order, or price inventory,

(b) Employ or discharge the employees of the retail establishment,

(c) Approve advertising, marketing programs of the licensee.

Authority: ~~(1) and (3)~~ T.C.A. ~~§ 57-818; (2)~~ §§ ~~67-101, 57-132, 57-136,~~ 57-1-209, 57-3-104, 57-3-204, 57-3-212, 57-3-221 and 57-3-404 ~~and Public Acts of 1974, Chapter 707, § 1~~.

0100-03-.16 Dual Interests Prohibited.

(1) Manufacturer, ~~and~~ Importer, Non-Resident Seller, and Non-manufacturer Non-Resident Seller.

(a) No manufacturer~~, or importer,~~ or representative of the same~~,~~ shall have any kind of direct or indirect interest ~~financial, fixtures, furnishings, stock ownership, loans, gifts, securing loans, guaranteeing payment of any loan, lease of property or participate in the profits, either directly or indirectly,~~ in any wholesaler or any retail on-premise or off-premise ~~liquor~~ establishment in Tennessee. A prohibited interest includes the possessing of any financial or other interest in the establishment, providing or having interest in any fixtures or furnishings, stock ownership, loans, gifts, the securing of loans, the guaranteeing of any loan payment, or participating in the profits.

(b) No importer, non-resident seller, non-manufacturer non-resident seller, or representative of the same shall have any kind of direct or indirect interest in any retail on-premise or off-premise establishment in Tennessee. A prohibited interest includes the possessing of any financial or other interest in the establishment, providing or having interest in any fixtures or furnishings, stock ownership, loans, gifts, the securing of loans, the guaranteeing of any loan payment, or participating in the profits.

(c) An importer, non-resident seller, non-manufacturer non-resident seller, or representative of the same may have a direct or indirect interest in a wholesaler.

(d) "Indirect interest" as used in this Rule means any kind of interest in the wholesaler, retail on-premise, or retail off-premise establishment by way of stock ownership, loan, partner's interest, or control, including the use of a brand name, trademark, or sponsorship of the, manufacturer wholesaler, importer, non-resident seller, non-manufacturer non-resident seller, or representative of the same.

(e) "Direct or indirect interest" between 1) a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative of the same and 2) an on-premise

establishment does not include:

1. An interest held by a spouse or child over the age of twenty-one (21) as separate and distinct property; provided, that there is no commingling of assets or sharing of control in such arrangement;

2. An interest of a person or entity having less than a five percent (5%) ownership interest in a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or on-premise establishment; or

3. An interest held in an irrevocable trust by an independent trustee.

(2) Wholesaler ~~or~~ and Retailer.

No wholesaler, and no partner, member, or person owning stock in a corporation licensed as a wholesaler, and no employee of same, shall have any interest ~~as set forth above~~ in any business licensed as an on-premise or off-premise retailer, and no retailer and no retailer's employee, shall have any such interest in any wholesale establishment. A prohibited interest includes the possessing of any financial or other interest in the establishment, providing or having interest in any fixtures or furnishings, stock ownership, loans, gifts, the securing of loans, the guaranteeing of any loan payment, or participating in the profits.

Authority: T.C.A. §§ ~~57-818, and~~ 57-1-209, 57-3-104, 57-3-210, 57-3-604, 57-4-201, Chapter 968, Public Acts of 2012, and Chapter 371, Public Acts of 2017.

0100-03-.17 Responsibility and Penalties for Violations.

(1) Employer Responsible for Employee's Action. Licensees are at all times responsible for the conduct of their businesses and are at all times directly responsible for any act or conduct of any employee which is in violation of the laws of Tennessee, the rules and regulations of the Commission, any local ordinance and/or any federal statute, ~~or the rules and regulations of the Commission,~~ whether the licensee be present at any such time or not. ~~This section is defined to mean that~~ Any unlawful, unauthorized, or prohibited act on the part of an agent or employee shall be construed as the act of the employer, and the employer shall be ~~proceeded against~~ liable as though he were present and had an active part in such unlawful, unauthorized, or prohibited act, and as if having been at the employer's direction and with his knowledge. Notwithstanding this provision, a licensee may present mitigating factors.

(2) In Disciplinary Action. In disciplinary proceedings, it shall be no defense that an employee or agent of a licensee acted contrary to order, or that a licensee did not personally participate in the violating action or actions – except as permitted under Rule 0100-05-.07.

(3) Avoidance of Tax Liability. Any manufacturer, importer, or representative of the same, and any wholesaler or retailer or employee of the same, who shall evade, or render direct or indirect assistance in the evasion of, the payment of the taxes imposed in T.C.A. §§ 57-3-302, 57-3-303, 57-4-301, and 57-6-201, or who shall violate, in any manner aid or abet, participate in any scheme to violate the local option law, or fail or neglect to comply with any regulations here in ~~before set out~~, shall be deemed to have given cause for suspension or revocation of his license, or permit, or if holding no license or permit, to have given cause for withdrawal or suspension of any privilege granted in Tennessee~~, as~~ by the Commission in its discretion.

Authority: T.C.A. §§ ~~57-818, 57-1-201, and~~ 57-1-209, 57-3-104, ~~to implement T.C.A. §§~~ 57-3-302, ~~and~~ 57-3-303, and 57-4-201.

0100-03-.18 Transfer of Licenses.

(1) The transfer of a retail liquor license from one location to another shall be subject to the following provisions:

(a) The new location must be within the same city as the original location.

(b) The application for transfer must pay or must have paid the full annual license fee for the year in which the transfer is requested.

(c) The physical transfer of the store must be completed within ninety (90) days after the transfer is granted. Under exceptional and unusual circumstances, the applicant may request an additional thirty (30) days' time. However, the request must be made in writing and must state the reasons for the extension. Such request must be submitted to the Commission prior to the aforementioned ninetieth (90th) day.

(d) The approval of all applications for the transfer of a retail liquor license shall be within the discretion of the Alcoholic Beverage Commission.

(e) Circumstances which may be considered by the Commission include:

1. Physical destruction of the premises not the fault of the licensee.

2. Bona fide termination of the lease, with the remaining term of the lease not to exceed one (1) year from the date the transfer is considered by the Commission.

(i) Accompanying each application for transfer shall be a sworn statement by the applicant declaring the reason for the lease termination.

(ii) If the applicant for transfer is purchasing the property for the proposed new location, then the appropriate documents shall be submitted with the application evidencing the purchase.

(iii) If the applicant for transfer is building a new structure for the proposed new location, the structure's blue prints or other building plans shall be submitted with the application.

3. Eminent domain or condemnation proceeding causing serious disruption of the business.

4. Substantial changes in traffic patterns surrounding the existing store.

5. Situations, which in the discretion of the Commission, are determined to be a material change of circumstances.

(f) The application for a transfer of a retail liquor license shall follow the procedural requirements prescribed for applications for new licenses contained in Rule 0100-03-.09(9).

(g) The proposed new location must comply with such statutes, regulations, and ordinances for new licenses as are determined to be applicable and material in the discretion of the Commission.

Authority: T.C.A. §§ ~~57-818,~~ 57-1-209, 57-3-104~~(c)(4)~~, 57-3-212, and 57-4-201~~(a)(2)~~.

0100-03-.19 ~~Repealed.~~ Manufacturer Representative Permits.

(1) A manufacturer representative permit issued pursuant to T.C.A. § 57-3-202(d) is only required for

owners, officers, employees, or representatives soliciting orders from licensed wholesalers in Tennessee and shall not be required of owners, officers, employees, or representatives that are marketing and promoting the product to the general public or to situations described in T.C.A § 57-3-202(k)(3). In addition, a manufacturer representative permit is not required for individuals who work at a manufacturer's or importer's premises unless they also perform such other tasks that require such a permit.

(2) A manufacturer representative permit issued pursuant to T.C.A § 57-3-202(d) shall be issued exclusively to the individual applying for such permit and shall not reference any manufacturer, rectifier, or importer. Such permit belongs to the individual holding such permit and not to any manufacturer, rectifier, or importer.

Authority: T.C.A. § ~~57-818~~ 57-3-104 and 57-3-202.

0100-03-.20 ~~Repealed.~~ Donations to Nonprofit Organizations.

(1) Any licensee shall be permitted to make withdrawals from inventory for donations to any organization that has been recognized as exempt from federal taxes under § 501(c) of the Internal Revenue Code (26 U.S.C. § 501(c)) and that will serve or sell the donated products at a special occasion licensed event. A donation may occur before a qualified entity receives a special occasion license from the Commission.

(2) Donations made pursuant to this rule may be delivered by the licensee to the recipient organization or may be picked up by the recipient organization at the licensees's premises.

(3) Licensee's making donations under this rule shall maintain adequate records of the donation, including the amount donated, the FEIN of the recipient organization, and a copy of the letter from the IRS granting exempt status to such recipient organization received by the licensee from recipient organization. Upon request, licensees shall present documentation to the Commission of such withdrawals.

(4) Licensees making donations under this rule are responsible for paying all required state and federal taxes for the donated product. Failure to do so could lead to suspension, revocation, or a fine not to exceed the statutory maximum.

Authority: T.C.A. § ~~57-818 to implement T.C.A. §§ 57-131, 57-132, 57-701 through 57-707 and 57-1-209~~ 57-3-104, ~~57-3-~~303, 57-4-201, and Chapter 147, Public Acts of 2017.

0100-03-.21 ~~Repealed.~~ Noncontiguous Premises of Manufacturers.

(1) A manufacturer licensed under T.C.A § 57-3-202 shall be permitted to have a noncontiguous area for storage of spirits as long as such noncontiguous premises have been authorized by the United States Alcohol and Tobacco Tax and Trade Bureau ("TTB").

(2) No application or application fee is required to establish this noncontiguous premises with the Commission and only the basic details of the location and a floor plan of such noncontiguous premises are required in addition to a copy of proof of TTB approval.

(3) Manufacturers shall notify the Commission within thirty (30) days after commencing use of this noncontiguous premises, or sooner if preferred by the manufacturer.

Authority: T.C.A. §§ ~~57-1-209~~,57-2-104, 57-3-104~~(c)(4), 57-2-104,~~ and ~~57-4-201(a)(2)~~ 57-3-202.

0100-03-.22 Private Events

A license or permit is not required for an event where alcoholic beverages are served if:

(1) The event is private and includes a bona fide guest list restricting access to invited guests only;

(2) The hosts or bona fide guests of the event are providing all of the alcoholic beverages;

(3) All alcoholic beverages are served without charge;

(4) There is no admission cost for the event, including ticket price, required donation, or door charge; and

(5) There is no commercial purpose related to the sale, marketing, or promotion of alcoholic beverages for the private party or event.

Authority: T.C.A. §§ 57-3-104, 57-4-101, 57-4-201, Public Chapter 147, Public Acts of 2017.

0100-03-.23 Rectifying

(1) The definition of "rectifier" in T.C.A § 57-3-101 includes anyone who blends alcoholic beverages with other ingredients or alcoholic beverages as long as such operations are permitted under and operated in compliance with the rules and regulations of the Alcohol and Tobacco Tax and Trade Bureau.

(2) An applicant for license under T.C.A § 57-3-202 shall not be required to designate whether they are a distiller, a rectifier, or both.

Authority: T.C.A. §§ 57-3-101, 57-3-104, 57-3-202 and 57-3-207.

Chapter 0100-06 Intra-Industry Conduct and Regulations is amended by deleting the chapter in its entirety and by substituting instead the following language:

RULES OF THE ALCOHOLIC BEVERAGE COMMISSION

CHAPTER 0100-06 INTRA-INDUSTRY CONDUCT AND REGULATIONS

TABLE OF CONTENTS

0100-06-.01 Definitions
0100-06-.02 General Prohibitions
0100-06-.03 Exceptions to General Prohibitions
0100-06-.04 Limitations on Credit Sales
0100-06-.05 Dual Permits Prohibited
0100-06-.06 Wholesale Sales and Employee Permits
0100-06-.07 Retail Employee Permits
0100-06-.08 Non-Resident Seller Permits
0100-06-.09 Prohibition on Discrimination

0100-06-.01 Definitions.

(1) General. As used in this chapter, unless the context otherwise requires, terms have the meanings given in this section. Any other term defined in Title 57 of the Tennessee Code Annotated shall have the meaning assigned to it by that Title.

(2) Consignment Sales. The term "consignment sales" shall mean arrangements where the trade buyer is under no obligation to pay for distilled spirits or wine until they are sold by the trade buyer.

(3) Equipment and Supplies. The term "equipment and supplies" shall include, but is not limited to, glassware (other than glassware bearing conspicuous and substantial advertising matter which is a consumer advertising specialty or similar containers made of different material), dispensing accessories, and carbon dioxide (and other gases used in dispensing equipment), pouring racks, and other similar items used to conduct a retailer's business. "Dispensing Accessories" include, but are not limited to, standards, faucets, cold plates, rods, vents, taps, tap boxes, tap standards, hoses, washers, couplings, gas gauges, vent tongues, shanks, and check valves.

(4) Exchange. The transfer of distilled spirits, wine, or other products from a trade buyer to an industry member with other product taken as a replacement.

(5) Industry Member. The term "industry member" shall mean any person engaged in business as a manufacturer, distiller, rectifier, blender, non-resident seller, non-manufacturer non-resident seller, or other producer, or as an importer, or wholesaler, of distilled spirits, or wine, or as a bottler, or warehousemen and bottler, of distilled spirits, licensed in the state of Tennessee.

(6) Product. The term "product" shall mean distilled spirits, wine, or alcoholic beverages, as defined in Title 57 of the Tennessee Code Annotated.

(7) Product Display. The term "product display" shall mean any wine racks, bins, barrels, casks, shelving, and the like from which distilled spirits, wine, and beverages are held, shelved, displayed, and sold.

(8) Retailer. The term "retailer" shall mean any person engaged in the sale of distilled spirits, wine, or alcoholic beverages to consumers, licensed in the state of Tennessee, whether such sales are made for consumption on or off the premises where sold.

(9) Retail Establishment. The term "retail establishment" shall mean any premises where distilled spirits, wine, or alcoholic beverages are sold or offered for sale to consumers, whether for consumption on or off the premises where sold.

(10) Return. The transfer of distilled spirits, wine, or other product from a trade buyer to the industry member from whom they were purchased, for cash or credit.

(11) Trade Buyer. Any person who is a wholesaler or retailer of distilled spirits, wine, or other product.

Authority: T.C.A. §§ ~~57-1-201 and~~ 57-1-209 and 57-3-104.

0100-06-.02 General Prohibitions.

(1) Except as provided in Rule 0100-03-.16, industry members are prohibited from acquiring or holding any interest, directly or indirectly, in any license (state, county, or municipal) with respect to the premises of a retailer.

(2) Except as provided in Rule 0100-03-.16, industry members are prohibited from acquiring any interest, directly or indirectly, in real or personal property owned, occupied, or used by a retailer in the conduct of the business.

(3) Subject to the exceptions listed herein, industry members, or any representative thereof, are prohibited from furnishing, giving, renting, lending, or selling to the retailer, and the retailer is prohibited from accepting any equipment, fixtures, signs, supplies, money, services, or other thing of value. The furnishing of free warehousing by delaying delivery of distilled spirits, wine, or alcoholic beverages or by storing such for a retailer by an industry member is prohibited.

(4) Industry members, or any representative thereof, are prohibited from paying or crediting the retailer, and the retailer is prohibited from accepting any advertising, display, or distribution service, whether or not the advertising, display or distribution service received is commensurate with the amount paid by the retailer.

(5) An industry member or any representative thereof is prohibited from requiring a trade buyer to take and dispose of any quota of distilled spirits, wine, or malt beverages.

(6) A requirement that a retailer purchase one product in order to purchase another is prohibited. This includes combination sales if one (1) or more products may be purchased only in combination with other products and not individually. However, an industry member is not prohibited from selling at a special combination price, two (2) or more kinds of brands of products to a retailer, provided that:

(a) The retailer has the option of purchasing either product at the usual price; and

(b) The retailer is not required to purchase any product he or she does not want.

(7) No retailer shall obtain alcoholic beverages from any source not designated to sell that brand under the brand registration statute, T.C.A. § 57-3-301.

(8) No manufacturer, importer, non-resident seller, non-manufacturing non-resident seller or any representative thereof – e.g. third party marketing entities – ~~may~~ shall solicit orders in

any manner for alcoholic beverages from anyone in this state except ~~from~~ those holding wholesale ~~liquor~~ licenses. The marketing, advertising, or promoting, or the encouraging of the public to purchase the manufacturer's, non-resident seller's, or non-manufacturer non-resident seller's product, does not constitute soliciting an order and does not require a permit.

(9) It is unlawful for one (1) industry member to sell, offer for sale, or contract to sell to any trade buyer, or for any such trade buyer to purchase, or contract to purchase any products:

(a) On consignment; or

(b) Under conditional sale; or

(c) With the privilege of return; or

(d) On any basis other than a bona fide sale; or

(e) If any part of the sale involves, directly or indirectly, the acquisition by such person of other products from the trade buyer or the agreement to acquire other products from the trade buyer. Transactions involving the bona fide return of products for ordinary and usual commercial reasons arising after the product has been sold are not prohibited.

(10) (a) Tied Sales Prohibited. A sale in which any part of the sale involves, directly or indirectly, the acquisition by the industry members from the trade buyer, or the agreement, as a condition to present or future sales, to accept other products from the trade buyer is prohibited.

(b) Exchange. The exchange of one product for another is prohibited as a sales transaction conditioned on the acquisition of other products. However, the exchange of a product for equal quantities (case for case) of the same type and brand of product, in containers of another size is not considered an acquisition of "other" products and is not prohibited if there was no direct or implied privilege of return extended when the product was originally sold. Industry members may make price adjustments on products eligible for exchange under this paragraph.

(c) Exclusion. An industry member, or any representative thereof – e.g. third party marketing entities — ~~may~~ shall not require, nor may a retailer request, offer, and/or accept an exclusive arrangement wherein the retailer agrees, in exchange for money, services, or any other thing of value from the industry member, to offer for sale the industry member's product ~~exclusively~~ to the exclusion of other related products.

Authority: T.C.A. §§ ~~57-1-201 and~~ 57-1-209, 57-3-104, 57-3-202, ~~57-1-209,~~ 57-3-210, 57-3-405, 57-3-604, 57-4-201, and Public Chapter 371, Public Acts of 2017.

0100-06-.03 Exceptions to General Prohibitions.

(1) General. An industry member or any representative thereof – e.g. third party marketing entities – may furnish a retailer equipment and supplies, signs, posters, place cards, decorations, devices, statuettes, or geographic displays (printed, painted, or electric) for point-of-sale advertising, and services or other things of value in accordance with the exceptions provided in this part and may install or set up such materials in the windows or

elsewhere in the interior of a retail establishment. The cost limitations imposed in this rule will be deemed adjusted upon any modification in a similar rule made by the Trade and Taxation Bureau of the United States Department of the Treasury.

(2) Product Displays.

(a) General. An industry member may furnish, give, rent, loan, or sell product displays to a retailer, subject to the limitations prescribed in subparagraph (b) of this ~~section~~ paragraph.

(b) Conditions and Limitations.

1. The total value of all product displays furnished by an industry member under subparagraph (a) of this ~~section~~ paragraph may not exceed three hundred dollars ($300) or current federal limits per brand in use at any one time in any one retail establishment. The value of a product display is the actual cost to the industry member who initially purchased it. Transportation and installation costs are excluded for the purposes of this calculation.

2. Industry members may not pool or combine their dollar limitations in order to provide a retailer a product display valued in excess of three hundred dollars ($300) or current federal limits per brand.

3. Product displays shall bear conspicuous and substantial advertising matter about the product or the industry member which is permanently inscribed or securely affixed.

4. The furnishing, giving, renting, loaning, or selling of such product displays may be conditioned upon the purchase of the products advertised on those displays in a quantity necessary to initially stock such display.

(3) Interior Signs.

(a) General. An industry member or any representative thereof – e.g. third party – marketing entities, may furnish, give, rent, loan, or sell to a retailer inside signs which bear advertising matter. Inside signs include such things as posters, placards, designs, mechanical devices, and window decorations.

(b) Conditions and limitations. Industry members or any representative thereof – e.g. third party marketing entities – may furnish inside signs to retailers under the following limitations:

1. The inside sign shall have no secondary value and be of value to the retailer only as advertising.
2. The inside sign shall be used only in the windows or other interior portions of the retail establishment.
3. The industry member may not directly or indirectly pay or credit the retailer for displaying the inside sign or for any expense incidental to its operation.

(4) Advertising Service. An industry member or any representative thereof – e.g. third party marketing entities – may list in its advertisement the names and addresses of all retailers selling the alcoholic beverage product(s) of the industry member within the geographic area targeted by the advertisement, provided that:

(a) The advertisement does not also contain the retail price of the product;

(b) The listing is the only reference to the retailers in the advertisement and is relatively inconspicuous in relation to the advertisement as a whole; and

(c) The advertisement does not refer only to one retailer or only to retail premises controlled directly or indirectly by the same licensed entity and refers to all retailers selling the alcoholic beverage product(s) of the industry member within the geographic area targeted by the advertisement.

~~(4)~~(5) Outside Signs.

(a) General. Subject to local ordinances, an industry member or any representative thereof – e.g. third party marketing entities – may furnish, give, rent, loan, or sell to a retailer outside signs (electrical, mechanical, inflatable, or otherwise) which bear advertising matter ~~subject to local ordinances~~.

(b) Conditions and limitations. Industry members, or any representative thereof – e.g. third party marketing entities – may furnish outside signs to retailers under the following limitations:

1. The sign must bear conspicuous and substantial advertising matter about the product or the industry member that is permanently inscribed or securely affixed.

2. The cost of the signs may not exceed four hundred dollars ($400) per brand, which includes installation costs.

3. The outside sign must be located on the wall or roof of a building adjacent to or occupied by the retailer, or in a retailer's parking lot.

4. The name and address of the retailer may appear on the outside sign.

5. The industry member, or any representative thereof – e.g. third party marketing entities – may not directly or indirectly pay or credit the retailer for displaying the sign or for any expense incidental to its operation.

~~(5)~~(6) Routine Business Entertainment. Nothing in this chapter shall prohibit an industry member or any representative thereof – e.g. third party marketing entities – from providing a retail licensee or its employee routine business entertainment which is defined as follows:

(a) Meals or beverages;

(b) Concerts, theatre, and arts entertainment;

(c) Sports participation and entertainment;

(d) Entertainment at charitable events;

(e) Private parties;

(f) Transportation and lodging costs associated with any of the forgoing listed under these subparagraphs (a)-(e).

~~(6)~~(7) Limitations on Routine Business Entertainment. For the purposes of this section:

(a) Routine business entertainment shall be provided only if such is provided without a corresponding obligation on the part of the retail licensee or on-premise consumption licensee to purchase alcoholic beverages or to provide any other benefit to such industry member or to exclude from sale the products of any other industry member.

(b) There is no maximum dollar amount for providing routine business entertainment designated under ~~Section~~ subparagraphs (b), (c), or (d) of paragraph (6) of this rule~~.~~, provided however that transportation pursuant to subparagraph (f) of paragraph (6) or lodging to or for an event under subparagraphs (b), (c), or (d) of paragraph (6) is subject to the three hundred dollar ($300) limit of subparagraph (c) below.

(c) Routine business entertainment expenses under subparagraphs (a), (e), or (f) of paragraph (6) shall not exceed a fair market value of ~~100.00~~ three hundred dollars ($300) per twenty-four (24) hour period for an employee of any retail or on-premise consumption licensee including a self-employed sole proprietor or, if the licensee is a partnership, ~~or~~ any partner or employee thereof, or if the licensee is a corporation, any corporate officer, director or shareholder, or the guest of such, or to any third party partnership, LLC, or corporation associated directly or indirectly with the retail or on-premise consumption licensee designed to circumvent the intent of this provision. Further, routine business entertainment expenses as stated above may not exceed six (6) employees/per day from the same licensee.

(d) No person enumerated in subparagraph (c) of paragraph (7) above may be entertained by a wholesaler more than four (4) times per calendar year. The wholesaler shall maintain documentation of all expenditures under this section containing sufficient information to fully document the expenditure.

(e) Routine business entertainment permitted under paragraph (6) above must occur either within the state of Tennessee or, if outside the state of Tennessee, within one hundred (100) miles of the premises of the retail licensee receiving the routine business entertainment.

~~(e) Routine business entertainment permitted under Section (5) above shall not include transportation to or from an event that is otherwise permitted beyond one hundred (100) miles.~~

~~(7)~~(8) Retailer Advertising Specialties – Point-of-Sale.

(a) General. An industry member or any representative thereof – e.g. third party marketing entities – may furnish, give, rent, loan, or sell point-of-sale advertising materials to a retailer if such items bear advertising matter and are primarily valuable to the retailer as point-of-sale advertising to attract consumer attention to the products of the industry member who furnished them. Such items include, but are not limited to: posters, placards, designs, inside signs (electric, mechanical, or otherwise), window decorations, trays, coasters, mats, menu cards, meal checks, paper napkins, napkin holders, foam scrapers, back bar mats, placemats, bar utensil caddies, other bar utensils, and items (such as strainers, citrus pressers, and stir rods), tap standards, shakers, stir sticks, ice molds and ice trays, cups, glassware, pitchers, carafes, and similar containers

made of other materials, thermometers, clocks, lamps, calendars, and alcoholic beverage lists or menus, lighted displays, display mirrors, chalkboards, bulletin boards, dart board backgrounds, table tents, menu and table tent holders, case cards, candles and holders, check and credit card holders, empty flash and jump drives, umbrellas, and apparel (such as shirts, hats, caps, and visors).

(b) Consumer Advertising Specialties. An industry member or any representative thereof – e.g. third party marketing entities - may furnish, give, rent, loan, or sell to a retailer, advertising specialties that are designed to be carried away by consumers, ~~such as~~ including, without limitation, trading stamps, pouring racks, non-alcoholic mixers, ash trays, bottle or can openers, cork screws, shopping bags, matches, candles and holders, printed recipes (including drink recipes), pamphlets, cards, leaflets, brochures, blotters, post cards, pencils, cups, mugs, glassware, pens, plates, knives, bar utensil caddies, shakers, pitchers, other bar utensils and items (such as strainers, citrus presses and stir rods), apparel (such as shirts, hats, caps, and visors), pins, buttons, key chains, check and credit card holders, empty flash and jump drives, and other branded items of nominal value.

(c) Conditions and Limitations.

1. All point-of-sale advertising materials and consumer advertising specialties must bear conspicuous and substantial advertising matter about the product or the industry member which is permanently inscribed or securely affixed. The name and address of the retailer may appear on the point-of-sale advertising materials and on the consumer advertising specialties.

2. The industry member or any representative thereof – e.g., third party marketing entities – may not directly or indirectly pay or credit the retailer for using or distributing these materials or for any expense incidental thereto.

~~(8)~~(9) Wine Lists or Menus. An industry member may furnish, give, rent, loan, or sell alcoholic beverage lists or menus to retailers whether in hard copy, electronic (digital or analogue), or online formats. Nothing in this paragraph 9 authorizes an industry member to provide a retailer with electronic hardware, including iPads, tablets, laptops, or other electronic devices used as menus.

~~(9)~~(10) Samples. An industry member may furnish or give a sample of branded distilled spirits, wine, or alcoholic beverages to a retailer (including, without limitation, any of their managers, salespersons, or bartenders) ~~who has not previously purchased the brand or vintage of wine from that member within the past twelve (12) months~~ for the purposes of enhancing sales of its products at retail. For each retail establishment, the industry member may give not more than 1.75 liters of any brand of distilled spirits or wine per sampling. If a particular product is not available in a size within the quantity limitations of this section, an industry member may furnish to a retailer the next largest size. An industry member may only provide such a sampling of a specific brand once every three months. An industry member who furnishes a container for sampling or tasting purposes must conspicuously mark the container as "not for resale."

~~(10)~~(11) Combination Packaging.

An industry member or trade buyer (other than a retailer which sells for consumption on the premises or a retail food store) may package, distribute, and sell wine or alcoholic

beverages in combination with other related items, other alcoholic beverages, or beer. ~~provided that:~~

~~(a) The items have no value or benefit to the retailer other than that of having the potential of attracting purchasers and thereby promoting sales;~~

~~(b) The package (product plus non-alcoholic item) is designed to be delivered intact to the consumer and consumer shall not dictate the specific packaging;~~

~~(c) The non-alcoholic item does not exceed twice the cost of the product, exclusive of the packaging material, to the industry member or trade buyer creating the package;~~

~~(d) The non-alcoholic item may not be a perishable food item; and~~

~~(e) Any additional cost incurred in creating the combination package may not be borne by the industry member.~~

~~(11)~~(12) Educational Seminars. An industry member may give or sponsor educational seminars for employees of retailers either at the industry member's premises or at the retail establishment. Examples would be seminars dealing with use of a retailer's equipment, training seminars for employees of retailers, or tours of an industry member's plant premises. This section does not authorize an industry member to pay a retailer's expense in conjunction with an educational seminar. This paragraph (12) does not preclude providing nominal hospitality during the event.

~~(12)~~(13) Stocking, Rotating, Pricing, and Other Services.

(a) A wholesaler, wholesale salesman, or permitted representative thereof may, at a retail package store ~~licensee~~, with the consent of the retailer, stock, rotate, and affix the price to distilled spirits, wine, or other alcoholic beverages that they sell, provided products purchased from other wholesalers are not altered or disturbed. Such wholesaler may also set up a point-of-sale display, product display, logoed and promotional items (including point-of sale advertising materials and consumer advertising specialties), rearrange or reset that portion of a retail package store ~~licensee~~ as is necessary for the display or placement of its product. In providing the services herein, a wholesaler, wholesale salesman or permitted representative thereof may enter the private or non-public areas of the retail package store ~~licensee~~.

(b) ~~When accompanied by a wholesaler, a wholesale salesman, or other representative of the~~ A wholesaler, a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or any representative thereof – e.g. third party marketing entities - may also provide ~~those services designated in 0100-06-.03(9)(a) above~~ recommended shelf plans or shelf schematics for alcoholic beverages, provided that such industry members may not provide anything of value, and retailers may not accept anything of value, in exchange for complying or otherwise using any recommended shelf plan or schematic.

(c) Notwithstanding the restrictions contained herein, a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative thereof – e.g. third party marketing entities – must deliver point-of-sale advertising materials intended for retail use to a wholesaler's warehouse, and a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller, or representative thereof – e.g. third party marketing entities - may provide and set up such point-of-sale ~~or logoed~~ advertising materials ~~(including, but not~~

~~limited to, product displays, interior signs, point-of-sale advertising materials, and consumer advertising specialties)~~ at a retail package store establishment only in consultation and by mutual agreement with the wholesaler from which such point of sale or logoed materials were obtained as to the intended use and recipient(s) thereof. In providing the services herein, a manufacturer, importer, non-resident seller, non-manufacturer non-resident seller or representative thereof – e.g. third party marketing entities - may enter the private or non-public areas of the retail package store. As used in this paragraph, "point-of-sale advertising materials" include point-of-sale displays and refer to the advertising items described under paragraph (1) of Rule 0100-03-.06 and paragraph (8) of this Rule. "Point of sale advertising materials" do not include product displays (i.e. wine racks, bins, barrels, casks, shelving, and the like from which distilled spirits, wine, and beverages are held, shelved, displayed and sold).

(d) Nothing in this paragraph (13) shall be construed to authorize any services or conduct that is otherwise prohibited for retail food stores in T.C.A. § 57-3-815.

~~(13)~~(14) Consumer Promotions – Direct Offerings. A manufacturer, supplier, importer, non-resident seller, non-manufacturer non-resident seller, distiller, ~~or~~ winery, or any representative thereof – e.g. third party marketing entities -, may offer coupons for refunds and contest prizes, premium offers, and sweepstakes to consumers only on the following basis:

(a) A refund coupon may be distributed to a consumer only as an element of the industry member's advertising or marketing program through newspapers or magazines, combination packaging, the internet, any other social media platform, neck hangers (on or in caps, cap liners, corks, containers, labels, cartons, cases, or other materials which comes with a purchased alcohol beverage), other point-of-sale advertising (e.g., tear pads that are part of shelf talkers, and case cards), flyers, and by direct mail. Retailers for on-premise consumption may not participate in such programs.

(b) Contest prizes, premium offers, sweepstakes, and like items may be offered by industry members or any representative thereof – e.g. third party marketing entities - directly to consumers at point-of-sale, via neck hangers (on or in caps, cap liners, corks, containers, labels, cartons, cases, or other materials which come with a purchased alcohol beverage) and other point-of-sale advertising (e.g., tear pads that are part of shelf talkers and case cards), through newspapers or magazines, and through the internet, mobile/other electronic communication devices and communications via social media, flyers, and by direct mail in conjunction with combination packaging. Retailers for on-premise consumption may participate in such programs.

(c) Officers, employees, and representatives of wholesalers and retailers are excluded from participation. Nothing of value may be supplied to a trade buyer by an industry member or any representative thereof – e.g. third party marketing entities - to induce or reward participation in any practice allowed hereunder. Industry members or any representative thereof – e.g. third party marketing entities - are prohibited from requiring any retailer to participate in any practice allowed hereunder nor shall a particular retailer or group of retailers be specified by an industry member or any representative thereof – e.g. third party marketing entities - for participation in any practice allowed hereunder.

(d) Notwithstanding subparagraph (c), an industry member or any representative thereof – e.g. third party marketing entities - may award prizes to a retail employee as part of a nationwide or statewide contest, such as a bartender's

contest or drink recipe contest, conducted by the industry member or such representative, in accordance with applicable contest rules; provided, that the entry or award is not based upon retail sales of the sponsor's product and the industry member has received advance written approval of the contest by the TABC. Such contest shall be open to all retail licensees of the same type - e.g., "on-premise or off-premise" consumption licensees, or both.

~~(d)~~(e) No coupon shall be permitted for a refund by a retailer at the point-of-sale ("cents-off" coupons). Refund coupons may be utilized by a manufacturer, supplier, importer, non-resident seller, non-manufacturer non-resident seller, distiller, ~~or~~ winery, or any representative thereof – e.g. third party marketing entities -, that are redeemable by a consumer's mailing or transmitting directly to such manufacturer, supplier, importer, non-resident seller, non-manufacturer non-resident seller, distiller, winery, or an authorized redemption agent.

~~(e)~~(f) No coupon may be redeemed by, or refund sent to any person who is under the age set by law to purchase, possess, and consume alcoholic beverages in Tennessee. No contest or sweepstakes prize shall be awarded to any person who is under the age set by law to purchase, possess, and consume alcoholic beverages in Tennessee. No premium offer shall be sent to any person who is under the age set by law to purchase, possess, and consume alcoholic beverages in Tennessee.

~~(14)~~(15) Equipment and Supplies. An industry member may sell equipment or supplies to a retailer.

(a) Equipment or supplies may be sold at a price not less than the cost to the industry member who initially purchased them and the price must be collected within ten (10) days of the date of sale or rent.

(b) An industry member may install dispensing accessories at the retailer's establishment as long as the retailer pays the cost of initial installation.

(c) An industry member may furnish, give, or sell coil cleaning services to a retailer.

~~(15)~~(16) Withdrawals for Special Occasion Licensees.

(a) An ~~industry member~~ licensee may deplete inventories for purposes of contributing to any qualified entity that has obtained has applied or will apply for a special occasion permit license issued by the Commission and may transport such inventories directly to the qualified entity. ~~If the industry member is a manufacturer, then such contribution shall be distributed through a licensed wholesaler.~~ The ~~licensed~~ donating licensee ~~wholesaler~~ shall retain records of all such withdrawals showing the amount of inventory withdrawn, the purpose of withdrawal, and the employee responsible for such withdrawal in accordance with Rule 0100-03-.14(1).

(b) In addition to product withdrawals for special occasion licensees, an industry member may further provide such items as promotional items, equipment, fixtures, posters, supplies, sponsorships, etc. to special occasion licensees without being subject to the limitations and restrictions found in Rules 0100-06-.02 and 0100-06-.03. However, any such physical promotional items provided to the special occasion licensee for an event must be returned to the industry member at the conclusion of the event and may not be given to or left for the use of a Tennessee-licensed retailer.

(c) Further, notwithstanding Rule 0100-06-.03(8), industry members may give branded or non-branded advertising specialty items that are designed to be carried away by consumers and that are of nominal value directly to the consumer and/or attendee at a special occasion licensed event. At the conclusion of the event, any remaining branded advertising items must be returned to the industry member.

(17) Retail and Industry Association Activities. An industry member may participate in the following retailer and industry association activities:

(a) Displaying its products at a convention or trade show;

(b) Renting display booth space if the rental fee is the same as paid by all exhibitors at the event;

(c) Providing its own hospitality, which is independent from association sponsored activities;

(d) Purchasing tickets to functions and paying registration fees if the payments or fees are the same paid by all attendees, participants, or exhibitors at the event; and

(e) Making payments for advertisements, programs, or brochures issued by retail associations at a convention or trade show if the total payments made by the member and its representatives do not exceed three hundred dollars ($300) per year.

Authority: T.C.A. §§ 57-1-209, ~~57-1-201, and~~ 57-3-104, 57-3-202, 57-3-404, 57-4-201 and ~~Public~~ Chapter 147, Public Acts of 2017.

0100-06-.04 Limitation On Credit Sales.

(1) No alcoholic beverage shall be sold by any wholesaler nor shall any retailer purchase any alcoholic beverages except for cash or on terms requiring payment by the purchaser within ten (10) days.

(2) Each and every delivery of merchandise by a wholesaler to a retailer must be accompanied by an invoice of sale bearing the actual date of the delivery. A wholesaler must keep and maintain a current and accurate accounts receivable ledger as a part of his records.

(3) (a) ~~The 10-day credit period begins on the day immediately following the invoice date and concludes at midnight of the tenth day including Sundays and holidays, immediately following which the account is considered delinquent.~~ The ten-day period begins from delivery and receipt by the retail licensee. The ten-day period cannot include any day that the wholesaler is not open to make deliveries, receive payment, or receive mail.

(b) ~~Payment sent by mail and postmarked by midnight of the due date shall be considered compliance.~~ Any suspension of deliveries is a credit decision to be made by a wholesaler and a retail licensee.

(4) (a) Wholesalers must deposit all checks for payment of retail accounts no later than the first banking day following actual receipt of said check.

(b) An account paid for by check within the ten-day (10) credit period but which is dishonored for any reason after the ten-day (10) credit period has elapsed is delinquent.

(c) A wholesaler shall not accept and a licensee shall not offer a postdated check.

~~(5)~~ ~~A wholesaler must report each and every delinquent account as set forth above by telephone to the Commission's nearest Regional Representative, and, as each such account is paid in full, he shall report that fact to the Commission's representative also.~~

~~(6)~~ ~~A retailer reported delinquent shall not be permitted to purchase merchandise for cash or otherwise from any licensed wholesaler until said licensee satisfies all obligations then outstanding to all wholesalers although the ten (10) day credit period may not have expired on such obligations.~~

~~(a)~~ ~~If such delinquency is the first in a license year, and such retailer sells for consumption on the premises all wholesalers will be required to sell such retailer merchandise only for cash on delivery for a minimum period of thirty (30) days from notice by the Commission.~~

~~(b)~~ ~~If such delinquency is the second in a license year, all wholesalers will be required to sell such retailer merchandise only for cash on delivery for a period of twenty (20) days, if such retailer sells for off-premises consumption, or for a period of sixty (60) days, if such retailer sells for on premises consumption.~~

~~(c)~~ ~~If such delinquency is the third in a license year, all wholesalers will be required to sell such retailer merchandise only for cash on delivery until notice to the contrary by the Commission. Such retailer shall be required by the Commission to appear and show cause why the retail liquor license should not be suspended or revoked, or why said licensee should not be placed on a cash on delivery basis for all merchandise sold to said licensee by any wholesaler for a period fixed by the Commission.~~

~~(7)~~(5) Payment by Electronic Funds Transfer ("EFT").

(a) Electronic Funds Transfer shall mean any transfer of funds other than a transaction originated by check, draft, or similar paper instrument, which is initiated through an electronic terminal, telephonic instrument, or computer, or magnetic tape so as to order, instruct, or authorize a financial institution to debit or credit an account. Such term includes, but is not limited to, point-of-sale transfers, automated teller machine transactions, direct deposits or withdrawals of funds, and transfers initiated by telephone.

(b) To facilitate payment between wholesale licensees and the retail on-premise and off-premise consumption licensees, Electronic Funds Transfers are an approved method of payment; however, participation by the retail on-premise and off-premise consumption licensees shall be voluntary. The wholesaler shall initiate the Electronic Fund Transfer transmittal. Payment is considered to be made when the funds are deposited in the wholesale licensee's account.

(c) The provisions of paragraph (5) are not intended to otherwise affect or amend paragraphs (1)-(4).

Authority: T.C.A. §§ ~~57-1-201 and~~ 57-1-209, 57-3-104, 57-3-202, 57-3-404, and 57-3-815.

0100-06-.05 Dual Permits Prohibited.

(1) No person shall be issued more than one (1) of the following permits:

(a) Manufacturer or importer representative permit;

(b) Wholesale salesman or representative permit;

(c) Wholesale employee's permit;

(d) Off-premises retail employee's permit;

(e) On-premises retail employee's permit; or

(f) Manager's permit.

(2) Notwithstanding the provisions of Rule 0100-06-.05(1) above, any individual may be issued an off-premise retail employee permit, an on-premise server permit, and a manager's permit, or any combination thereof, if that individual has completed and submitted the appropriate applications. Further, that person must qualify for and meet all the requirements to obtain each permit.

(3) In all cases, the industry member is responsible for the actions of their employees and/or representatives only when such employee and/or representative is acting within the scope of their employment of such industry member, but not within the scope of employment of another industry member.

Authority: T.C.A. §§ ~~57-1-201,~~ 57-1-209, and 57-3-104~~(c)(4)~~, 57-3-710, and 57-4-202.

0100-06-.06 Wholesale Sales and Employee Permits.

(1) Any permit issued by the Commission pursuant to T.C.A. § 57-3-203(d) or (e) shall be valid for a period of five (5) years from its date of issuance.

(2) Any person seeking a permit authorized pursuant to T.C.A. § 57-3-203(d) or (e) shall submit an application in writing to the Commission on forms approved by the Commission.

(3) No application for permit issued pursuant to T.C.A. § 57-3-203(d) or (e) shall be considered unless the application is accompanied by a processing fee of twenty dollars ($20).

Authority: T.C.A. §§ ~~57-1-201,~~ 57-1-209~~,~~ 57-3-203, ~~and~~ 57-3-709 and 57-3-710.

0100-06-.07 Retail Employee Permits.

~~(1) Any permit issued by the Commission pursuant to T.C.A. § 57-3-204(c) shall be valid for a period of five (5) years from its date of issuance.~~

~~(2) Any person seeking a permit authorized pursuant to T.C.A. § 57-3-204(c) shall submit an application in writing to the Commission on forms approved by the Commission.~~

~~(3) No application for permit issued pursuant to T.C.A. § 57-3-204(c) shall be considered unless the application is accompanied by a processing fee of twenty dollars ($20.00).~~

(4) After the conclusion of business on June 30, 2016, no permit issued pursuant to T.C.A. § 57-3-204(c) shall be issued by the Commission. Any permit issued by such time shall

remain in effect and be valid for five (5) years after the permit's issuance, and any employee of a retail package store who has a valid permit under T.C.A. § 57-3-204(c) on July 1, 2016, shall not be required to be a certified clerk pursuant to T.C.A. § 57-3-818 until that permit expires.

Authority: T.C.A. §§ ~~57-1-201,~~ 57-1-209, 57-3-104~~(c)(4)~~, 57-3-204~~(c)~~, and 57-3-~~709~~ 710.

0100-06-.08 Non-resident Seller Permits.

(1) Anyone desiring to import, ship, or transport alcoholic beverages into the State of Tennessee for distribution and/or sale within the State of Tennessee must make application to the Commission for a non-resident seller's permit. Such application shall include the name of the entity applying for the permit, and the true ownership thereof. Before alcohol may be imported, shipped, or transported into the State of Tennessee for distribution and/or sale within the boundaries of the State of Tennessee, such importer, broker, manufacturer, or supplier of the alcoholic beverage must first have obtained and be issued a non-resident permit by the Commission. Further, before alcohol may be imported, shipped, or transported into the State of Tennessee for distribution and/or sale within the boundaries of the State of Tennessee, such importer, broker, manufacturer, or supplier of the alcoholic beverage must have received from the Tennessee Department of Revenue a brand approval letter. However, only after the receipt of a non-resident seller permit issued by the Commission may that importer, broker, manufacturer, or supplier, attempt to register their brands with the Tennessee Department of Revenue.

(2) Each non-resident seller permit shall be valid for one (1) calendar year, and shall expire on December 31 of that year. Failure to timely and properly renew the non-resident seller permit shall be deemed a violation of the rule, and may result in the prohibition of the importation and/or distribution of each brand of alcohol registered by the non-resident seller permittee.

(3) Should the non-resident seller change ownership, the new owner must make application for a non-resident seller's permit as referenced in paragraph (1) above before importing, shipping, or transporting any alcoholic beverages into the State of Tennessee for distribution and/or sale within the state.

Authority: T.C.A. §§ ~~57-1-201,~~ 57-1-209, 57-3-104, ~~and~~ 57-3-202, 57-3-602 and 57-3-605.

0100-06-.09 Prohibition On Discrimination.

(1) No wholesaler, holding a license issued pursuant to T.C.A. § 57-3-203, shall discriminate, directly or indirectly, in price, in discounts on quantity of merchandise sold, between one retailer and another retailer purchasing wine or alcoholic beverages bearing the same brand or trade name and of like age and quality.

(2) The restrictions imposed in paragraph (1), above, shall not prevent a wholesaler from offering wine or alcoholic beverages to a licensee holding a license issued pursuant to T.C.A. § 57-4-101, while not offering such wine or alcoholic beverages to any licensee holding a license issued pursuant to T.C.A. § ~~57-4-203~~ 57-3-204 or 57-3-803 pursuant to a bona fide marketing plan.

(3) Notwithstanding the prohibitions of paragraph (1), above, a wholesaler may change its pricing on any wine or alcoholic beverage to meet competition, respond to bona fide market conditions, or provide a one-time, introductory offer to a retailer to introduce or promote a new product not previously purchased by such retailer.

(4) Nothing herein shall restrict the ability of a wholesaler to provide a discount to a retailer for quantity purchases or special combination offers so long as such discount is available on similar terms to other retailers.

Authority: T.C.A. §§ ~~57-1-201,~~ 57-1-209, 57-3-104, 57-3-202, and 57-4-201.

* 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)
Richard Skiles	X				
Ashleigh Harb Roberts	X				
John A. Jones	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Alcoholic Beverage Commission (board/commission/ other authority) on 09/27/2018 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 01/17/2017

Rulemaking Hearing(s) Conducted on: (add more dates). 03/14/2017

Date: 9/27/2018

Signature:

Name of Officer: Clay Byrd

Title of Officer: Executive Director

STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY Commission Expires AUG. 20, 20

Subscribed and sworn to before me on: 9/27/18

Notary Public Signature:

My commission expires on: 8/20/19

Agency/Board/Commission:

Rule Chapter Number(s):

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

1/17/2019
Date

Department of State Use Only

Filed with the Department of State on: 1/25/19

Effective on: 4/25/19

Tre Hargett
Secretary of State

RECEIVED
2019 JAN 25 PM 1:06
SECRETARY OF STATE

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Board for Licensing Health Care Facilities
SUBJECT:	Standards for Hospitals, Standards for Ambulatory Surgical Treatment Centers, Standards for Home Care Organizations Providing Home Medical Equipment, Standards for Home Care Organizations Providing Professional Support Services, and Licensing Procedures
STATUTORY AUTHORITY:	No federal or state law or regulation mandates the promulgation of the rule or establishes guidelines relevant thereto.
EFFECTIVE DATES:	June 6, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	The amendment to Rule 1200-08-01 -.05(25) adds a new paragraph regarding "caregiver" requirements. The amendment to Rule 1200-08-10-. 06(13)(a) allows other experienced physicians, other than pain management specialists, to perform non-interventional pain procedures near the spine, for which they are trained. The amendment to Rule 1200-08-29-.01 (31) adds a definition for "Mail Order Company". The amendment to Rule 1200-08-29-.06(4)(a) corrects a typographical error. The amendment to Rule 1200-08-29-.06(4)(b) adds an exception for mail order companies under Equipment Management. The amendment to Rule 1200-08-29-. 11 (3)(a) adds an exception to in-home patient education and instruction for mail order companies. Lastly, the amendment to Rule 1200-08·34-.02(2)(b) adds a new subparagraph requiring a contract with DIDDs and that failure to maintain the contract may lead to discipline.

Public Hearing Comments

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

Mr. Jim Schmidt commented on behalf of Medtronic, Inc., on Rule 1200-08-10-.06.
Mr. Schmidt suggested that Rule 1200-08-10-.06 Basic Services be amended by deleting subparagraph (13)(a) in its entirety, creating a new part (13)(a)(6) and substituting instead the following language, so that as amended, the new subparagraphs and part shall read:

> (a) For purposes of interventional pain management, only a medical doctor, licensed pursuant to T.C.A. § 63-6-101 et seq., or an osteopathic physician, licensed pursuant to T.C.A. § 63-9-101 et seq., who meet the following qualifications will be permitted to perform invasive procedures of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine.
>
> 6. This section shall not apply to a medical doctor, licensed pursuant to T.C.A. § 63-6-101 et seq., or an osteopathic physician, licensed pursuant to T.C.A. § 63-9-101 et seq., in the placement of medical devices used in the treatment of conditions not primarily related to pain.

Ms. Tausha Alexander, commented on behalf of The Tennessee Association of Nurse Anesthetists (TANA), on Rule 1200-08-10-.06. TANA is a nonprofit association whose purpose is to advance the profession of nurse anesthesia, enhance the art and science of anesthesiology, and facilitate the provision of accessible, affordable, high quality care. Membership is limited to Certified Registered Nurse Anesthetists (CRNA) who are members of the American Association of Nurse Anesthetists (AANA). CRNAs are advanced practice nurses registered by the Tennessee Board of Nursing. Ms. Alexander seconded Mr. Schmidt's comments. Ms. Alexander stated that she had worked with Mr. Schmidt and the Tennessee Medical Association to come up with amenable language for all parties.

Dr. Rene Saunders asked why the language had to be changed.

Ms. Alexander responded that in 2011, a public chapter was passed which contained the language used in this rule. The legislation's purpose, at that time, was intended to impact chronic pain, not acute pain. CRNAs treat acute pain. The language as currently written without the suggested amendment will limit the practice of CRNAs working in ambulatory surgical centers in Tennessee. Ms. Alexander stated that chronic pain and acute pain are not defined, as the statute solely refers to the definition of "interventional pain management."

Dr. Saunders then asked if operative anesthesia treatment was the treatment of acute pain?

Ms. Alexander indicated it was not, as it was surgical anesthesia service. She indicated that a nerve block is the treatment of acute pain, but that a nerve block was not surgical anesthesia.

Danna Willis commented on behalf of TANA on Rule 1200-08-10-.06. Ms. Willis is a CRNA. She provided clarity on the scope of acute pain treatment provided by CRNAs. She indicated that CRNAs who are using nerve blocks provide treatment of pain prior to surgical intervention, thus, reducing the need for opioids after surgery. She indicated that this is an important treatment necessary in the opioid crisis.

Dr. Saunders then questioned the speakers as to why the language, as currently written, was a problem?

Tausha Alexander responded that as currently written, when placed in the ambulatory surgical treatment center rule will make ambulatory surgical treatment practices more restrictive than unlicensed facilities. The original law when put in place was to focus on unlicensed facilities. This law was written prior to the pain clinic statutes The proposed changes that she and Mr. Schmidt had presented to the Board provide restriction to physicians, but does not restrict CRNAs. Ms. Alexander seconded Mr. Schmidt's proposed rule changes. Ms. Alexander stated that she had worked with Mr. Schmidt and the Tennessee Medical Association to come up with amenable language for all parties.

The Board then asked their counsel, Caroline Tippens, if Mr. Schmidt and Ms. Alexander's changes were in line with the proposed rules. Ms. Tippens answered that the proposed changes were consistent and provided clarity to the suggested language.

The Tennessee Community Organization (TNCO) an organization for home care providers that provide service to patients receiving services under the Tennessee Department of Intellectual and Developmental Disabilities proposed changes to the Professional Support Services (PSS) rules 1200-08-34 for consideration and approval for rulemaking hearing by the Board. Representative for TNCO was Melanie Keller, Chair, TNCO Health Committee. She asked that the Board consider a rewrite of the entire chapter regarding personal support service agencies. She indicated that that some of the language was outdated.

Ms. Tippens responded that unfortunately, the scope of this rulemaking hearing was limited to the previously noticed section of rules governing personal support service agencies, which was 1200-08-34-.02. Ms. Tippens indicated that she would work with Ms. Keller to incorporate her changes on a chapter re-write for the personal support services agency rules.

Thereafter, the Board voted to accept the revised language proposed changes as proposed by Medtronic, TMA, and TANA.

Regulatory Flexibility Addendum

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

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

These rule amendments 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.**

These rules amendments establish clarity, conciseness, and lack of ambiguity.

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

These rule amendments do not create any new compliance or reporting requirements.

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

These rule amendments do not create any new compliance or reporting requirements.

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

These rule amendments do not create any new compliance or reporting requirements.

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

These rule amendments do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

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

These rule amendments do not create unnecessary barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board for Licensing Health Care Facilities

Rulemaking hearing date: June 6, 2018

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:**

   These rules would directly affect hospitals, ambulatory surgical treatment centers, home care organizations providing professional support services and all companies currently offering or wishing to offer home medical equipment services by mail order.

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:**

   As a result of these rules, hospitals will be required to record the name of the patient's designated caregiver in the patient's record, but the costs associated with this rule should be minimal. The additional amendments should not have any impact on reporting or compliance requirements.

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

   Small businesses offering or wishing to offer home medical equipment services by mail order will benefit from these proposed rules. Tennessee consumers may also benefit from these proposed rules as more companies may apply to offer such services. The remaining rules should not directly affect business or consumers.

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

   There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule.

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

   Federal: None.

   State: None.

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.**

   These rules do not provide for exemptions regarding small businesses.

Impact on Local Governments

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

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

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The amendment to Rule 1200-08-01-.05(25) adds a new paragraph regarding "caregiver" requirements.

The amendment to Rule 1200-08-10-.06(13)(a) allows other experienced physicians, other than pain management specialists, to perform non-interventional pain procedures near the spine, for which they are trained.

The amendment to Rule 1200-08-29-.01(31) adds a definition for "Mail Order Company"

The amendment to Rule 1200-08-29-.06(4)(a) corrects a typographical error.

The amendment to Rule 1200-08-29-.06(4)(b) adds an exception for mail order companies under Equipment Management.

The amendment to Rule 1200-08-29-.11(3)(a) adds an exception to in-home patient education and instruction for mail order companies

Lastly, the amendment to Rule 1200-08-34-.02(2)(b) adds a new subparagraph requiring a contract with DIDDs and that failure to maintain the contract may lead to discipline.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

None.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules would directly affect hospitals, ambulatory surgical treatment centers, home care organizations providing professional support services and all companies currently offering or wishing to offer home medical equipment services by mail order.

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

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

These rules should not affect state or local government revenues or expenditures.

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

Caroline Tippens, Assistant General Counsel, Department of Health.

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

Caroline Tippens, Assistant General Counsel, Department of Health.

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Caroline.Tippens@tn.gov.

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

None.

On April 3, 2019, the Government Operations Committee filed a 60-day stay of the effective date of the rules; new effective date June 6, 2019. See page 70.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 01-12-19
Rule ID(s): 8109-8112
File Date: 1/7/19
Effective Date: 4/7/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission: Board for Licensing Health Care Facilities
Division:
Contact Person: Caroline Tippens, Assistant General Counsel
Address: 665 Mainstream Drive, Nashville, Tennessee
Zip: 37243
Phone: (615) 741-1611
Email: Caroline.Tippens@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-08-01	Standards for Hospitals
Rule Number	**Rule Title**
1200-08-01-.05	Admissions, Discharges, and Transfers

Chapter Number	**Chapter Title**
1200-08-10	Standards for Ambulatory Surgical Treatment Centers
Rule Number	**Rule Title**
1200-08-10-.06	Basic Services

Chapter Number	**Chapter Title**
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	**Rule Title**
1200-08-29-.01	Definitions
1200-08-29-.06	Basic Agency Functions
1200-08-29-.11	Records and Reports

Chapter Number	**Chapter Title**
1200-08-34	Standards for Home Care Organizations Providing Professional Support Services

Rule Number	Rule Title
1200-08-34-.02	Licensing Procedures

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Sequence Number: 04-05-19
Rule ID(s): N/A
File Date: 4/3/19
Effective Date: 4/3/19

Filing Form for Stay of Effective Date on Rules, Withdrawal of Stay, and Withdrawal of Rules

Agency/Board/Commission:	Board for Licensing Health Care Facilities
Division:	
Contact Person:	Doug Garrett
Address:	425 5th Ave North, Suite 922, Nashville, TN
Zip:	37243
Phone:	(615)741-9532
Email:	doug.garrett@capitol.tn.gov

Type of Action on Rule:

X **Stay of Effective Date of Rules**

Rule Filing Date: *01/07/19*
Rule Original Effective Date: *04/07/19*
Length of Stay (not to exceed 75 days): 60 days
New Effective Date of Rule Filing: *06/06/19*

____ **Notice of Withdrawal of Stay**

Stay Filing Date: *(mm/dd/yy)*
Stay Effective Date: *(mm/dd/yy)*
New Effective Date of Rule Filing: *(mm/dd/yy)*

____ **Notice of Withdrawal of Rules**

Rule Filing Date: *(mm/dd/yy)*
Rule Effective Date: *(mm/dd/yy)*

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-08-01	Standards for Hospitals
Rule Number	**Rule Title**
1200-08-01-.05	Admissions, Discharges, and Transfers

Chapter Number	**Chapter Title**
1200-08-10	Standards for Ambulatory Surgical Treatment Centers
Rule Number	**Rule Title**

1200-08-10-.06	Basic Services

Chapter Number	Chapter Title
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	**Rule Title**
1200-08-29-.01	Definitions
1200-08-29-.06	Basic Agency Functions
1200-08-29-.11	Records and Reports

Chapter Number	Chapter Title
1200-08-34	Standards for Home Care Organizations Providing Professional Support Services
Rule Number	**Rule Title**
1200-08-34-.02	Licensing Procedures

Date: 4/3/19

Signature:

Name of Officer: Doug Garrett

Title of Officer: Legislative Attorney

Subscribed and sworn to before me on: April 3, 2019

Notary Public Signature: Jamika Lee Whitmore

My commission expires on: 8/20/2019

8/20/2019

Department of State Use Only

Filed with the Department of State on: 4/3/19

Tre Hargett
Secretary of State

2019 APR -3 PM 3:14
SECRETARY OF STATE

(Rule 1200-08-01-.04, continued)

It is against the law to perform an abortion on you against your will. You have the right to contact any local or state law enforcement agency to receive protection from any actual or threatened criminal offense to coerce an abortion.

(b) The sign shall be printed in languages appropriate for the majority of clients of the hospital with lettering that is legible and that is Arial font, at least 40-point bold-faced type.

(c) A hospital in which abortions are performed that is not a private physician's office or ambulatory surgical treatment center shall post the required sign in the admissions or registration department used by patients on whom abortions are performed.

(d) A hospital shall be assessed a civil penalty by the board for licensing health care facilities of two thousand five hundred dollars ($2,500.00) for each day of violation in which:

1. The sign required above was not posted during business hours when patients or prospective patients are present; and

2. An abortion other than an abortion necessary to prevent the death of the pregnant female was performed in the hospital.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-15-202, 39-17-1803, 39-17-1805, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-11-268 and 71-6-121.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed June 18, 2002; effective September 1, 2002. Amendment filed December 2, 2003; effective February 15, 2004. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Amendment filed December 23, 2009; effective March 23, 2010. Amendments filed February 22, 2010; effective May 23, 2010. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-01-.05 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(Rule 1200-08-01-.05, continued)

(1) Every person admitted for care or treatment to any hospital covered by these rules shall be under the supervision of a physician who holds an unlimited license to practice in Tennessee. The name of the patient's attending physician shall be recorded in the patient's medical record.

(2) The above does not preclude the admission of a patient to a hospital by a dentist or podiatrist or certified nurse midwife licensed to practice in Tennessee with the concurrence of a physician member of the medical staff.

(3) This does not preclude qualified oral and maxillo-facial surgeons from admitting patients and completing the admission history and physical examination and assessing the medical risk of the procedure on their patients. A physician member of the medical staff is responsible for the management of medical problems.

(4) A diagnosis must be entered in the admission records of the hospital for every person admitted for care or treatment.

(5) Except in emergencies, no medication or treatment shall be given or administered to any patient in a hospital except on the order of a physician, dentist or podiatrist lawfully authorized to give such an order.

(6) The facility shall ensure that no person on the grounds of race, color, national origin, or handicap, will be excluded from participation in, be denied benefits of, or otherwise subjected to discrimination in the provision of any care or service of the facility. The facility shall protect the civil rights of residents under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

(7) For purposes of this chapter, the requirements for signature or countersignature by a physician, dentist, podiatrist or other person responsible for signing, countersigning or authenticating an entry may be satisfied by the electronic entry by such person of a unique code assigned exclusively to him or her, or by entry of other unique electronic or mechanical symbols, provided that such person has adopted same as his or her signature in accordance with established hospital protocol or rules.

(Rule 1200-08-01-.05, continued)

(8) The hospital must ensure continuity of care and provide an effective discharge planning process that applies to all patients. The hospital's discharge planning process, including discharge policies and procedures, must be specified in writing and must:

(a) Be developed and/or supervised by a registered nurse, social worker or other appropriately qualified personnel;

(b) Begin upon admission of any patient who is likely to suffer adverse health consequences;

(c) Be provided when identified as a need by the patient, a person acting on the patient's behalf, or by the physician;

(d) Include the likelihood of a patient's capacity for self-care or the possibility of the patient returning to his or her pre-hospitalization environment;

(e) Identify the patient's continuing physical, emotional, housekeeping, transportation, social and other needs and must make arrangements to meet those needs;

(f) Be completed on a timely basis to allow for arrangement of post-hospital care and to avoid unnecessary delays in discharge;

(g) Involve the patient, the patient's family or individual acting on the patient's behalf, the attending physician, nursing and social work professionals and other appropriate staff, and must be documented in the patient's medical record; and

(h) Be conducted on an ongoing basis throughout the continuum of hospital care. Coordination of services may involve promoting communication to facilitate family support, social work, nursing care, consultation, referral or other follow-up.

(9) A discharge plan is required on every patient, even if the discharge is to home.

(Rule 1200-08-01-.05, continued)

(10) The hospital must arrange for the initial implementation of the patient's discharge plan and must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(11) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-hospital care.

(12) The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

(13) The governing body of each hospital must adopt transfer and acceptance policies and procedures in accordance with these rules and the provisions of T.C.A. §§ 68-11-701 through 68-11-705. These policies must include a review of all such involuntary transfers, with special emphasis on those originating in the emergency room.

(14) Transfer agreements with other health care facilities are subject to these statutory and regulatory provisions.

(15) When a hospital proceeding in compliance with these rules seeks to appropriately transfer a patient to another hospital, the proposed receiving hospital may not decline the transfer for reasons related to the patient's ability to pay or source of payment, rather than the patient's need for medical services. The determination of the availability of space at the receiving hospital may not be based on the patient's ability to pay or source of payment.

(16) Anyone arriving at a hospital and/or the emergency department of a hospital requesting or requiring an examination or treatment for a medical condition must be provided an appropriate medical screening examination within the capability of the hospital's staff to determine whether or not a medical emergency exists.

(Rule 1200-08-01-.05, continued)

(17) The hospital must provide further medical examination and treatment as may be required to stabilize the medical emergency within the hospital's available staff and facilities. Such treatment may include, but is not limited to, the following:

(a) Establishing and assuring an adequate airway and adequate ventilation;

(b) Initiating control of hemorrhage;

(c) Stabilizing and splinting the spine or fractures;

(d) Establishing and maintaining adequate access routes for fluid administration;

(e) Initiating adequate fluid and/or blood replacement; and

(f) Determining that the patient's vital signs (including blood pressure, pulse, respiration, and urinary output, if indicated) are sufficient to sustain adequate perfusion.

(18) A hospital is deemed to meet the requirements of this section with respect to an individual if:

(a) The hospital offers to provide the further medical examination and treatment necessary but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the examination or treatment; or

(b) The hospital offers to transfer the individual to another hospital in accordance with this section but the individual, or legally responsible person acting on the individual's behalf, refuses to consent to the transfer.

(19) If a patient at a hospital has not been or cannot be stabilized within the meaning of this section, the hospital may not transfer the patient unless:

(Rule 1200-08-01-.05, continued)

(a) The patient, or legally responsible person acting on the patient's behalf, requests that a transfer be implemented after having been given complete and accurate information about matters pertaining to the transfer decision including:

1. The medical necessity of the movement;

2. The availability of appropriate medical services at both the transferring and receiving hospitals;

3. The availability of indigent care at the hospital initiating the transfer and the facility's legal obligations, if any, to provide medical services without regard to the patient's ability to pay; and,

4. Any obligation of the hospital through its participation in medical assistance programs of the federal, state or local government to accept the medical assistance program's reimbursement as payment in full for the needed medical care.

(b) A physician, or other appropriately qualified medical personnel when a physician is not available, makes a determination based upon the reasonable risk, expected benefits to the patient, and current available information that the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risk to the individual's medical condition resulting from a transfer; and

(c) The transfer is appropriate within the meaning of this section.

(20) An appropriate transfer includes:

(a) A physician at the receiving hospital agreeing to accept transfer of the patient and to provide appropriate medical treatment;

(Rule 1200-08-01-.05, continued)

(b) The receiving hospital having space available and personnel qualified to treat the patient;

(c) The transferring hospital providing the receiving hospital with appropriate medical records, or copies thereof, of any examination and/or treatment initiated by the transferring hospital; and

(d) The transfer being effected with qualified personnel, appropriate transportation equipment, and the use of necessary and medically appropriate life support measures as required.

(21) Transfers made pursuant to a regionalized plan for the delivery of health care services, approved by the department or other authorized governmental planning agency, are presumed to be appropriate.

(22) After an appropriate transfer has been effected, the receiving hospital may transfer the patient back to the original hospital, and the original hospital may accept the patient, if:

(a) The original receiving hospital has stabilized the medical emergency or provided treatment of the active labor and the patient no longer has a medical emergency; and

(b) The transfer is made in accordance with (21) of this section.

(23) When a hospital determines the need to exceed its licensed bed capacity upon an occurrence of a justified emergency, the following procedures must be followed:

(a) The hospital's administrator must make written notification to the Department within forty-eight (48) hours of exceeding its licensed bed capacity.

(b) The notification must include a detailed description of the emergency including:

(Rule 1200-08-01-.05, continued)

1. Why the licensed bed capacity was exceeded, i.e., lack of hospital beds in vicinity, specialized resources only available at the facility, etc.;

2. The estimated length of time the licensed bed capacity is expected to be exceeded; and,

3. The number of admissions in excess of the facility's licensed bed capacity.

(c) As soon as the hospital returns to its licensed bed capacity, the administrator must notify the department in writing of the effective date of its return to compliance.

(d) Staff will review all notifications of excess bed capacity with the Chairman of the Board. If, upon review of the notification, department staff concurs that a justified emergency existed, staff will notify the facility in writing. A report of the occurrence will be made to the board at the next regularly scheduled meeting as information purposes only.

(e) However, if department staff does not concur that a justified emergency existed, the facility will be notified in writing that a representative is required to appear at the next regularly scheduled board meeting to justify the need for exceeding its licensed bed capacity.

(24) Infant Abandonment.

(a) Any hospital shall receive possession of any newborn infant left on hospital premises with any hospital employee or member of the professional medical community, if the infant:

1. Was born within the preceding seventy-two (72) hour period, as determined within a reasonable degree of medical certainty;

(Rule 1200-08-01-.05, continued)

2. Is left in an unharmed condition; and

3. Is voluntarily left by a person who purported to be the child's mother and who did not express an intention of returning for the infant.

(b) The hospital, any hospital employee and any member of the professional medical community at such hospital shall inquire whenever possible about the medical history of the mother or newborn and whenever possible shall seek the identity of the mother, infant, or the father of the infant. The hospital shall also inform the mother that she is not required to respond, but that such information will facilitate the adoption of the child. Any information obtained concerning the identity of the mother, infant or other parent shall be kept confidential and may only be disclosed to the Department of Children's Services. The hospital may provide the parent contact information regarding relevant social service agencies, shall provide the mother the name, address and phone number of the department contact person, and shall encourage the mother to involve the Department of Children's Services in the relinquishment of the infant. If practicable, the hospital shall also provide the mother with both orally delivered and written information concerning the requirements of these rules relating to recovery of the child and abandonment of the child.

(c) The hospital, any hospital employee and any member of the professional medical community at such hospital shall perform any act necessary to protect the physical health or safety of the child.

(d) As soon as reasonably possible, and no later than twenty-four (24) hours after receiving a newborn infant, the hospital shall contact the Department of Children's Services, but shall not do so before the mother leaves the hospital premises. Upon receipt of notification, the department shall immediately assume care, custody and control of the infant.

(e) Notwithstanding any provision of law to the contrary, any hospital, any hospital employee and any member of the professional medical community shall be immune from any criminal or civil liability for damages as a result of any actions taken pursuant to the requirements of these rules, and no lawsuit shall be predicated thereon; provided, however, that nothing in these rules shall be construed to abrogate any existing standard of care for medical treatment or to preclude a cause

(Rule 1200-08-01-.05, continued)

of action based upon violation of such existing standard of care for medical treatment.

(25) Caregiver

(a) The hospital shall give a patient admitted to the hospital the opportunity to designate a caregiver who will assist the patient with continuing care after discharge from the hospital.

1. Caregiver means any individual designated as a caregiver by a patient who provides after-care assistance to a patient in a private residence. The term includes, but is not limited to, a relative, spouse, partner, friend or neighbor who has a significant relationship with the patient.

2. The hospital shall document the designated caregiver in the patient record and include contact information; and

3. If the patient declines to designate a caregiver, the hospital shall document the patient's choice in the medical record.

(b) The hospital shall notify the designated caregiver as soon as practicable before the patient is discharged back to a private residence.

(c) If the hospital is unable to contact the designated caregiver when changes occur, the lack of contact shall not interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient. Nothing in this paragraph shall interfere with, delay or otherwise affect the medical care provided to the patient or the transfer or discharge of the patient.

(d) The hospital shall make reasonable efforts to contact the designated caregiver and document those efforts in the patient record, to include dates and times attempted.

(e) The patient may give written consent to allow the hospital to release medical information to the designated caregiver, pursuant to the hospital's established procedures for the release of personal health information.

(f) Prior to the patient being discharged, the hospital shall provide discharge instructions for continuing care needs to the patient and designated caregiver, which shall include:

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1. The name and contact information of the designated caregiver and relation to the patient;

2. A description of continuing care tasks that the patient requires, communicated in a culturally competent manner; and

3. Contact information for any health care, community resources, and long-term services and supports necessary to successfully carry out the patient's discharge instructions.

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(Rule 1200-08-01-.05, continued)

(g) Prior to the patient being discharged, the hospital shall provide the designated caregiver with an opportunity for instruction in continuing care tasks outlined in the discharge instructions, which shall include:

1. Demonstration of the continuing care tasks by hospital personnel; and

2. Opportunity for the patient and designated caregiver to ask questions and receive answers regarding the continuing care tasks; and

3. Education and counseling about medications, including dosing and proper use of delivery devices.

(h) The hospital shall document the instruction given to the patient and designated caregiver in the patient record, to include the date, time and contents of the instructions.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-209, and 68-11-255.* ***Administrative History:*** *Original rule filed March 18, 2000; effective May 30, 2000. Amendment filed April 17, 2000; effective July 1, 2000. Amendment filed September 17, 2002; effective December 1, 2002.*

1200-08-01-.06 BASIC HOSPITAL FUNCTIONS.

(1) Performance Improvement.

(a) The hospital must ensure that there is an effective, hospital-wide performance improvement program to evaluate and continually improve patient care and performance of the organization.

(b) The performance improvement program must be ongoing and have a written plan of implementation which assures that:

1. All organized services including services furnished by a contractor, are evaluated (all departments including engineering, housekeeping, and accounting need to show evidence of process improvement.);

2. Nosocomial infections and medication therapy are evaluated;

(Rule 1200-08-10-.05, continued)

(12) As needed, the patient and family members or interested persons must be taught and/or counseled to prepare them for post-operative care.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003.*

1200-08-10-.06 BASIC SERVICES.

(1) Surgical Services.

(a) Facilities restricted in services they provide, e.g. those that restrict services to radiation therapy or use of local anesthetics only, may be exempted from all or part of the requirements of this rule pertaining to laboratory services, food and dietetic services, surgical services, and anesthesia services.

(b) If the facility provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(c) A hospital may choose to separately license a portion of the facility as an Ambulatory Surgical Treatment Center; the licensure fee for such is not required.

(d) The organization of the surgical services must be appropriate to the scope of the services offered.

(e) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(Rule 1200-08-10-.06, continued)

(f) An ASTC may use scrub nurses in its operating rooms. For the purposes of this rule, a "scrub nurse" is defined as a registered nurse or either a licensed practical nurse (L.P.N.) or a surgical technologist (operating room technician) supervised by a registered nurse who works directly with a surgeon within the sterile field, passing instruments, sponges, and other items needed during the procedure and who scrubs his or her hands and arms with special disinfecting soap and wears surgical gowns, caps, eyewear, and gloves, when appropriate.

(g) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies.

(h) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(i) Surgical services must be consistent with needs and resources. Policies covering surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(j) Surgical technologists must:

1. Hold current national certification established by the Liaison Council on Certification for the Surgical Technologist (LCC-ST); or

2. Have completed a program for surgical technology accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP); or

(Rule 1200-08-10-.06, continued)

3. Have completed an appropriate training program for surgical technologists in the armed forces or at a CAAHEP accredited hospital or CAAHEP accredited ambulatory surgical treatment center; or

4. Successfully complete the surgical technologists LCC-ST certifying exam; or

5. Provide sufficient evidence that, prior to May 21, 2007, the person was at any time employed as a surgical technologist for not less than eighteen (18) months in the three (3) years preceding May 21, 2007 in a hospital, medical office, surgery center, or an accredited school of surgical technology; or has begun the appropriate training to be a surgical technologist prior to May 21, 2007, provided that such training is completed within three (3) years of May 21, 2007.

(k) An ASTC can petition the director of health care facilities of the department for a waiver from the provisions of 1200-08-10-.06(1)(j) if they are unable to employ a sufficient number of surgical technologists who meet the requirements. The facility shall demonstrate to the director that a diligent and thorough effort has been made to employ surgical technologist who meet the requirements. The director shall refuse to grant a waiver upon finding that a diligent and thorough effort has not been made. A waiver shall exempt a facility from meeting the requirements for not more than nine (9) months. Additional waivers may be granted, but all exemptions greater than twelve (12) months shall be approved by the Board for Licensing Health Care Facilities.

(l) Surgical technologists shall demonstrate continued competence in order to perform their professional duties in surgical technology. The employer shall maintain evidence of the continued competence of such individuals. Continued competence activities may include but are not limited to continuing education, in-service training, or certification renewal. Persons qualified to be employed as surgical technologists shall complete fifteen (15) hours of continuing education or contact hours annually. Current certification by the National Board of Surgical Technology and Surgical Assisting shall satisfy this requirement.

(m) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If the history has been dictated, but not yet

(Rule 1200-08-10-.06, continued)

recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(n) Properly executed informed consent, advance directive, if available, and organ donation forms, if available, must be in the patient's chart before surgery, except in emergencies. The patient is not required to sign advance directive and organ donation forms.

(o) Adequate equipment and supplies must be available as determined by the governing body and the medical staff, and must meet the current acceptable standards of practice in the ASTC industry. In conjunction with their governing body and the medical staff, the facility shall develop policies and procedures specifying the types of emergency equipment that are appropriate for the facility's patient population, and shall make the items immediately available at the ASTC to handle inter- or post-operative emergencies.

(p) At least one registered nurse shall be in the recovery area during the patient's recovery period.

(q) The operating room register must be complete and up-to-date.

(r) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

(s) The ASTC shall provide one or more surgical suites which shall be constructed, equipped, and maintained to assure the safety of patients and personnel.

(t) Surgical suites are required to meet the same standards as hospital operating rooms, including those using general anesthesia.

(u) The ASTC shall have separate areas for waiting rooms, recovery rooms, treatment and/or examining rooms.

(Rule 1200-08-10-.06, continued)

(2) Anesthesiology Services. Anesthesia shall be administered by:

(a) A qualified anesthesiologist;

(b) A doctor of medicine or osteopathy (other than an anesthesiologist);

(c) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(d) A certified registered nurse anesthetist (CRNA); or

(e) A graduate registered nurse anesthetist under the supervision of an anesthesiologist who is immediately available if needed.

(f) After the completion of anesthesia, patients shall be constantly attended by competent personnel until responsive and able to summon aid. Each center shall maintain a log of the inspections made prior to each day's use of the anesthesia equipment. A record of all service and maintenance performed on all anesthesia machines, vaporizers and ventilators shall also be on file.

(g) When inhaled general anesthesia known to trigger malignant hyperthermia and/or succinylcholine are maintained in the facility, there shall be thirty-six (36) ampules of Dantrolene for injection onsite. This requirement applies to anesthesia agents, current or future, that are shown to cause malignant hyperthermia. If Dantrolene is administered, appropriate monitoring must be provided post-operatively.

(h) Written policies and procedures relative to the administration of anesthesia shall be developed and approved by the Medical Staff and governing body.

(Rule 1200-08-10-.06, continued)

(i) Any patient receiving conscious sedation shall receive:

1. continuous EKG monitoring;

2. continuous oxygen saturations;

3. serial BP monitoring at intervals no less than every 5 minutes; and

4. supplemental oxygen therapy and immediately available:

(i) ambubag;

(ii) suction;

(iii) endotracheal tube; and

(iv) crash cart.

(3) Medical Staff.

(a) The ASTC shall have a medical staff organized under written by-laws that are approved by the governing body. The medical staff of the ASTC shall define a mechanism to:

1. Assure that an optimal level of professional performance is maintained;

2. Appoint independent practitioners through a defined credentialing process;

(Rule 1200-08-10-.06, continued)

3. Apply credentialing criteria uniformly;

4. Utilize the current license, relevant training and experience, current competence and the ability to perform requested privileges in the credentialing process; and

5. Provide for participation in required committees of the facility to ensure that quality medical care is provided to the patients.

(b) Each licensed independent practitioner shall provide care under the auspices of the facility in accordance with approved privileges.

(c) Clinical privileges shall be granted based on the practitioners' qualifications and the services provided by the facility, and shall be reviewed and/or revised at least every two (2) years.

(4) Nursing Service. A licensed registered nurse (R.N.) shall be on duty at all times. Additional appropriately trained staff shall be provided as needed to ensure that the medical needs of the patients are fully met.

(a) The ASTC shall be organized under written policies and procedures relating to patient care, establishment of standards for nursing care and mechanisms for evaluating such care and nursing services.

(b) A qualified registered nurse designated by the administrator shall be responsible for coordinating and supervising all nursing services.

(c) There shall be a sufficient staffing pattern of registered nurses to provide quality nursing care to each surgical patient from admission through discharge. Additional

(Rule 1200-08-10-.06, continued)

staff shall be on duty and available to assist the professional staff to adequately handle routine and emergency patient needs.

(d) The ASTC shall establish written procedures for emergency services which will ensure that professional staff members who have been trained in emergency resuscitation procedures shall be on duty at all times when there is a patient in the ASTC and until the patient has been discharged.

(e) Nursing care policies and procedures shall be consistent with professionally recognized standards of nursing practice and shall be in accordance with the Nurse Practice Act of the State of Tennessee and the Association of Operating Room Nurses Standards of Practice.

(f) Staff development and training shall be provided to the nursing staff and other ancillary staff in order to maintain and improve knowledge and skills. The educational/training program shall be planned, documented and conducted on a continuing basis. There shall be at least appropriate training on equipment, safety concerns, infection control and emergency care on an annual basis.

(5) Pharmaceutical Services. The ASTC must provide drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice. Such drugs and biologicals must be stored in a separate room or cabinet which shall be kept locked at all times.

(6) Ancillary Services. All ancillary or supportive health or medical services, including but not limited to, radiological, pharmaceutical, or medical laboratory services shall be provided in accordance with all applicable state and federal laws and regulations.

(7) Radiological Services. The ASTC shall provide within the facility, or through arrangement, diagnostic radiological services commensurate with the needs of the ambulatory surgical treatment center.

(Rule 1200-08-10-.06, continued)

(a) If radiological services are provided by facility staff, the services shall be maintained free of hazards for patients and personnel.

(b) New installations of radiological equipment, and subsequent inspections for the identification of radiation hazards shall be made as specified in state and federal requirements.

(c) Personnel monitoring shall be maintained for each individual working in the area of radiation. Readings shall be on at least a monthly basis and reports kept on file and available for review.

1. Personnel - The ASTC shall have a radiologist either full-time or part-time on a consulting basis, both to supervise the service and to discharge professional radiological services.

2. The use of all radiological apparatus shall be limited to personnel designated as qualified by the radiologist; and use of fluoroscopes shall be limited to physicians.

(d) If provided under arrangement with an outside provider, the radiological services must be directed by a qualified radiologist and meet state and federal requirements.

(8) Laboratory Services.

(a) The ASTC shall provide on the premises or by written agreement with a laboratory licensed under T.C.A. § 68-29-105, a clinical laboratory to provide those services commensurate with the needs and services of the ASTC.

(b) Any patient terminating pregnancy in an ASTC shall have an Rh type, documented prior to the procedure, performed on her blood. In addition, she shall be given the opportunity to receive Rh immune globulin after an appropriate crossmatch procedure is performed within a licensed laboratory.

(Rule 1200-08-10-.06, continued)

(9) Food and Dietetic Services. If a patient will be in the facility for more than four (4) hours post-op, an appropriate diet shall be provided.

(10) Environmental Services.

(a) The facility shall provide a safe, accessible, effective and efficient environment of care consistent with its mission, service, law and regulation.

(b) The facility shall develop policies and procedures that address:

1. Safety;

2. Security;

3. Control of hazardous materials and waste;

4. Emergency preparedness;

5. Life safety;

6. Medical equipment; and,

7. Utility systems.

(c) Staff shall have been oriented to and educated about the environment of care and possess knowledge and skills to perform responsibilities under the environment of care policies and procedures.

(Rule 1200-08-10-.06, continued)

(d) Utility systems, medical equipment, life safety elements, and safety elements of the environment of care shall be maintained, tested and inspected.

(e) Safety issues shall be addressed and resolved.

(f) Appropriate staff shall participate in implementing safety recommendations and monitoring their effectiveness.

(g) The building and grounds shall be suitable to services provided and patients served.

(11) Infection Control. An Ambulatory Surgical Treatment Center shall have an annual influenza vaccination program which shall include at least:

(a) The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Ambulatory Surgical Treatment Center will encourage all staff and independent practitioners to obtain an influenza vaccination;

(b) A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at http://tennessee.gov/health/topic/hcf-provider);

(c) Education of all employees about the following:

1. Flu vaccination,

2. Non-vaccine control measures, and

(Rule 1200-08-10-.06, continued)

3. The diagnosis, transmission, and potential impact of influenza;

(d) An annual evaluation of the influenza vaccination program and reasons for non-participation; and

(e) A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

(12) Medical Records.

(a) The ASTC shall comply with the Medical Records Act of 1974, T.C.A. § 68-11-301, et seq.

(b) A medical record shall be maintained for each person receiving medical care provided by the ASTC and shall include:

1. Patient identification;

2. Name of nearest relative or other responsible agent;

3. Identification of primary source of medical care;

4. Dates and times of visits;

5. Signed informed consent;

6. Pertinent medical history;

(Rule 1200-08-10-.06, continued)

7. Diagnosis;

8. Physician examination report;

9. Anesthesia records of pertinent preoperative and postoperative reports including preanesthesia evaluation, type of anesthesia, technique and dosage used;

10. Operative report;

11. Discharge summary, including instructions for self care and instructions for obtaining postoperative emergency care;

12. Reports of all laboratory and diagnostic procedures along with tests performed and the results authenticated by the appropriate personnel; and,

13. X-ray reports.

(c) Medical records shall be current and confidential. Medical records and copies thereof shall be made available when requested by an authorized representative of the board or the department.

(13) Invasive Procedures

~~(a) Only a medical doctor, licensed pursuant to T.C.A. § 63-6-101 et seq., or an osteopathic physician, licensed pursuant to T.C.A. § 63-9-101 et seq., who meet the following qualifications will be permitted to perform invasive procedures of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine:~~

(Rule 1200-08-10-.06, continued)

(a) For purposes of interventional pain management, only a medical doctor, licensed pursuant to T.C.A. § 63-6-101 et seq., or an osteopathic physician, licensed pursuant to T.C.A. § 63-9-101 et seq., who meets the following qualifications will be permitted to perform invasive procedures of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine.

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1. Board certified through the American Board of Medical Specialties (ABMS) or the American Osteopathic Association (AOA) or the American Board of Physician Specialties (ABPS)/American Association of Physician Specialists (AAPS) in one of the following medical specialties:

   (i) Anesthesiology;

   (ii) Neurological surgery, or Neuromusculoskeletal medicine;

   (iii) Orthopedic surgery;

   (iv) Physical medicine and rehabilitation;

   (v) Radiology; or

   (vi) Any other board certified physician who had completed an ABMS subspecialty board in pain medicine or completed an ACGME accredited pain fellowship;

2. A recent graduate in a medical specialty listed in part 1 not yet eligible to apply for ABMS, AOA, or ABPS/AAPS board certification; provided, there is a practice relationship with a medical doctor or an osteopathic physician who meets the requirements of part 1.;

(Rule 1200-08-10-.06, continued)

3. A licensee who is not board certified in one of the specialties listed in part 1, but is board certified in a different ABMS, AOA, or ABPS/AAPS specialty and has completed a post-graduate training program in interventional pain management approved by the board;

4. A licensee who serves as a clinical instructor in pain medicine at an accredited Tennessee medical training program; or

5. A licensee who has an active pain management practice in a clinic accredited in outpatient interdisciplinary pain rehabilitation by the Commission on Accreditation of Rehabilitation Facilities or any successor organizations.

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6. This subparagraph (13)(a) shall not apply to a medical doctor, licensed pursuant to T.C.A. § 63-6-101 et seq., or an osteopathic physician, licensed pursuant to T.C.A. § 63-9-101 et seq., in the placement of medical devices used in the treatment of conditions not primarily related to pain.

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(b) An advanced practice nurse or physician assistant shall only perform invasive procedures involving any portion of the spine, spinal cord, sympathetic nerves of the spine or block of major peripheral nerves of the spine under the direct supervision of a medical doctor or an osteopathic physician who meets the qualifications of Rule 1200-08-10-.06 (12)(a)1 or 3. Direct supervision is defined as being physically present in the center at the time the invasive procedure is performed.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68, 68-11-209, 68-11-216, 68-57-101, 68-57-102, 68-57-104, and 68-57-105.* ***Administrative History:*** *Original rule filed July 22, 1977; effective August 22, 1977. Amendment filed September 10, 1991; effective October 25, 1991. Repeal and new rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 21, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed February 23, 2006; effective May 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed December 16, 2013; effective March 16, 2014.*

(Rule 1200-08-10-.06, continued)

Amendments filed March 27, 2015; effective June 25, 2015. Amendment filed October 20, 2015; effective January 18, 2016. Amendments filed July 18, 2016; effective October 16, 2016.

1200-08-10-.07 RESERVED.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-57-105.* ***Administrative History:*** *Original rule filed June 30, 1992; effective August 14, 1992. Repeal and new rule filed March 4, 2000; effective June 4, 2000. Amendment filed June 16, 2003; effective August 30, 2003. Amendment filed January 3, 2012; effective April 2, 2012.*

1200-08-10-.08 BUILDING STANDARDS.

(1) An ASTC shall construct, arrange, and maintain the condition of the physical plant and the overall ASTC environment in such a manner that the safety and well-being of the patients are assured.

(2) After the applicant has submitted an application and licensure fees, the applicant must submit the building construction plans to the department. All facilities shall conform to the current edition of the following applicable codes as approved by the Board for Licensing Health Care Facilities: International Building Code (excluding Chapters 1 and 11) including referenced International Fuel Gas Code, International Mechanical Code, and International Plumbing Code; National Fire Protection Association (NFPA) NFPA 101 Life Safety Code excluding referenced NFPA 5000; Guidelines for Design and Construction of Health Care Facilities (FGI) including referenced Codes and Standards; U.S. Public Health Service Food Code; and Americans with Disabilities Act (ADA) Standards for Accessible Design. When referring to height, area or construction type, the International Building Code shall prevail. Where there are conflicts between requirements in local codes, the above listed codes, regulations and provisions of this chapter, the most stringent requirements shall apply.

(3) The codes in effect at the time of submittal of plans and specifications, as defined by these rules, shall be the codes to be used throughout the project.

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RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-29
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING HOME MEDICAL EQUIPMENT

TABLE OF CONTENTS

1200-08-29-.01	Definitions	1200-08-29-.08	Reserved
1200-08-29-.02	Licensing Procedures	1200-08-29-.09	Reserved
1200-08-29-.03	Disciplinary Procedures	1200-08-29-.10	Infectious and Hazardous Waste
1200-08-29-.04	Administration	1200-08-29-.11	Records and Reports
1200-08-29-.05	Admissions, Discharge and Transfers	1200-08-29-.12	Patient Rights
1200-08-29-.06	Basic Agency Functions	1200-08-29-.13	Repealed
1200-08-29-.07	Reserved	1200-08-29-.14	Disaster Preparedness

1200-08-29-.01 DEFINITIONS.

(1) Abuse. The willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

(2) Administrator. A person who:

(a) Is a licensed physician with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(b) Is a registered nurse with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(c) Has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs.

(Rule 1200-08-29-.01, continued)

(3) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(4) Agency. A Home Care Organization providing home medical equipment.

(5) Assistive Technology Practitioner (ATP). Service providers primarily involved in evaluating the consumer's needs and training in the use of a prescribed wheeled mobility device.

(6) Assistive Technology Supplier (ATS). Service providers involved in the sale and service of commercially available wheeled mobility devices.

(7) Board. The Tennessee Board for Licensing Health Care Facilities.

(8) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(9) Clinical Note. A written and dated notation containing a patient assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the patient.

(10) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(11) Competent. For the purpose of this chapter only, a patient who has decision-making capacity.

(Rule 1200-08-29-.01, continued)

(12) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(13) Department. The Tennessee Department of Health.

(14) Do-Not-Resuscitate Order (DNR). A written order, other than a POST, not to resuscitate a patient in cardiac or respiratory arrest in accordance with accepted medical practices.

(15) Evaluation. The determination and documentation of the physiological and functional factors that impact the selection of an appropriate seating and wheeled mobility device.

(16) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(17) Health care decision. A decision made by an individual or the individual's health care decision-maker, regarding the individual's health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(18) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient's health care decision-maker is one of the following:

(Rule 1200-08-29-.01, continued)

the patient's health care agent as specified in an advance directive, the patient's court-appointed legal guardian or conservator with health care decision-making authority, or the patient's surrogate as determined pursuant to Rule 1200-08-29-.13 or T.C.A. §33-3-220.

(19) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(20) Home Medical Equipment.

(a) Medical equipment intended for use by the consumer including, but not limited to the following:

1. A device, instrument, apparatus, machine, or other similar article whose label bears the statement: "Caution: Federal law requires dispensing by or on the order of a physician.";

2. Ambulating assistance equipment;

3. Mobility equipment;

4. Rehabilitation seating;

5. Oxygen care equipment and oxygen delivery systems;

6. Respiratory care equipment and respiratory disease management devices.

7. Rehabilitation environmental control equipment;

(Rule 1200-08-29-.01, continued)

8. Ventilators;

9. Apnea monitors;

10. Diagnostic equipment;

11. Feeding pumps;

12. A bed prescribed by a physician to treat or alleviate a medical condition;

13. Transcutaneous electrical nerve stimulator;

14. Sequential compression devices; and

15. Neonatal home phototherapy devices.

(b) Home medical equipment does not include:

1. Medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities as defied in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual's residence;

2. Upper and lower extremity prosthetics and related orthotics;

3. Canes, crutches, walkers, and bathtub grab bars;

(Rule 1200-08-29-.01, continued)

4. Medical equipment provided through a physician's office incident to a physician's service;

5. Equipment provided by a pharmacist which is used to administer drugs or medicine that can be dispensed only by a pharmacist; or

6. Enteral and parenteral equipment provided by a pharmacist.

(21) Home medical equipment provider. Any person who provides home medical equipment services.

(22) Home medical equipment services. A service provided by any person who sells or rents home medical equipment for delivery to the consumer' place of residence in this state, regardless of the location of the home medical equipment provider.

(23) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(24) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(25) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(Rule 1200-08-29-.01, continued)

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(26) Legal Conservator. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 5 and 11 through 13.

(27) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(28) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(29) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(30) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

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(31) Mail Order Company. A company which lists its products for consumers to buy, rent or lease via telephone, mailed check with order form, or Internet order and delivers such products directly to the consumer via a postal service, such as the U.S. Postal Service (USPS), UPS, FedEx or another courier service; provided, however, that a company that supplies respiratory care and oxygen equipment or any other home medical equipment necessary to avert an immediate threat to a consumer's health or safety, without which a consumer might be required to seek emergency medical treatment, shall not be considered to be a mail order company for purposes of this rule.

(~~31~~32) Medical Record. Information that pertains to confinement or services rendered to patients, including one or more of the following:

(a) medical histories;

(Rule 1200-08-29-.01, continued)

(b) records;

(c) reports;

(d) clinical notes;

(e) summaries; or

(f) orders.

If the patient does not require any clinical services from the home medical equipment company, the medical record will consist of the physician order only.

(~~32~~33) Medical Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(~~33~~34) Misappropriation of Patient/Resident Property. The deliberate misplacement, exploitation or wrongful, temporary or permanent use of an individual's belongings or money without the individual's consent.

(~~34~~35) Neglect. The failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of the living will, shall not be deemed "neglect" for purposes of these rules.

(Rule 1200-08-29-.01, continued)

(~~35~~36) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(~~36~~37) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed by the Tennessee Board of Osteopathic Examination. For the purpose of this chapter only, a physician who is licensed to practice medicine or osteopathy in a state contiguous to Tennessee, who have previously provided treatment to the patient and has an ongoing physician-patient relationship with the patient for whom a referral is to be made, may refer a patient residing in this state to a home care organization providing hospice services duly licensed under this chapter. This shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§ 63-6-201 or 63-9-104.

(~~37~~38) Physician Assistant. A person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under title 63, chapter 19.

(~~38~~39) Qualified Rehabilitation Professional. A health care professional with in the professional's scope of practice licensed under Title 63; or an individual who has appropriately obtained the designation of ATS or ATP, meeting all requirements thereof, as established by the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA).

(~~39~~40) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(~~40~~41) Shall or Must. Compliance is mandatory.

(~~41~~42) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(Rule 1200-08-29-.01, continued)

(~~42~~43) Surrogate. The patient's conservator, or if none, a competent adult most likely to know the wishes of the patient with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

(~~43~~44) Wheeled Mobility Device. A wheelchair or wheelchair and seated positioning system prescribed by a physician and required for use by the patient for a period of six (6) months or more. The following Medicare wheelchairs base codes are exempt: K0001, K0002, K0003, K0004, K0006, and K0007 as long as the consumer weighs less than three hundred (300) pounds.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-226, 68-11-268, and 68-11-303.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendments filed December 23, 2009; effective March 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-29-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the home care organization providing home medical equipment shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home medical equipment.

(2) In order to make application for a license:

(2) Patients shall be transferred or referred to other organizations/agencies in the community when service needs are identified by staff or patients which cannot be met by the agency.

(3) The agency shall ensure that no person, on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise be subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed June 25, 2007; effective September 8, 2007.*

1200-08-29-.06 BASIC AGENCY FUNCTIONS.

(1) Patient Instruction. The agency shall have written guidelines relating to patient and/or caregiver training and education that includes at a minimum:

(a) Financial responsibilities;

(b) Equipment use and maintenance;

(c) Patient rights and responsibilities;

(d) Emergency/back-up systems and trouble shooting procedures, if applicable; and

(e) How to contact the agency during regular business hours and after hours, if applicable.

(2) Infection Control. The agency shall have written policies and procedures relating to infection control. Employees shall consistently follow infection control procedures in the

(Rule 1200-08-29-.06, continued)

provision of care to the agency's patients. The written policies and procedures at a minimum must address standards and education of staff about:

(a) Infection control measures;

(b) Handwashing;

(c) Use of universal precautions and personal protective equipment;

(d) Appropriate cleaning and disinfection of reusable equipment and supplies; and,

(e) Disposal of regulated waste.

(f) A Home Care Organization Providing Home Medical Equipment shall have an annual influenza vaccination program which shall include at least:

1. The offer of influenza vaccination to all staff and independent practitioners at no cost to the person or acceptance of documented evidence of vaccination from another vaccine source or facility. The Home Care Organization Providing Home Medical Equipment will encourage all staff and independent practitioners to obtain an influenza vaccination;

2. A signed declination statement on record from all who refuse the influenza vaccination for reasons other than medical contraindications (a sample form is available at http://tennessee.gov/health/topic/hcf-provider);

3. Education of all employees about the following:

(i) Flu vaccination,

(Rule 1200-08-29-.06, continued)

(ii) Non-vaccine control measures, and

(iii) The diagnosis, transmission, and potential impact of influenza;

4. An annual evaluation of the influenza vaccination program and reasons for non-participation; and

5. A statement that the requirements to complete vaccinations or declination statements shall be suspended by the administrator in the event of a vaccine shortage as declared by the Commissioner or the Commissioner's designee.

(3) In-Home Safety. The agency shall educate staff, patients, and caregivers about basic home safety related to the use of equipment delivered to the home. There shall be a procedure for reporting and documenting all incidents. There shall be an incident report form and identification of the types of situations that should be reported and documented.

(4) Equipment Management.

~~(a) Client-ready equipment shall be durable in nature, sanitized, and in proper working order. The agencyzation shall have clearly defined guidelines for the cleaning, storage, and transportation of client-ready equipment. These guidelines shall include, but are not limited to:~~

(a) Client-ready equipment shall be durable in nature, sanitized, and in proper working order. The agency shall have clearly defined guidelines for the cleaning, storage, and transportation of client-ready equipment. These guidelines shall include, but are not limited to:

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1. Separation of clean and unclean equipment;

2. Appropriate warehousing and tagging of equipment;

(Rule 1200-08-29-.06, continued)

3. Use of appropriate cleaning agents, as directed by the manufacturer;

4. Routine maintenance of equipment; and

5. Separation of inoperative equipment.

~~(b) Agency employees shall be qualified to deliver, perform environmental assessments, set up, and demonstrate safe and proper use of all home medical equipment according to manufacturer's guidelines.~~

(b) Except for mail order companies, agency employees shall be qualified to deliver, perform environmental assessments, set up, and demonstrate safe and proper use of all home medical equipment according to manufacturer's guidelines.

(c) Agency guidelines shall clearly define training, qualifications, and skills validation required by employees to perform routine maintenance and repairs of all home medical equipment. Routine maintenance, preventive maintenance, and repairs shall be performed according to manufacturer's guidelines. Agency employees shall only perform repair services within their respective areas of documented training and expertise. There shall be guidelines that define appropriate use of outside repair sources.

(d) The agency shall have written guidelines for accurate performance quality tracking of equipment in compliance with the FDA's Medical Device Tracking program and facilitate any recall notices sent by the manufacturer. These guidelines shall address the:

1. Immediate removal from equipment inventory;

2. Notification to the client; and

(Rule 1200-08-29-.06, continued)

3. Exchange of equipment in the field.

(e) Disposition of recalled inventory shall be handled according to manufacturer's guidelines.

(f) Only durable medical equipment shall be returned to the company for processing. The agency shall have written policies and procedures for processing contaminated or soiled durable medical equipment and shall be in compliance with universal precautions. Guidelines shall specify the separation of dirty equipment from client ready equipment in the warehouse and delivery vehicles.

(5) Physical Location. Each parent and/or branch shall:

(a) Be located in Tennessee;

(b) Be staffed during normal business hours and have a working telephone;

(c) Be used for the dispensing, servicing, and storage of home medical equipment or be used to provide home medical equipment services;

(d) Meet all local zoning requirements; and

(e) Have all required current licenses and/or permits conspicuously posted in the agency.

(6) Additional Compliance Requirements. The agency shall comply with all federal, state, and local laws and regulations.

(a) Written policies and procedures shall be established and implemented by the agency regarding compliance with all applicable federal, state, and local laws and regulations.

(Rule 1200-08-29-.06, continued)

(b) An agency providing prescribed wheeled mobility devices shall obtain a complete face-to-face written evaluation and recommendation by a qualified rehabilitation professional for consumers of prescribed wheeled mobility devices.

(c) The agency must have on staff, or contract with, a qualified rehabilitation professional.

(d) As of July 1, 2007, a one hundred eighty (180) day grace period shall be provided to agencies that provide prescribed wheeled mobility devices if the qualified rehabilitation professional on staff ceases to be employed and the agency has no other qualified rehabilitation professional on staff.

(e) All agencies making available prescribed wheeled mobility devices to consumers in Tennessee shall have a repair service department or a contract with a repair service department located in the state. The agency shall have a qualified technician with knowledge and capability of servicing the product provided to the consumer. As used in this section, "consumer" means an individual for whom a wheeled mobility device, manual or powered, has been prescribed by a physician, and required for use for a period of six (6) months or more.

(f) Delivery and final fitting of a wheeled mobility device shall be determined by a qualified rehabilitation professional. Exempt are wheeled mobility devices under category Group 1 Medicare codes.

(g) The agency shall comply with the following supplier standards:

1. Fill orders from its own inventory or inventory of other companies with which it has contracts to fill such orders, or fabricates or fits items for sale from supplies it buys under a contract;

2. Oversee delivery of items that the supplier ordered for the patient. The supplier is also responsible to assure delivery of large items to the patient;

(Rule 1200-08-29-.06, continued)

3. Honor all warranties, express or implied, under applicable state law;

4. Answer questions or complaints about an item or use of an item that is sold or rented to the patient. If the patient has questions, the supplier will refer the patient to the appropriate carrier;

5. Maintain and repair directly, or through a service contract with another company, items it rents to a patient;

6. Accept returns for substantial medical equipment;

7. Provide the following disclosure information to the department:

   (i) The identity of each person having a five percent (5%) or more ownership or controlling interest in the agency.

   (ii) The identity of subcontractors in which the agency has a five percent (5%) or more ownership interest;

   (iii) At the time such information is disclosed or at any time during the three (3) year period preceding the date such information is supplied, managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any other entity providing items or services that receives payment under title XVIII; and

   (iv) Managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose

(Rule 1200-08-29-.06, continued)

any penalties, assessments, or exclusions assessed against such person under Section 1128, 1128A, or 1128B of the Social Security Act;

8. Maintain general and product liability insurance; and

9. Disclose consumer information to each patient. This consists of a copy of the supplies standards to which it must conform.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-206, 68-11-209, 68-11-226, and 68-11-304.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed October 11, 2007; effective December 25, 2007. Amendment filed December 23, 2009; effective March 16, 2010. Amendment filed December 16, 2013; effective March 16, 2014. Amendments filed July 18, 2016; effective October 16, 2016.*

1200-08-29-.07 RESERVED.

1200-08-29-.08 RESERVED.

1200-08-29-.09 RESERVED.

1200-08-29-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(Rule 1200-08-29-.10, continued)

protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents, and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-08-29-.11 RECORDS AND REPORTS.

(1) The home care organization providing home medical equipment shall report all incidents of abuse, neglect, and misappropriation to the Department of Health in accordance with T.C.A. § 68-11-211.

(2) The home care organization providing home medical equipment shall report the following incidents to the Department of Health in accordance with T.C.A. § 68-11-211.

(a) Strike by staff at the facility;

(b) External disasters impacting the facility;

(Rule 1200-08-29-.11, continued)

(c) Disruption of any service vital to the continued safe operation of the home care organization providing home medical equipment or to the health and safety of its patients and personnel; and

(d) Fires at the home care organization providing home medical equipment that disrupt the provision of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires.

(3) Patient Records shall be maintained for each patient who receives in-home services. The patient record must contain detailed, accurate documentation that reflects all of the services or care provided, directly or by contract. The patient record shall contain at a minimum the following:

~~(a) Documentation of patient education and instruction~~;

(a) Except for mail order companies, documentation of in-home patient education and instruction.

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(b) Physician orders as required;

1. A home care organization providing home medical equipment is authorized to receive and appropriately act on a written order for a plan of care for a patient concerning a home health service signed by a physician that is transmitted to the agency by electronically signed electronic mail. Such order that is transmitted by electronic mail shall be deemed to meet any requirement for written documentation imposed by this regulation.

(c) Documentation that patient has been fully informed of patient rights and responsibilities and at a minimum, the right to:

(Rule 1200-08-29-.11, continued)

1. Be fully informed in advance about care and treatment to be provided by the agency;

2. Be fully informed in advance of any changes in the care or treatment to be provided by the agency when those changes may affect the patient's well-being;

3. Voice grievances without fear of discrimination or reprisal;

4. Confidentiality of personal information;

5. Have one's property treated with respect; and

6. Be fully informed of the agency's telephone number for information, questions, and/or complaints about services provided by the agency and a description of the process for investigating and resolving complaints. The agency shall investigate and resolve all patient complaints and document the results in a timely manner. The agency shall label all equipment with the name, address, and telephone number of the agency.

(4) Patient Confidentiality. The agency shall have written policies dealing with patient information. Patient records shall contain signed release of information statements/forms when the agency bills a third-party payor or shares information with others outside the agency. Patient confidentiality polices will address, at a minimum, the following:

(a) A definition of confidential information;

(b) Persons/positions authorized to release confidential information;

(c) Conditions which warrant release of confidential information;

(Rule 1200-08-29-.11, continued)

(d) Persons to whom confidential information may be released;

(e) Policies and procedures for obtaining signatures on, using, and filing release of information forms;

(f) Who has authority to review patient records; and

(g) A statement that training in confidentiality is mandatory for all employees, so that personnel are knowledgeable about and consistently follow confidentiality polices and procedures.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, 68-11-211, and 68-11-260.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed September 1, 2004; effective November 15, 2004. Amendment filed February 23, 2007; effective May 9, 2007. Amendments filed January 3, 2012; effective April 2, 2012.*

1200-08-29-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, and the refusal and its reason must be reported to the treating physician and documented in the medical record;

(Rule 1200-08-34-.01, continued)

(55) Speech Language Pathologist. As defined in T.C.A. § 63-17-103, a person currently licensed as such by the Tennessee Board of Communications Disorders and Sciences.

(56) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(57) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(58) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(59) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.

(60) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.*

1200-08-34-.02 LICENSING PROCEDURES.

(Rule 1200-08-34-.02, continued)

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing professional support services without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. The name of the home care organization providing professional support services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing professional support services.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

(b) The home care organization must maintain a contract with the Department of Intellectual and Developmental Disabilities (DIDD). Failure to maintain this contract is a violation of this rule and will subject the license of the home care organization to disciplinary action.

(c)~~(b)~~ Home care organizations authorized to provide only professional support services shall pay an annual fee of one thousand eighty dollars ($1,080.00), except that this annual fee shall be two hundred seventy dollars ($270.00) for (i) home care organizations that also pay a fee to be licensed by the Department of Mental Health and Developmental Disabilities; (ii) home care organizations owned and operated by therapists who pay a fee to be licensed under Title 63, Chapter 13 or 17; or (iii) home care organizations that are owned and controlled by another home care organization that pay an annual license fee of at least one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.

(d)~~(c)~~ The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Consumers shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial

(Rule 1200-08-34-.02, continued)

compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.

(e)~~(d)~~ The applicant must prove the ability to meet the financial needs of the agency providing professional support services.

(f)~~(e)~~ The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(g)~~(f)~~ The applicant shall allow the home care organization providing professional support services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.

(Rule 1200-08-34-.02, continued)

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate facility owner with one or more corporations; or,

7. Transfers between levels of government.

(d) 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;

(Rule 1200-08-34-.02, continued)

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each home care organization providing professional support services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(Rule 1200-08-34-.02, continued)

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-34-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-34-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

* 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)
Paul Boyd	X				
Robert Breeden	X				
Evelyn Brock	X				
Joshua Crisp	X				
Thomas Gee	X				
Jennifer Gordon-Maloney				X	
Chuck Griffin	X				
Patricia Ketterman	X				
Carissa Lynch	X				
Annette Marlar				X	
Roger Mynatt	X				
Lisa Piercey	X				
Sherry Robbins		X			
Kenneth Robertson				X	
Rene Saunders			X		
Jim Shulman	X				
Gina Thorneberry	X				
Janet Williford	X				
Bobby Wood				X	

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities (board/commission/ other authority) on 06/06/2018 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *04/10/18 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *06/06/18 (mm/dd/yy)*

Date: July 5, 2018

Signature: Caroline R. Tippens

Name of Officer: Caroline Tippens

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: July 5, 2018

Notary Public Signature: Mark Andrew Cole

My commission expires on: March 6, 2021

MARK ANDREW COLE
STATE OF TENNESSEE
NOTARY PUBLIC
DAVIDSON COUNTY

Agency/Board/Commission: Board for Licensing Health Care Facilities

Rule Chapter Number(s): 1200-08-01; 1200-08-10; 1200-08-29, 1200-08-34

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

12/21/2018
Date

Department of State Use Only

Filed with the Department of State on: 1/7/19

Effective on: 4/7/19

Tre Hargett
Secretary of State

2019 JAN -7 PM 3:25
SECRETARY OF STATE

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Board for Licensing Health Care Facilities
SUBJECT:	Standards for Prescribed Child Care Centers, Standards for Residential Hospices, Standards for Birthing Centers, Standards for Assisted-Care Living Facilities, Standards for Home Care Organizations Providing Hospice Services, Standards for HIV Supportive Living Centers, Standards for Home Care Organizations Providing Home Medical Equipment, Standards for End Stage Renal Dialysis Clinic, Standards for Home Care Organizations Providing Professional Support Services, Standards for Outpatient Diagnostic Centers, Standards for Adult Care Homes – Level 2, and Traumatic Brain Injury Residential Homes – Annual Renewal Fees
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 68-11-216
EFFECTIVE DATES:	June 24, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	The amendment to 1200-08-02-.02 increases annual renewal fees for Prescribed Child Care Centers. The amendment to 1200-08-15-.02 increases annual renewal fees for Residential Hospices, per bed. The amendment to 1200-08-24-.02 increases annual renewal fees for Birthing Centers. The amendment to 1200-08-25-.04 increases annual renewal fees for ACLFs, per bed. The amendment to 1200-08-27-.02 increases annual renewal fees for Home Care Organizations Providing Hospice Services. The amendment to 1200-08-28-.02 increases annual renewal fees for HIV Supportive Living Centers, per bed.

The amendment to 1200-08-29-.02 increases annual renewal fees for Home Care Organizations Providing Home Medical Equipment.

The amendment to 1200-08-32-.02 increases annual renewal fees for End Stage Renal Dialysis Clinics.

The amendment to 1200-08-34-.02 increases annual renewal fees for Home Care Organizations Providing Professional Support Services.

The amendment to 1200-08-35-.02 increases annual renewal fees for Outpatient Diagnostic Centers.

The amendment to 1200-08-36-.03 increases annual renewal fees for Adult Care Homes - Level 2.

The amendment to 1200-08-37-.01 changes the definition of "Traumatic brain injury residential home" to the statutory definition.

The amendment to 1200-08-37-.02 deletes obsolete language regarding an eight (8) bed limit for TBI homes.

The amendment to 1200-08-37 -.03 adds a new "per bed" fee structure for Traumatic Brain Injury Residential Homes.

The amendment to 1200-08-37-.07 deletes obsolete language regarding an eight (8) bed limit for TBI homes in two places.

Public Hearing Comments

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

Ms. Martha M. Gentry, attorney at law, appeared on behalf of Tennessee Argentum, to thank the Board for the opportunity to submit comments, both written and oral, regarding the proposed rules governing licensing fees for assisted care living facilities in Tennessee. Argentum is the largest national association comprised of professional managed senior care living communities providing assisted care living, independent living, memory care, CCRCs, hospice and home care services. In Tennessee, Argentum represents senior living communities who serve a population that is predominantly female, widowed, with an average age of 87 years old, and who need assistance with two or more activities of daily living. The fees in the amendment to the rules before you today propose an increase of nearly thirty-two (32%) percent. This is a significant fee increase to this industry and to Argentum members. As you vote today, please consider this recommendation. Argentum members agree that more surveyors are needed to support this growing industry. Residents, families, providers and regulators all support efforts to keep bad actors from operating. To that end, we agree it is vital for surveys, both licensing and complaint driven, to be performed in a thorough and timely manner. However, Argentum members believe it is equally import to have surveyors specifically dedicated to assisted living licensing who are trained and experienced in the needs and demands of the assisted living facility industry. Assisted living is regulated under a different set of rules than skilled nursing care and operates under a different philosophy. Because of these differences, it is critical to have surveyor staff who are trained in assisted living laws and regulations. Our request is that if this large increase in licensing fees is adopted, it should be used to hire and train a dedicated assisted living survey team. This would ensure that assisted living providers are surveyed in the most meaningful way and that assisted living resident rights and services are protected.

The Board did not have any response for Ms. Gentry's comments.

Vincent Davis, Director of Health Care Facilities, stated that all of the surveyors that have been hired and will be hired for surveys in assisted care living facilities going forward are and will be appropriately trained for surveys in assisted care living facilities.

Regulatory Flexibility Addendum

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

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

These rule amendments 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.

These rule amendments establish clarity, conciseness, and lack of ambiguity.

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

These rule amendments do not create flexible compliance or reporting requirements.

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

These rule amendments do not create any new compliance or reporting requirements. All fees are due on the same schedule as listed in the existing rule.

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

These rule amendments increase the fees necessary to acquire and maintain licensure. So, the rules do not consolidate or simplify any compliance or reporting requirements.

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

These rule amendments do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

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

These rule amendments do not create unnecessary barriers or other effects that stifle entrepreneurial activity or curb innovation.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board for Licensing Health Care Facilities

Rulemaking hearing date: 10/03/2018

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:**

   These rules would directly affect prescribed child care centers, residential hospices, birthing centers, assisted-care living facilities, home care organizations providing hospice services, HIV supportive living centers, home care organizations providing home medical equipment, end stage renal dialysis clinics, home care organizations providing professional support services, outpatient diagnostic centers, adult care homes – level 2, and traumatic brain injury residential homes.

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:**

   These rules will increase administrative costs for the above-listed facilities as the application and renewal fees are being increased.

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

   The above-listed facilities will have to pay an increased application and renewal fee.

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

   There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule.

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

   Federal: None.

   State: None.

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.**

   These rules do not provide for exemptions regarding small businesses.

Impact on Local Governments

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

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

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The amendment to 1200-08-02-.02 increases annual renewal fees for Prescribed Child Care Centers.

The amendment to 1200-08-15-.02 increases annual renewal fees for Residential Hospices, per bed.

The amendment to 1200-08-24-.02 increases annual renewal fees for Birthing Centers.

The amendment to 1200-08-25-.04 increases annual renewal fees for ACLFs, per bed.

The amendment to 1200-08-27-.02 increases annual renewal fees for Home Care Organizations Providing Hospice Services.

The amendment to 1200-08-28-.02 increases annual renewal fees for HIV Supportive Living Centers, per bed.

The amendment to 1200-08-29-.02 increases annual renewal fees for Home Care Organizations Providing Home Medical Equipment.

The amendment to 1200-08-32-.02 increases annual renewal fees for End Stage Renal Dialysis Clinics.

The amendment to 1200-08-34-.02 increases annual renewal fees for Home Care Organizations Providing Professional Support Services.

The amendment to 1200-08-35-.02 increases annual renewal fees for Outpatient Diagnostic Centers.

The amendment to 1200-08-36-.03 increases annual renewal fees for Adult Care Homes – Level 2.

The amendment to 1200-08-37-.01 changes the definition of "Traumatic brain injury residential home" to the statutory definition.

The amendment to 1200-08-37-.02 deletes obsolete language regarding an eight (8) bed limit for TBI homes.

The amendment to 1200-08-37 -.03 adds a new "per bed" fee structure for Traumatic Brain Injury Residential Homes.

The amendment to 1200-08-37-.07 deletes obsolete language regarding an eight (8) bed limit for TBI homes in two places.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Tenn. Code Ann. § 68-11-216.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

These rules would directly affect prescribed child care centers, residential hospices, birthing centers, assisted-care living facilities, home care organizations providing hospice services, HIV supportive living centers, home care organizations providing home medical equipment, end stage renal dialysis clinics, home care organizations providing professional support services, outpatient diagnostic centers, adult care homes – level 2, and traumatic brain injury residential homes. Many facilities and associations connected with these facilities support these proposed fee increases.

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

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

These rules should not affect state or local government revenues or expenditures.

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

Caroline Tippens, Assistant General Counsel, Department of Health.

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

Caroline Tippens, Assistant General Counsel, Department of Health.

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37243, (615) 741-1611, Caroline.Tippens@tn.gov.

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

None.

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Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-15-19
Rule ID(s): 8868-8879
File Date: 3/26/19
Effective Date: 6/24/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Board for Licensing Health Care Facilities
Division:	
Contact Person:	Caroline Tippens, Assistant General Counsel
Address:	665 Mainstream Drive, Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-1611
Email:	Caroline.Tippens@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1200-08-02	Standards for Prescribed Child Care Centers
Rule Number	**Rule Title**
1200-08-02-.02	Licensing Procedures

Chapter Number	**Chapter Title**
1200-08-15	Standards for Residential Hospices
Rule Number	**Rule Title**
1200-08-15-.02	Licensing Procedures

Chapter Number	**Chapter Title**
1200-08-24	Standards for Birthing Centers
Rule Number	**Rule Title**
1200-08-24-.02	Licensing Procedures

Chapter Number	**Chapter Title**
1200-08-25	Standards for Assisted-Care Living Facilities
Rule Number	**Rule Title**
1200-08-25-.04	Fees

Chapter Number	Chapter Title
1200-08-27	Standards for Home Care Organizations Providing Hospice Services
Rule Number	**Rule Title**
1200-08-27-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-28	Standards for HIV Supportive Living Centers
Rule Number	**Rule Title**
1200-08-28-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-29	Standards for Home Care Organizations Providing Home Medical Equipment
Rule Number	**Rule Title**
1200-08-29-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-32	Standards for End Stage Renal Dialysis Clinics
Rule Number	**Rule Title**
1200-08-32-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-34	Standards For Home Care Organizations Providing Professional Support Services
Rule Number	**Rule Title**
1200-08-34-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-35	Standards For Outpatient Diagnostic Centers
Rule Number	**Rule Title**
1200-08-35-.02	Licensing Procedures

Chapter Number	Chapter Title
1200-08-36	Standards for Adult Care Homes - Level 2
Rule Number	**Rule Title**
1200-08-36-.03	Fees

Chapter Number	Chapter Title
1200-08-37	Traumatic Brain Injury Residential Homes
Rule Number	**Rule Title**
1200-08-37-.01	Definitions
1200-08-37-.02	Licensure and Renewal
1200-08-37-.03	Fees
1200-08-37-.07	Admissions, Discharges, and Transfers

(Rule 1200-08-02-.01, continued)
effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.

1200-08-02-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any Prescribed Child Care Center (PCCC) without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the PCCC.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Each applicant for a license, with the exception of the U.S. Government, the State of Tennessee or local government, shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Each applicant for a license, with the exception of the U.S. Government, the State of Tennessee or local government, shall pay an annual license fee in the amount of one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. No child shall be admitted to the PCCC until a license has been issued. Applicants shall not hold themselves out to the public as being a PCCC until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by T.C.A. §68-11-206(a)(1), or as later amended, and of all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the facility.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the prescribed child care center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a PCCC has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership

(Rule 1200-08-02-.02, continued)

occurs whenever this ultimate legal authority for the responsibility of the PCCC operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the PCCC is owned and operated.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Removal of the general partners or general partner, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are cancelled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfer between levels of government.

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(Rule 1200-08-02-.02, continued)

(a) In order to renew a license, each prescribed child care center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure; and

2. the license fee provided in rule 1200-08-02-.02 (2)(b).

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

(5) All PCCCs may maintain certification as a Community Health Clinic (see Chapter 1200-13-02, Tennessee Department of Health) and as a Comprehensive Outpatient Rehabilitation Facility (see 42 U.S.C. 1395x(cc) of the Social Security Act and Subpart B of 42 Code of Federal Regulations [CFR] Part 485).

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. § 68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule certified June 7, 1974. Amendment filed July 3, 1984; effective August 1, 1984. Repeal and new rule filed May, 22, 1986; effective July 21, 1986. Amendment filed October 22, 1987; effective December 6, 1987. Amendment filed April 1, 1992; effective May 16, 1992. Amendment filed November 3, 1992; effective December 18, 1992. Amendment filed March 7, 1994; effective May 21, 1994. Amendment filed December 30, 1994; effective March 18, 1995. Amendment filed June 13, 1997; effective August 27, 1997. Repeal filed March 18, 2000; effective May 30, 2000. New rule filed June 13, 2002; effective August 27, 2002. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendments filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-02-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statues;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the PCCC;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the children in the PCCC; and

(Rule 1200-08-15-.01, continued)

(78) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(79) Student. A person currently enrolled in a course of study that is approved by the appropriate licensing board or equivalent body.

(80) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(81) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these regulations.

(82) Surrogate. An individual, other than a patient's or resident's agent or guardian, authorized to make a health care decision for the patient or resident.

(83) Terminally ill. An individual with a medical prognosis that his or her life expectancy is six (6) months or less if the illness runs its normal course.

(84) Transfer. The movement of a patient or resident at the direction of a physician or other qualified medical personnel when a physician is not readily available, but does not include such movement of a patient or resident who leaves the facility against medical advice.

(85) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient or resident.

(86) Volunteer. An individual who agrees to provide services to a hospice care patient or HIV resident and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed November 22, 2005; effective February 5, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.*

1200-08-15-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any residential hospice without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic areas specified by the certificate of need or at the time of the original licensing. The name of the residential hospice shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the residential hospice.

(2) In order to make application for a license:

(Rule 1200-08-15-.02, continued)

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:~~

~~1.~~	~~Less than 25 beds~~	~~$ 800.00~~
~~2.~~	~~25 to 49 beds, inclusive~~	~~$1,025.00~~
~~3.~~	~~50 to 74 beds, inclusive~~	~~$1,225.00~~
~~4.~~	~~75 to 99 beds, inclusive~~	~~$1,425.00~~
~~5.~~	~~100 to 124 beds, inclusive~~	~~$ 1,625.00~~
~~6.~~	~~125 to 149 beds, inclusive~~	~~$ 1,825.00~~
~~7.~~	~~150 to 174 beds, inclusive~~	~~$ 2,025.00~~
~~8.~~	~~175 to 199 beds, inclusive~~	~~$ 2,225.00~~

~~For residential hospice of two hundred (200) beds or more the fee shall be two thousand four hundred twenty-five dollars ($2,425.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

1.	Less than 25 beds	$1,040.00
2.	25 to 49 beds, inclusive	$1,333.00
3.	50 to 74 beds, inclusive	$1,593.00
4.	75 to 99 beds, inclusive	$1,853.00
5.	100 to 124 beds, inclusive	$2,133.00
6.	125 to 149 beds, inclusive	$2,373.00
7.	150 to 174 beds, inclusive	$2,633.00
8.	175 to 199 beds, inclusive	$2,893.00

For a residential hospice of two hundred (200) beds or more the fee shall be two thousand eight hundred and ninety-three dollars ($2,893.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients or residents shall not be admitted to the residential hospice until a license has been

(Rule 1200-08-15-.02, continued)

issued. Applicants shall not hold themselves out to the public as being a residential hospice until the license has been issued. A license shall not be issued until the residential hospice is in substantial compliance with these rules and regulations, including submission of all information required by T.C.A. § 68-11-206(l) or as later amended, and all information required by the commissioner.

(d) The applicant must prove the ability to meet the financial needs of the residential hospice.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the residential hospice to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a residential hospice has the ultimate responsibility for the operation of the residential hospice, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the residential hospice's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the residential hospice is owned and operated.

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

1. Transfer of the residential hospice's legal title;

2. Lease of the residential hospice's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the residential hospice;

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

5. Removal of the general partner or general partners, if the residential hospice is owned by a limited partnership;

6. Merger of a residential hospice owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate residential hospice owner with one or more corporations; or,

8. Transfers between levels of government.

(Rule 1200-08-15-.02, continued)

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the residential hospice. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the residential hospice's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each residential hospice shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. A completed application for licensure;

2. The license fee provided in rule 1200-08-15-.02(2)(b); and

3. Any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), § 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-*

(Rule 1200-08-15-.02, continued)
206(a)(5) [effective January 1, 2009]. ***Administrative History:*** *Original rule filed August 18, 1995; effective November 1, 1995. Repeal and new rule filed April 27, 2000; effective July 11, 2000. Amendment filed November 19, 2003; effective February 2, 2004 Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-15-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the residential hospice;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients or residents of the residential hospice; or

(e) Failure to renew the license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the residential hospice;

(c) The conduct of the residential hospice in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(d) Any prior violations by the residential hospice of statutes, regulations or orders of the board.

(3) When a facility is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(4) Either the failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the facility's license to possible disciplinary action.

(Rule 1200-08-24-.01, continued)

(50) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(51) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(52) Transfer. The movement of a patient to a hospital at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(53) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(54) Voluntary Delivery. The action of a mother in leaving an unharmed infant aged seventy-two (72) hours or younger on the premises of a birthing center with any birthing center employee or member of the professional medical community without expressing any intention to return for such infant, and failing to visit or seek contact with such infant for a period of thirty (30) days thereafter.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-255, and 68-11-1802.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed September 17, 2002; effective December 1, 2002. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed January 3, 2006; effective March 19, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-24-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any birthing center without having a license. A license shall be issued only to the applicant named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the birthing center.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the birthing center until a license has been issued. Applicants shall not hold themselves out to the public as being a birthing center until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.

(Rule 1200-08-24-.02, continued)

(d) The applicant must prove the ability to meet the financial needs of the facility.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the birthing center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a birthing center has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the facilities operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the birthing center is owned and operated.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Removal of the general partner or general partners, if the facility is owned by a limited partnership;

6. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate facility owner with one or more corporations; or,

8. Transfers between levels of government.

(d) 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;

(Rule 1200-08-24-.02, continued)

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

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However. if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each birthing center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-24-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-206(a)(5), 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, §1.* ***Administrative History:*** *Original rule filed March 31, 1998; effective June 12, 1998. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-24-.03 DISCIPLINARY PROCEDURES.

1200-08-25-.04 FEES.

~~(1) Each ACLF, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee based on the number of ACLF beds, as follows:~~

~~(a) Less than 25 beds $ 800.00~~

~~(b) 25 to 49 beds, inclusive $ 1,000.00~~

~~(c) 50 to 74 beds, inclusive $ 1,200.00~~

~~(d) 75 to 99 beds, inclusive $ 1,400.00~~

~~(e) 100 to 124 beds, inclusive $ 1,600.00~~

~~(f) 125 to 149 beds, inclusive $ 1,800.00~~

~~(g) 150 to 174 beds, inclusive $ 2,000.00~~

~~(h) 175 to 199 beds, inclusive $ 2,200.00~~

~~For ACLFs of two hundred (200) beds or more, the fee shall be two thousand four hundred dollars ($2,400.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.~~

(1) Each ACLF, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee based on the number of ACLF beds, as follows:

(a) Less than 25 beds $1,040.00

(b) 25 to 49 beds, inclusive $1,300.00

(c) 50 to 74 beds, inclusive $1,560.00

(d) 75 to 99 beds, inclusive $1,820.00

(e) 100 to 124 beds, inclusive $2,080.00

(f) 125 to 149 beds, inclusive $2,340.00

(g) 150 to 174 beds, inclusive $2,600.00

(h) 175 to 199 beds, inclusive $2,860.00

For ACLFs of two hundred (200) beds or more, the fee shall be two thousand eight hundred and sixty dollars ($2,860.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

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(Rule 1200-08-25-.04, continued)

(2) Each ACLF administrator shall submit to the Board's administrative office an application fee of one hundred eighty dollars ($180.00). The fee shall be submitted with the initial application or renewal application and is not refundable.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-216, 68-3-511, 68-11-257, and 71-6-121.* ***Administrative History:*** *Original rule filed February 9, 1998; effective April 25, 1998. Amendment filed November 25, 1998; effective February 8, 1999. Amendment filed September 21, 2001; effective December 5, 2001. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rule filed May 13, 2009; through October 25, 2009. Emergency rule filed October 22, 2009; effective through April 20, 2010. Amendment filed September 24, 2009; effective December 23, 2009.*

1200-08-25-.05 REGULATORY STANDARDS.

(1) A Department of Health representative shall make an unannounced inspection of every ACLF holding a license granted by the Board for its compliance with applicable state law and regulations within fifteen (15) months following the date of its last inspection, and as necessary, to protect the public's health, safety and welfare. An ACLF must cooperate during Department of Health conducted inspections, including allowing entry at any hour and providing all required records.

(2) Plan of Correction. When Department of Health inspectors find that an ACLF has committed a violation of this chapter, the Department of Health, as the Board's representative, will issue a statement of deficiencies to the ACLF. Within ten (10) days of receipt of the statement of deficiencies, the ACLF must return a plan of correction including the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(3) Either failure to submit a plan of correction in a timely manner or a finding by the Department of Health that the plan of correction is unacceptable may subject the ACLF's license to disciplinary action.

(4) Upon a finding by the Board that an ACLF has violated any provision of the Health Facilities and Resources Act, Part 2—Regulation of Health and Related Facilities (T.C.A. §§ 68-11-201, *et seq.*) or the rules promulgated pursuant thereto, action may be taken, upon proper notice to the licensee, to impose a civil penalty, deny, suspend, or revoke its license.

(5) Civil Penalties. The Board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the Board in accordance with the following schedule:

Violation	Penalty
T.C.A. § 68-11-201(4)(B) (Provision of Room and Board and Non-Medical Living Assistance Services)	$0-$1000

1200-08-27-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing hospice services without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure and for the geographic area specified by the certificate of need or at the time of the original licensing. The name of the home care organization providing hospice services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organizations providing hospice services.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

~~(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

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(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. §68-11-206(1) or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the home care agency providing hospice services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(Rule 1200-08-27-.02, continued)

(b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.

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

1. Transfer of the agency's legal title;

2. Lease of the agency's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;

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

5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;

6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate agency owner with one or more corporations; or

8. Transfers between levels of government.

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(Rule 1200-08-27-.02, continued)

(a) In order to renew a license, each home care agency providing hospice services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-27-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed April 17, 2000; effective July 1, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 12, 2013; effective March 16, 2014.*

1200-08-27-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the agency;

(d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or

(e) Failure to renew the license.

(2) The Board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(Rule 1200-08-28-.01, continued)

(82) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the resident.

(83) Volunteer. An individual who agrees to provide services to a resident, staff, significant other and/or family member(s), without monetary compensation, with appropriate supervision by the facility.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.*

1200-08-28-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any HIV supportive living center without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure at the time of the original licensing. The name of the HIV supportive living center shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the HIV supportive living center.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:~~

~~1. Less than 25 beds $ 800.00~~

~~2. 25 to 49 beds, inclusive $ 1,000.00~~

~~3. 50 to 74 beds, inclusive $1,200.00~~

~~4. 75 to 99 beds, inclusive $1,400.00~~

~~5. 100 to 124 beds, inclusive $ 1,600.00~~

~~6. 125 to 149 beds, inclusive $ 1,800.00~~

~~7. 150 to 174 beds, inclusive $ 2,000.00~~

~~8. 175 to 199 beds, inclusive $ 2,200.00~~

~~For HIV supportive living facilities of two hundred (200) beds or more the fee shall be two thousand four hundred dollars ($2,400.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee based on the number of beds as

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(Rule 1200-08-28-.01, continued)

follows:

1.	Less than 25 beds	$1,040.00
2.	25 to 49 beds, inclusive	$1,300.00
3.	50 to 74 beds, inclusive	$1,560.00
4.	75 to 99 beds, inclusive	$1,820.00
5.	100 to 124 beds, inclusive	$2,080.00
6.	125 to 149 beds, inclusive	$2,340.00
7.	150 to 174 beds, inclusive	$2,600.00
8.	175 to 199 beds, inclusive	$2,860.00

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For HIV supportive living facilities of two hundred (200) beds or more the fee shall be two thousand eight hundred and sixty dollars ($2,860.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Residents shall not be admitted to the HIV supportive living facility until a license has been issued. Applicants shall not hold themselves out to the public as being a HIV supportive living facility until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. § 68-11-206(1) or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the HIV supportive living facility.

(e) The applicant shall answer each question provided in the application fully and truthfully, shall not supply false or misleading information and shall not use any deceptive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and Review process.

(f) The applicant shall allow the HIV supportive living facility to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of a HIV supportive living facility has the ultimate responsibility for the operation of the HIV supportive living facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the HIV supportive living facility's operation is transferred.

(Rule 1200-08-28-.02, continued)

(b) A change of ownership occurs whenever there is a change in the legal structure by which the HIV supportive living facility is owned and operated.

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

1. Transfer of the HIV supportive living facility's legal title;

2. Lease of the HIV supportive living facility's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the HIV supportive living facility;

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

5. Removal of the general partner or general partners, if the HIV supportive living facility is owned by a limited partnership;

6. Merger of a HIV supportive living facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate HIV supportive living facility owner with one or more corporations; or,

8. Transfers between levels of government.

(d) 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 for board of trustees;

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

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the HIV supportive living facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the HIV supportive living facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(Rule 1200-08-28-.02, continued)

(a) In order to renew a license, each HIV supportive living facility shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure; and

2. the license fee provided in rule 1200-08-28-.02(2)(b).

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-206(a)(5), 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, §1.* ***Administrative History:*** *Original rule filed July 27, 2000; effective October 10, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-28-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the HIV supportive living facility;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the residents of the HIV supportive living facility; or

(e) Failure to renew the license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the residents in the HIV supportive living facility;

(Rule 1200-08-29-.01, continued)

(43) Wheeled Mobility Device. A wheelchair or wheelchair and seated positioning system prescribed by a physician and required for use by the patient for a period of six (6) months or more. The following Medicare wheelchairs base codes are exempt: K0001, K0002, K0003, K0004, K0006, and K0007 as long as the consumer weighs less than three hundred (300) pounds.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, 68-11-226, 68-11-268, and 68-11-303.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed June 25, 2007; effective September 8, 2007. Amendment filed October 11, 2007; effective December 25, 2007. Amendments filed December 23, 2009; effective March 23, 2010. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-29-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and for the premises listed in the application for licensure. The name of the home care organization providing home medical equipment shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing home medical equipment.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

~~(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

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(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid an inspection and review process.

(Rule 1200-08-29-.02, continued)

(f) The applicant shall allow the home care organization providing home medical equipment to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purpose of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.

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

1. Transfer of the agency's legal title;

2. Lease of the agency's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;

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

5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;

6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate agency owner with one or more corporations; or

8. Transfers between levels of government.

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or

(Rule 1200-08-29-.02, continued)

5. Corporate stock transfer or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each home care organization providing home medical equipment shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-29-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed November 19, 2003; effective February 2, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed February 22, 2010; effective May 23, 2010. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-29-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(Rule 1200-08-32-.01, continued)

(64) Shall or Must. Compliance is mandatory.

(65) Social Worker. A person who is licensed by the Tennessee Board of Social Worker Certification and Licensure, if applicable, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program and has established a consultative relationship with a social worker who qualifies in paragraph (1) of this definition.

(66) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(67) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(68) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(69) Survey. An on-site examination by the Department to determine compliance with state and federal regulations.

(70) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(71) Treating Physician. The physician selected by or assigned to the patient and who has the primary responsibility for the treatment and care of the patient. Where more than one physician shares such responsibility, any such physician may be deemed to be the "treating physician."

(72) Water Treatment. The process of treating water used for dialysis purposes in order to maintain a continuous water supply that meets AAMI (Association for the Advancement of Medical Instrumentation) standards.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment filed April 28, 2003; effective July 12, 2003. Amendments filed December 15, 2005; effective February 28, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed December 9, 2010 to have been effective March 9, 2011 was stayed for 28 days by the Government Operations Committee; new effective date March 29, 2011. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-32-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any renal dialysis clinic without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Satellite facilities shall be prohibited. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the renal dialysis clinic.

(2) In order to make application for a license:

(Rule 1200-08-32-.02, continued)

(a) The applicant shall submit an application on a form provided by the department.

~~(b) Each initial and renewal application for licensure shall be submitted with the fee of one thousand eighty dollars ($1,080.00). All fees submitted are nonrefundable. Any applicant who files an application during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought.~~

(b) Each initial and renewal application for licensure shall be submitted with the fee of one thousand four hundred and four dollars ($1,404.00). All fees submitted are nonrefundable. Any applicant who files an application during the fiscal year must pay the full license fee. A fee must be submitted for each facility at each site for which licensure is being sought.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be accepted for treatment to the renal dialysis clinic until a license has been issued. Applicants shall not hold themselves out to the public as being a renal dialysis clinic until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules, including submission of all information required by T.C.A. § 68-11-206(a)(1) or as later amended, and all information required by the Commissioner.

(d) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(e) The applicant shall allow the end stage renal dialysis clinic to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purpose of licensing, the licensee of a renal dialysis clinic has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the renal dialysis clinic's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

(Rule 1200-08-32-.02, continued)

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

5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate facility owner with one or more corporations; or,

7. Transfers between levels of government.

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each end stage renal dialysis clinic shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure; and

(Rule 1200-08-32-.02, continued)

2. the license fee provided in rule 1200-08-32-.02(2)(b).

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), T.C.A. §68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. §68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed April 22, 2003; effective July 6, 2003. Amendment file January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-32-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal statutes or rules and regulations;

(b) Violation of state statutes or the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the renal dialysis clinic;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the renal dialysis clinic; and

(e) Failure to renew the license.

(2) The board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the facility of statutes, rules or orders of the commissioner or the board.

(3) When a renal dialysis clinic is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies, the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(Rule 1200-08-34-.01, continued)

(49) Professional Support Services. Nursing, occupational, physical or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services.

(50) Qualified Emergency Medical Service Personnel. Includes, but shall not be limited to, emergency medical technicians, paramedics, or other emergency services personnel, providers, or entities acting within the usual course of their professions, and other emergency responders.

(51) Reasonably Available. Readily able to be contacted without undue effort and willing and able to act in a timely manner considering the urgency of the consumer's health care needs. Such availability shall include, but not be limited to, availability by telephone.

(52) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(53) Shall or Must. Compliance is mandatory.

(54) Site Code. An approved location from which the professional support services may be provided as deemed by the Department of Mental Retardation Services with written notice provided to the Department of Health by the professional support service agency for each site code approved for such agency.

(55) Speech Language Pathologist. As defined in T.C.A. § 63-17-103, a person currently licensed as such by the Tennessee Board of Communications Disorders and Sciences.

(56) State. A state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(57) Supervising Health Care Provider. The designated physician or, if there is no designated physician or the designated physician is not reasonably available, the health care provider who has undertaken primary responsibility for an individual's health care.

(58) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(59) Surrogate. An individual, other than a consumer's agent or guardian, authorized to make a health care decision for the consumer.

(60) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the consumer.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 39-11-106, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, 68-11-213, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendments filed December 2, 2005; effective February 15, 2006. Amendment filed February 7, 2007; effective April 23, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015. Amendment filed September 15, 2015; effective December 14, 2015.*

1200-08-34-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any home care organization providing professional

(Rule 1200-08-34-.02, continued)

support services without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. The name of the home care organization providing professional support services shall not be changed without first notifying the department in writing. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the home care organization providing professional support services.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Home care organizations authorized to provide only professional support services shall pay an annual fee of one thousand eighty dollars ($1,080.00), except that this annual fee shall be two hundred seventy dollars ($270.00) for (i) home care organizations that also pay a fee to be licensed by the Department of Mental Health and Developmental Disabilities; (ii) home care organizations owned and operated by therapists who pay a fee to be licensed under Title 63, Chapter 13 or 17; or (iii) home care organizations that are owned and controlled by another home care organization that pay an annual license fee of at least one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Home care organizations authorized to provide only professional support services shall pay an annual fee of one thousand four hundred and four dollars ($1,404.00), except that this annual fee shall be three hundred and fifty-one dollars ($351.00) for (i) home care organizations that also pay a fee to be licensed by the Department of Intellectual and Developmental Disabilities; (ii) home care organizations owned and operated by therapists who pay a fee to be licensed under Title 63, Chapter 13 or 17; or (iii) home care organizations that are owned and controlled by another home care organization that pays an annual license fee of at least one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Consumers shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules, including submission of all information required by T.C.A. § 68-11-206(1) or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the agency providing professional support services.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the home care organization providing professional support services to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(Rule 1200-08-34-.02, continued)

(3) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate facility owner with one or more corporations; or,

7. Transfers between levels of government.

(d) 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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(Rule 1200-08-34-.02, continued)

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(4) Renewal.

(a) In order to renew a license, each home care organization providing professional support services shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. A completed application for licensure;

2. The license fee provided in rule 1200-08-34-.02(2)(b); and

3. Any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, § 68-11-209(a)(1), § 68-11-210, 68-11-216, Chapter 846 of the Public Acts of 2008, §1, T.C.A. § 68-11-206(a)(5) [effective January 1, 2009].* ***Administrative History:*** *Original rule filed January 24, 2003; effective April 9, 2003. Amendment filed May 27, 2004; effective August 10, 2004. Amendment filed January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-34-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the agency or the consumer's home; or

(d) Conduct or practice found by the Board to be detrimental to the health, safety, or welfare of the consumers of the agency.

(Rule 1200-08-35-.01, continued)

(71) Surrogate. An individual, other than a patient's agent or guardian, authorized to make a health care decision for the patient.

(72) Transfer. The movement of a patient at the direction of a physician or other qualified medical personnel when a physician is not readily available but does not include such movement of a patient who leaves the facility against medical advice.

(73) Treating Health Care Provider. A health care provider who at the time is directly or indirectly involved in providing health care to the patient.

(74) Vascular Embolization. Therapeutic introduction of various substances into the circulation to occlude vessels, either to arrest or prevent hemorrhaging, to devitalize a structure, tumor or organ by occluding its blood supply or to reduce blood flow to an arteriovenous malformation.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-211, 68-11-216, 68-11-224, and 68-11-1802.* ***Administrative History:*** *Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed February 23, 2007; effective May 9, 2007. Amendment filed January 3, 2012; effective April 2, 2012. Amendment filed March 27, 2015; effective June 25, 2015.*

1200-08-35-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any outpatient diagnostic center as defined, without having a license. A license shall be issued only to the person or persons named and only for the premises listed in the application for licensure. Licenses are not transferable or assignable and shall expire and become invalid annually on the anniversary date of their original issuance. The license shall be conspicuously posted in the outpatient diagnostic center.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the department.

~~(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand eighty dollars ($1,080.00). The fee must be submitted with the application and is not refundable.~~

(b) Each applicant for a license shall pay an annual license fee in the amount of one thousand four hundred and four dollars ($1,404.00). The fee must be submitted with the initial application or renewal application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the department. Patients shall not be admitted to the Outpatient Diagnostic Center until a license has been issued. Applicants shall not hold themselves out to the public as being an Outpatient Diagnostic Center until the license has been issued. A license shall not be issued until the facility is in substantial compliance with these rules and regulations including submission of all information required by Tennessee Code Annotated § 68-11-206(l), or as later amended, and all information required by the Commissioner.

(d) The applicant must prove the ability to meet the financial needs of the facility.

(Rule 1200-08-35-.02, continued)

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid inspection and review process.

(f) The applicant shall allow the outpatient diagnostic center to be inspected by a Department surveyor. In the event that deficiencies are noted, the applicant shall submit a plan of corrective action to the Board that must be accepted by the Board. Once the deficiencies have been corrected, then the Board shall consider the application for licensure.

(3) Each Outpatient Diagnostic Center, when issued a license, shall be classified according to the type of services rendered or category of patients served. The Outpatient Diagnostic Center shall confine its services to those described in its license and shall advertise only the services which it is licensed to perform. The classification shall be listed on the license.

(4) A proposed change of ownership must be reported to the department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the department before the license may be issued.

(a) For the purposes of licensing, the licensee of an Outpatient Diagnostic Center has the ultimate responsibility for the operation of the facility, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of Outpatient Diagnostic Center operations is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the facility is owned and operated and any ownership interest of the preceding or succeeding entity changes.

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

1. Transfer of the facility's legal title;

2. Lease of the facility's operation;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the facility;

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

5. Merger of a facility owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

6. The consolidation of a corporate facility owner with one or more corporations; or,

7. Transfers between levels of government.

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

(Rule 1200-08-35-.02, continued)

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;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government; or,

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

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the facility. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the facility's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the same legal form as the former owner.

(5) Renewal.

(a) In order to renew a license, each outpatient diagnostic center shall submit to periodic inspections by Department surveyors for compliance with these rules. If deficiencies are noted, the licensee shall submit an acceptable plan of corrective action and shall remedy the deficiencies. In addition, each licensee shall submit a renewal form approved by the board and applicable renewal fee prior to the expiration date of the license.

(b) If a licensee fails to renew its license prior to the date of its expiration but submits the renewal form and fee within sixty (60) days thereafter, the licensee may renew late by paying, in addition to the renewal fee, a late penalty of one hundred dollars ($100) per month for each month or fraction of a month that renewal is late; provided that the late penalty shall not exceed twice the renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, then the licensee shall reapply for a license by submitting the following to the Board office:

1. a completed application for licensure;

2. the license fee provided in rule 1200-08-35-.02(2)(b); and

3. any other information required by the Health Services and Development Agency.

(d) Upon reapplication, the licensee shall submit to an inspection of the facility by Department of Health surveyors.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-206(a)(5), 68-11-206, 68-11-209, 68-11-209(a)(1), 68-11-210, 68-11-216, and Chapter 846 of the Public Acts of 2008, §1.* ***Administrative History****: Original rule filed October 26, 2005; effective January 9, 2006. Amendment filed*

(Rule 1200-08-35-.02, continued)
January 19, 2007; effective April 4, 2007. Amendment filed July 18, 2007; effective October 1, 2007. Public necessity rules filed April 29, 2009; effective through October 11, 2009. Emergency rules filed October 9, 2009; effective through April 7, 2010. Amendment filed September 24, 2009; effective December 23, 2009. Amendment filed December 16, 2013; effective March 16, 2014.

1200-08-35-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of the rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act in the Outpatient Diagnostic Center;

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the patients of the Outpatient Diagnostic Center; and

(e) Failure to renew license.

(2) The board may consider all factors that it deems relevant, including but not limited to the following when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patients in the facility;

(c) The conduct of the facility in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and,

(d) Any prior violations by the facility of statutes, regulations or orders of the board.

(3) When an Outpatient Diagnostic Center is found by the department to have committed a violation of this chapter, the department will issue to the facility a statement of deficiencies. Within ten (10) days of the receipt of the statement of deficiencies the facility must return a plan of correction indicating the following:

(a) How the deficiency will be corrected;

(b) The date upon which each deficiency will be corrected;

(c) What measures or systemic changes will be put in place to ensure that the deficient practice does not recur; and

(d) How the corrective action will be monitored to ensure that the deficient practice does not recur.

(4) Either failure to submit a plan of correction in a timely manner or a finding by the department that the plan of correction is unacceptable shall subject the Outpatient Diagnostic Center's license to possible disciplinary action.

(Rule 1200-08-36-.02, continued)

(c) Training. The ACH provider is responsible for the supervision, training and overall conduct of resident managers, substitute caregivers and adult care home staff as it relates to their job performance and responsibilities. The ACH provider shall:

1. Train all staff to meet the routine and emergency needs of residents;

2. Orient all staff to the home including the location of any fire extinguishers; demonstration of evacuation procedures; location of residents' records; location of telephone numbers for the residents' physicians and other emergency contacts; location of medications and keys for medication cabinets; instructions for caring for each resident and delegation by a registered nurse for nursing tasks if applicable.

3. Train resident managers, substitute caregivers, and staff on the health care tasks that can be administered through self administration.

(15) Continuing Education. All adult care home providers, resident managers and substitute caregivers shall complete annually twelve (12) hours of continuing education related to the following topics:

(a) Care of elderly persons;

(b) Care of persons with disabilities;

(c) Business operations of ACHs; and

(d) State rules and regulations for ACHs.

(16) The licensee shall immediately notify the Board's administrative office in the event of an absence or change of resident manager due to serious illness, incapacity, death or resignation of its named resident manager.

Authority: *T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Emergency rule filed November 2, 2010; effective through May 1, 2011. New rule filed January 28, 2010; effective April 28, 2011. Amendment filed December 16, 2013; effective March 16, 2014.*

1200-08-36-.03 FEES.

~~(1) Each ACH, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee in the amount of $1,080.00.~~

(1) Each ACH, except those operated by the United States of America or the State of Tennessee, making application for licensure or renewing licensure under this chapter shall pay annually to the Board's administrative office, a fee in the amount of $1,404.00.

Authority: T.C.A. §§ 68-11-209 and 68-11-216. **Administrative History:** Emergency rule filed November 2, 2010; effective through May 1, 2011. New rule filed January 28, 2011; effective April 28, 2011.

1200-08-36-.04 REGULATORY STANDARDS.

(1) A Department of Health representative shall make an unannounced inspection of every ACH holding a license granted by the Board for its compliance with applicable state law and regulations within fifteen (15) months following the date of its last inspection, and as

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RULES
OF
DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-08-37
TRAUMATIC BRAIN INJURY RESIDENTIAL HOMES

TABLE OF CONTENTS

1200-08-37-.01	Definitions	1200-08-37-.11	Building Standards
1200-08-37-.02	Licensure and Renewal	1200-08-37-.12	Life Safety
1200-08-37-.03	Fees	1200-08-37-.13	Infectious and Hazardous Waste
1200-08-37-.04	Regulatory Standards	1200-08-37-.14	Reports
1200-08-37-.05	Administration	1200-08-37-.15	Resident Rights
1200-08-37-.06	Services Provided	1200-08-37-.16	Policies and Procedures for Health Care Decision-Making
1200-08-37-.07	Admissions, Discharges, and Transfers		
1200-08-37-.08	Personal and Health Care Needs	1200-08-37-.17	Disaster Preparedness
1200-08-37-.09	Resident Records	1200-08-37-.18	Appendix I
1200-08-37-.10	Facility Standards		

1200-08-37-.01 DEFINITIONS.

(1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation or punishment with resulting physical harm, pain or mental anguish.

(2) "Activities of Daily Living (ADL's)" means those activities which indicate a resident's independence in eating, dressing, personal hygiene, bathing, toileting, ambulating, and medication management.

(3) "Adequate evacuation" means the ability of the TBI residential home provider or the Administrator, including such additional minimum staff as may be required by the Board in regulation, to evacuate all residents from the dwelling within five (5) minutes.

(4) "Administering medication" means the direct application of a single dose of a medication to the body of a resident by injection, inhalation, ingestion, topical application or by any other means and the placement of a single dose of medication into a container.

(5) "Adult" means a person 18 years of age or older.

(6) "Adult care home (ACH)" means a single family residence licensed pursuant to this act in which twenty-four (24) hour residential care, including assistance with activities of daily living, is provided in a homelike environment to no more than five (5) elderly or disabled adults.

(7) "Assessment" means a procedure for determining the nature and extent of the problem(s) and needs of a resident or potential resident to ascertain if the TBI residential home can adequately address those problems, meet those needs, and secure information for use in the development of the individual care plan.

(8) "Board" means the Board for Licensing Health Care Facilities.

(9) "Cardiopulmonary resuscitation (CPR)" means the administering of any means or device to restore or support cardiopulmonary functions in a resident, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(Rule 1200-08-37-.01, continued)

(10) "CBIS" means a Certified Brain Injury Specialist who is certified by the Academy of Certified Brain Injury Specialists.

(11) "Disabled" means a resident who suffers from the effects of a traumatic brain injury.

(12) "Do-not-resuscitate resuscitation order (DNR)" means a written order, other than a POST, not to resuscitate a patient in cardiac or respiratory arrest in accordance with accepted medical practices.

(13) "Elderly" means an individual who is fifty-five (55) years of age or older.

(14) "Emergency" means any situation or condition which presents an imminent danger of death or serious physical or mental harm to residents.

(15) "Exploitation" shall have the same meaning as set forth in T.C.A. § 68-11-1002.

(16) "Health care" means any care, treatment, service or procedure to maintain, diagnose, treat, or otherwise affect a resident's physical or mental condition, and includes medical care as defined in T.C.A. § 32-11-103(5).

(17) "Health care decision" means a resident's consent, refusal of consent, or withdrawal of consent to health care.

(18) "Health care decision-maker" means, in the case of a resident who lacks capacity, the resident's health care decision-maker is one of the following: the resident's health care agent as specified in an advance directive; the resident's court-appointed guardian or conservator with health care decision-making authority; the resident's surrogate as determined pursuant to T.C.A. § 68-11-1806; or the resident's designated physician pursuant to T.C.A. § 68-11-1802(a)(4).

(19) "Home like" means an environment that promotes the dignity, security and comfort of residents through the provision of personalized care and services and encourages independence, choice and decision-making by the residents.

(20) "Infectious waste" means solid or liquid waste which contains pathogens with sufficient virulence and quantity such that exposure could result in an infectious disease.

(21) "Licensed health care professional" means any health care professional currently licensed by the State of Tennessee to practice within the scope of a regulated profession, such as a nurse practitioner, registered nurse, licensed practical nurse, (nurses may be licensed or hold multistate licensure pursuant to T.C.A. §§ 63-7-101 et seq.), dietitian, dentist, occupational therapist, pharmacist, physical therapist, physician, physician assistant, psychologist, clinical social worker, respiratory therapist, speech-language pathologist, and emergency medical services personnel.

(22) "Licensee" means the person, association, partnership, corporation, company or public agency to which the license is issued. For the purposes of these rules, the term "licensee" is synonymous to "TBI residential home provider."

(23) "Medical record" means documentation of nursing notes, when applicable; medical histories; treatment records; care needs summaries; physician orders; and records of treatment and medication ordered and given which must be maintained by the TBI residential home, regardless of whether such services are rendered by TBI residential home staff or by arrangement with an outside source.

(Rule 1200-08-37-.01, continued)

(24) "Misappropriation of patient/resident property" means the deliberate misplacement, exploitation or wrongful, temporary or permanent use of an individual's belongings or money without the individual's consent.

(25) "NFPA" means the National Fire Protection Association.

(26) "Neglect" means the failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical care would conflict with the terms of the living will, shall not be deemed "neglect" for purposes of these rules.

(27) "Occupant" means anyone residing in or using a TBI residential home.

(28) "Person" means an individual, association, estate, trust, corporation, partnership, joint venture, government, governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.

(29) "Physician assistant" means a person who has graduated from a physician assistant educational program accredited by the Accreditation Review Commission on Education for the Physician Assistant, has passed the Physician Assistant National Certifying Examination, and is currently licensed in Tennessee as a physician assistant under title 63, chapter 19.

(30) "Physician orders for scope of treatment or POST" means written orders that:

(a) Are on a form approved by the Board for Licensing Health Care Facilities;

(b) Apply regardless of the treatment setting and that are signed as required herein by the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist; and

(c)

1. Specify whether, in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should or should not be attempted;

2. Specify other medical interventions that are to be provided or withheld; or

3. Specify both 1 and 2.

(31) "Power of Attorney for Health Care" means the legal designation of an agent to make health care decisions for the resident who grants such power under T.C.A. § 34-6-201 et seq.

(32) "Resident" means an adult residing at the TBI residential home who suffers from the effects of a traumatic brain injury.

(33) "Residential care" means care rendered to residents who need supervision or assistance in activities of daily living. Residential care does not include nursing or medical care.

(34) "Retaliation" means increasing charges, decreasing services, rights or privileges; taking or threatening to take any action to coerce or compel the resident to leave the home; or abusing or threatening to harass or abuse a resident in any manner.

(Rule 1200-08-37-.01, continued)

(35) "Self-administration of medication" means assistance in reading labels, opening dosage packaging, reminding residents of their medication, and observing the resident while taking medication in accordance with the plan of care.

(36) "Specialized services" means services provided to residents suffering from the effects of a traumatic brain injury.

(37) "Supervising health care provider" means the health care provider who has undertaken primary responsibility for a resident's health care.

(38) "Surrogate" means an individual, other than a resident's agent or guardian, authorized to make a health care decision for the resident pursuant to T.C.A. § 68-11-1806.

(39) "Traumatic brain injury (TBI)" means an acquired injury to the brain caused by an external physical force resulting in total or partial disability or impairment. Traumatic brain injury includes open and closed head injuries and may result in seizures, and/or mild, moderate, or severe impairment in one (1) or more areas including cognition, language, memory, attention, reasoning, abstract thinking, judgment, problem-solving, sensory, perceptual and motor abilities, psychosocial behavior, physical functions, information processing, and speech. Such term does not include brain injuries induced by birth trauma, but may include brain injuries caused by anoxia and other related causes, infectious disease not of a degenerative nature, brain tumor, toxic chemical or drug reaction.

~~(40) "Traumatic brain injury residential home" means a single family residence owned and operated by a community-based traumatic brain injury (TBI) adult care home provider in which residential care, including assistance with activities of daily living, is provided in a homelike environment to no more than eight (8) disabled adults suffering from the effects of a traumatic brain injury as defined in T.C.A. § 68-55-101.~~

(40) "Traumatic brain injury residential home" means a facility owned and operated by a community-based traumatic brain injury (TBI) adult care home provider in which residential care, including assistance with activities of daily living, is provided in a homelike environment to disabled adults suffering from the effects of a traumatic brain injury as defined in § 68-55-101.

(41) "Traumatic brain injury residential home provider" means a person who is twenty-one (21) years of age or older that owns and operates a TBI residential home. A traumatic brain injury residential home provider shall hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brian Injury Specialist (CBIS) or hold a current professional license as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional, or licensed mental health professional who is trained and experienced in the care and rehabilitation of disabled adults suffering from the effects of a traumatic brain injury.

(42) "Treating health care provider" means a health care provider directly or indirectly involved in providing health care to a resident at the time such care is needed by the resident.

Authority: *T.C.A. §§ 68-11-201, 68-11-202, and 68-11-273.* ***Administrative History:*** *Original rule filed October 28, 2015; effective January 26, 2016.*

1200-08-37-.02 LICENSURE AND RENEWAL.

(1) Licensure. An applicant for a TBI residential home license shall submit the following to the Board office:

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

(Rule 1200-08-37-.02, continued)

(b) Nonrefundable application fee;

(c) The requirements contained in T.C.A. § 68-11-206(a)(1) and (2);

(d) Demonstration of the ability to meet the financial obligations of the TBI residential home with a financial statement prepared by a certified public accountant;

(e) A copy of a local business license (if one is required by the locality);

(f) A copy of any and all documents demonstrating the legal status of the business organization that owns the TBI residential home. If the applicant is a corporation or a limited liability company the applicant must submit a certificate of good standing;

(g) Proof of liability insurance; and

(h) Any other documents or information requested by the Board.

(2) Before a license is granted, the 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.

(3) Before a license is granted, the applicant shall submit to an inspection conducted by Department of Health inspectors to ensure compliance with all applicable laws and rules.

(4) If the Board determines that a license for a TBI residential home shall not be granted, it shall notify the applicant. The decision of the board shall be final.

(5) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an applicant has been denied a license or has had a license disciplined or has attempted to avoid the survey and review process.

(6) Renewal. TBI residential home licenses expire annually on the anniversary date of their original issuance and must be renewed by that date.

(a) In order to successfully renew a license, a licensee shall submit a completed renewal application with the applicable fee to the Board office. Department inspectors will periodically inspect each TBI residential home to determine its compliance with these rules and regulations. If the inspectors find deficiencies, the licensee shall submit an acceptable corrective action plan and shall remedy the deficiencies.

(b) Should the licensee fail to renew its license prior to the expiration date, yet within sixty (60) days after the expiration date, the licensee shall pay the licensure renewal fee and a late renewal penalty fee of one hundred dollars ($100.00) per month for each month or fraction of a month that renewal is late; provided that the late renewal penalty fee shall not exceed twice the licensure renewal fee.

(c) In the event that a licensee fails to renew its license within the sixty (60) day grace period following the license expiration date, the licensee shall reapply for a license by submitting the following to the Board office:

1. A completed application for licensure; and

2. The license fee provided in Rule 1200-08-37-.03(1).

(d) Upon reapplication, the licensee shall submit to an inspection of the TBI residential home by Department of Health inspectors.

(Rule 1200-08-37-.02, continued)

(7) The Board shall issue a license only for the licensee and the location designated on the license application. If a TBI residential home moves to a new location, it shall obtain a new license and submit to an inspection of the new building before admitting residents.

(8) A separate license shall be required for each TBI residential home when more than one TBI residential home is operated by a TBI residential home provider.

~~(9) Any admission of residents to a single TBI residential home in excess of eight (8) disabled residents is prohibited.~~

(9)~~(10)~~ Change of Ownership.

(a) A change of ownership occurs whenever the ultimate legal authority for the responsibility of the TBI residential home's operation is transferred, including a change in the legal structure by which the TBI residential home is owned and operated and/or ownership of the preceding or succeeding entity changes.

(b) A licensee shall notify the Board's administrative office of a proposed change of ownership at least thirty (30) days prior to its occurrence by submitting the following to the Board office:

1. A completed change of ownership application on a form approved by the Board which includes all information required by Rule 1200-08-37-.02(1)(a);

2. Nonrefundable application fee;

3. Demonstration of ability to meet the financial obligations of the TBI residential home with a financial statement prepared by a certified public accountant;

4. A copy of a local business license (if one is required by the locality);

5. A copy of any and all documents demonstrating the formation of the business organization that owns the TBI residential home;

6. The bill of sale and/or closing documents indicating the transfer of operations of the business entity;

7. Comprehensive business plan for the first two years of operation;

8. Proof of liability insurance; and

9. Any other documents or information requested by the Board.

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

1. Transfer of the TBI residential home's legal title;

2. Lease of the TBI residential home's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the TBI residential home;

4. The removal, addition or substitution of a partner;

(Rule 1200-08-37-.02, continued)

5. Removal of the general partner or general partners, if the TBI residential home is owned by a limited partnership;

6. Merger of a TBI residential home owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate TBI residential home owner with one or more corporations; or

8. Transfers between levels of government.

(d) 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. Merger of two (2) or more corporations where one of the originally-licensed corporations survives;

3. Changes in the membership of a non-profit corporation;

4. Transfers between departments of the same level of government;

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

6. Sale/lease-back agreements if the lease involves the TBI residential home's entire real and personal property and if the identity of the lessee, who shall continue the operation, retains the same legal form as the former owner; or

7. Management agreements if the owner continues to retain ultimate authority for the operation of the TBI residential home; however, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(10)~~(11)~~ Qualification and Training Requirements.

(a) Qualifications for a TBI residential home provider serving residents suffering from the effects of a traumatic brain injury.

1. A TBI residential home provider serving residents with traumatic brain injury shall hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brain Injury Specialist (CBIS) or hold a current license as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury, or shall employ an Administrator who meets the qualifications specified in Rule 1200-08-37-.02(11)(a)2.

2. An Administrator for a TBI residential home serving residents with traumatic brain injury shall hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brain Injury Specialist (CBIS) or hold a current license as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury.

(Rule 1200-08-37-.02, continued)

3. Staff members providing overnight care and/or supervision of residents in a TBI residential home shall hold national certification by the Academy of Certified Brain Injury Specialists as a Certified Brain Injury Specialist (CBIS) or hold a current license as a physician, nurse practitioner, registered nurse, licensed rehabilitation professional or licensed mental health professional trained and experienced in the care and rehabilitation of residents with traumatic brain injury and shall demonstrate competency in caring for persons with traumatic brain injury.

(b) Training. The TBI residential home provider is responsible for the supervision, training and overall conduct of the Administrator and TBI residential home staff as it relates to their job performance and responsibilities. The TBI residential home provider shall:

1. Train all staff to meet the routine and emergency needs of residents;

2. Orient all staff to the home including the location of any fire extinguishers; demonstration of evacuation procedures; location of residents' records; location of telephone numbers for the residents' physicians and other emergency contacts; location of medications and keys for medication cabinets, if applicable; instructions for caring for each resident; and delegation by a registered nurse for nursing tasks, if applicable.

3. Train the Administrator and TBI residential home staff on the health care tasks that can be administered through self-administration.

(11)~~(12)~~ Continuing Education.

(a) All TBI residential home providers and Administrators shall complete annually twelve (12) hours of continuing education related to the following topics:

1. Care of elderly persons;

2. Care of persons with disabilities;

3. Business operations of TBI residential homes; and

4. State rules and regulations for TBI residential homes.

(b) Continuing education hours offered by and/or approved by the Academy of Certified Brain Injury Specialists regarding care of elderly persons, care of persons with disabilities, and business operations of TBI residential homes will be accepted towards the twelve (12) hour continuing education requirement.

(12)~~(13)~~ The licensee shall immediately notify the Board's administrative office in the event of an absence or change of Administrator due to serious illness, incapacity, death or resignation of its named Administrator.

Authority: T.C.A. §§ 68-11-201, 68-11-202, 68-11-206, 68-11-209, 68-11-210, 68-11-270, and 68-11-273. **Administrative History:** Original rule filed October 28, 2015; effective January 26, 2016.

1200-08-37-.03 FEES.

~~(1) Each TBI residential home, except those operated by the United States of America or the State of Tennessee, making application for licensure under this chapter shall pay annually to the Board's administrative office, a fee in the amount of $1,080.00.~~

(1) Each applicant for a license shall pay an annual license fee based on the number of beds as follows:

(a)	Less than 25 beds	$1,040.00
(b)	25 to 49 beds, inclusive	$1,300.00
(c)	50 to 74 beds, inclusive	$1,560.00
(d)	75 to 99 beds, inclusive	$1,820.00
(e)	100 to 124 beds, inclusive	$2,080.00
(f)	125 to 149 beds, inclusive	$2,340.00
(g)	150 to 174 beds, inclusive	$2,600.00
(h)	175 to 199 beds, inclusive	$2,860.00

For TBI residential homes of two hundred (200) beds or more the fee shall be two thousand eight hundred and sixty dollars ($2,860.00) plus two hundred dollars ($200.00) for each twenty-five (25) beds or fraction thereof in excess of one hundred ninety-nine (199) beds. The fee shall be submitted with the application or renewal and is not refundable.

Authority: T.C.A. §§ 68-11-202, 68-11-216, and 68-11-273. **Administrative History:** Original rule filed October 28, 2015; effective January 26, 2016.

1200-08-37-.04 REGULATORY STANDARDS.

(1) A Department of Health representative shall make an unannounced inspection of every TBI residential home holding a license granted by the Board for its compliance with applicable state law and regulations within fifteen (15) months following the date of its last inspection, and as necessary, to protect the public's health, safety and welfare, with the first unannounced inspection completed prior to the first annual license renewal. A TBI residential home must cooperate during Department of Health conducted inspections, including allowing entry at any hour and providing all required records.

(2) A Department of Health investigator, as the Board's representative, shall be permitted access to enter and inspect any TBI residential home upon the receipt of an oral or written complaint; any time the Board has cause to believe that a TBI residential home is operating without a license; or any time there exists a threat to the health, safety or welfare of any resident.

(3) A Department of Health investigator, as the Board's representative, shall investigate all complaints within timeframes established in applicable statutes or regulations, or as expeditiously as necessary to ensure the health, safety and welfare of TBI residential home residents.

(a) The investigation findings shall be reported to the Board in an anonymous probable cause presentation.

(b) Once the Board determines the appropriate discipline, the TBI residential home provider shall be informed by written correspondence.

(Rule 1200-08-37-.06, continued)

6. A TBI residential home provider may contract with an outside food management company if the company has a dietitian who serves the TBI residential home on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section while providing for constant liaison with the TBI residential home for recommendations on dietetic policies affecting resident treatment.

7. A TBI residential home shall have a current therapeutic diet manual approved by a dietitian readily available to all TBI residential home personnel.

8. Menus shall be planned one week in advance and posted in a location accessible to residents and families.

9. A TBI residential home shall:

   (i) Provide sufficient food provision capabilities and dining space.

   (ii) Maintain and properly store a forty-eight (48) hour food supply at all times.

   (iii) Provide appropriate, properly-repaired equipment and utensils for cooking and serving food to serve all residents.

   (iv) Maintain a clean and sanitary kitchen.

   (v) Ensure employees shall wash and sanitize equipment, utensils and dishes after each use.

Authority: T.C.A. §§ 68-11-202, 68-11-206, 68-11-209, 68-11-270, 68-11-273, and 68-11-274.
Administrative History: Original rule filed October 28, 2015; effective January 26, 2016.

1200-08-37-.07 ADMISSIONS, DISCHARGES, AND TRANSFERS.

(1) Admissions.

(a) A TBI residential home may only admit and continue to care for residents requiring specialized services, where assistance is provided with ADL's in a homelike environment.

(b) A TBI residential home may not admit or serve a resident who is ventilator dependent.

~~(c) A TBI residential home may serve up to eight (8) disabled adults, who suffer from the effects of a traumatic brain injury and who are unrelated to the TBI residential home provider by blood or marriage.~~

~~(d) A TBI residential home provider may choose to serve one (1) or more elderly adult members of their own family as long as the TBI residential home provider serves at least two (2) additional disabled adults unrelated to the TBI residential home provider by blood or marriage. In no event shall a TBI residential home provider serve more than eight (8) disabled residents in the licensed TBI residential home.~~

(c) A TBI residential home provider may choose to serve one (1) or more elderly adult members of their own family as long as the TBI residential home provider serves at least two (2) additional disabled adults unrelated to the TBI residential home provider by blood or marriage.

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(Rule 1200-08-37-.07, continued)

(d)~~(e)~~ A TBI residential home may not admit or retain a resident who cannot be evacuated within five (5) minutes.

(e)~~(f)~~ A TBI residential home shall upon admission of a resident:

1. Be able to identify at the time those residents whose needs for services are consistent with these rules and regulations, and those residents who should be transferred to a more appropriate level of care;

2. Document plans and procedures to show evacuation of the resident within five (5) minutes.

3. Provide to each resident a written admission agreement signed and dated by the TBI residential home provider and the resident or the resident's family member or the resident's legal representative and presented both verbally and in writing. The admission agreement shall be reviewed and updated as necessary as a part of the residential plan of care review process and contain the following:

   (i) A copy of the resident rights for the resident's review and signature;

   (ii) A copy of house rules and the rate schedules, including any payment for services for which the resident will be responsible;

   (iii) An accurate written statement providing that the TBI residential home provider shall give thirty (30) days written notice to the resident prior to making any changes in the rates;

   (iv) The consequences for non-payment for services which includes involuntary discharge from the TBI residential home;

   (v) An accurate written statement regarding services which will be provided residents upon admission;

   (vi) Procedures for handling the transfer or discharge of residents that does not violate the residents' rights under the law or these rules;

   (vii) A copy of the medication disposal policy.

4. Disclose in writing to the resident or to the resident's legal representative, the identity of the TBI residential home's primary liability insurance carrier. If the TBI residential home is self-insured, its statement shall reflect that fact and indicate the corporate entity responsible for payment of any claims;

5. Document evidence of annual vaccination against influenza for each resident, in accordance with the recommendation of the Advisory Committee on Immunization Practices of the Centers for Disease Control most recent to the time of vaccine, unless such vaccination is medically contraindicated or the resident or the resident's legal representative has refused the vaccine. Influenza vaccination for all residents accepting the vaccine shall be completed by November 30 of each year or within ten (10) days of the vaccine becoming available. Residents admitted after this date during the flu season and up to February 1, shall, as medically appropriate, receive influenza vaccination prior to or on admission unless refused by the resident or the resident's legal representative; and

(Rule 1200-08-37-.07, continued)

6. Document evidence of vaccination against pneumococcal disease for all residents who are sixty-five (65) years of age or older, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control at the time of vaccination, unless such vaccination is medically contraindicated or the resident or the resident's legal representative has refused the offer of vaccine. The TBI residential home shall provide or arrange for the pneumococcal vaccination of residents who have not received this immunization prior to or on admission unless the resident or resident's legal representative refuses offer of the vaccine.

(2) Discharges and Transfers.

(a) Residents may only be moved, transferred or discharged from a TBI residential home for the following reasons:

1. Medical reasons. The resident has a medical or nursing condition that exceeds the level of health care services the home provides;

2. Welfare of the resident or of other residents. This includes, but is not limited to the following: The TBI residential home is unable to accomplish timely evacuation of the resident in the event of an emergency; the resident exhibits behavior that poses an imminent danger to self or others; the resident engages in behavior or actions that repeatedly and substantially interfere with the rights, health or safety of residents or others; or the resident engages in illegal drug use, or commits a criminal act that causes potential harm to the resident or others;

3. Nonpayment for services provided to the resident by the home; or

4. Closing or selling the facility.

(b) A TBI residential home resident shall be discharged and transferred to another appropriate setting such as home, a hospital, or a nursing home when the resident, the resident's legal representative, or the resident's treating physician determines that the TBI residential home cannot safely and effectively meet the resident's needs, including medical services.

(c) The Board may require that a TBI residential home resident be discharged or transferred to another level of care if it determines that the resident's needs, including medical services, cannot be safely and effectively met in the TBI residential home.

(d) In the event of a discharge or transfer due to medical reasons, for the welfare of the resident or for the welfare of other residents, or due to nonpayment for services provided to the resident by the home, the TBI residential home provider shall give the resident, the resident's family member, or the resident's legal representative written notice at least thirty (30) days prior to the proposed transfer or discharge.

(e) In the event of a discharge or transfer due to medical reasons, the welfare of the resident, or for the welfare of other residents, the TBI residential home provider shall work with the Board to develop a transition plan in order to maintain continuity of care for the resident and to minimize the impact of the transition. The TBI residential home provider shall assist the resident in locating an alternate appropriate setting.

(f) In the case of a medical emergency that requires immediate action, the TBI residential home provider shall give the resident, the resident's family member, or the resident's legal representative written notice as soon as possible under the circumstances.

(Rule 1200-08-37-.07, continued)

(g) In the event of discharge or transfer due to selling the home to another TBI residential home provider, the current TBI residential home provider shall develop a transition plan for all residents to facilitate the transition to a new TBI residential home and shall maintain its license and operation of the home until the point in time the new TBI residential home's license is approved.

(h) In the event of discharge or transfer due to the closing of the home, the TBI residential home provider shall provide ninety (90) days advance notice to residents and shall work with the Board to develop a transition plan to maintain continuity of care for the residents and to minimize the impact of transition. The TBI residential home shall assist each resident in locating an alternative placement.

Authority: *T.C.A. §§ 68-11-202, 68-11-206, 68-11-209, 68-11-270, and 68-11-273.*
Administrative History: *Original rule filed October 28, 2015; effective January 26, 2016.*

1200-.08-36-.08 PERSONAL AND HEALTH CARE NEEDS.

(1) A TBI residential home provider shall conduct an assessment of a prospective resident before admitting the resident. The assessment shall include:

(a) Diagnoses;

(b) Medications;

(c) Personal care needs;

(d) Health care needs;

(e) Nutritional needs;

(f) Activities; and

(g) Lifestyle preferences.

(2) A TBI residential home provider shall be able to meet the needs of a resident, including personal and health care needs and night care needs, before admitting the resident.

(3) Plan of Care.

(a) The TBI residential home shall develop a resident plan of care for the day-to-day delivery of residential services, including personal and health care needs and night care needs with input and participation from the resident or the resident's legal representative, the resident's family, and the resident's treating physician or other licensed health care professionals or entity delivering patient services within five (5) days of admission.

(b) The plan of care shall include, at a minimum the following elements:

1. Health and functional status, including cognitive/behavioral health status and any ADL deficiencies;

2. Resident needs and preferences, personal and health care needs, and night care needs;

3. Significant health conditions and required course of treatment for management of chronic conditions;

* 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)
Carissa S. Lynch, Pharm.D.	X				
Evelyn J. Brock, D.O.	X				
Patricia P. Ketterman	X				
Thomas H. Gee	X				
Lisa M. Piercey, M.D.	X				
Jennifer Gordon-Maloney, DDS	X				
Sherry Robbins, M.D.	X				
Patsy E. Crihfield	X				
Robert C. Breeden	X				
Roger L. Mynatt	X				
Janet Williford	X				
Chuck V. Griffin	X				
Joshua A. Crisp	X				
Gina Throneberry	X				
Paul C. Boyd				X	
Bobby Wood	X				
Rene Saunders, M.D., Chairman				X	
Jim Shulman				X	
Vacant					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board for Licensing Health Care Facilities (board/commission/ other authority) on 10/03/2018 (mm/dd/yyyy), and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: *08/08/18 (mm/dd/yy)*

Rulemaking Hearing(s) Conducted on: (add more dates). *10/03/18 (mm/dd/yy)*

Date: 10/16/18

Signature: Caroline R. Tippens

Name of Officer: Caroline Tippens

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: October 16, 2018

Notary Public Signature: Lisa Williams

My commission expires on: December 22, 2020

LISA WILLIAMS
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF ROBERTSON

Agency/Board/Commission: Board for Licensing Health Care Facilities

Rule Chapter Number(s): 1200-08-02, 1200-08-15, 1200-08-24, 1200-08-25, 1200-08-27, 11200-08-28, 1200-08-29, 1200-08-32, 1200-08-34, 1200-08-35, 11200-08-36, 1200-08-37

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

3/25/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/26/19

Effective on: 6/24/19

Tre Hargett
Secretary of State

RECEIVED
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PUBLIC DOCS

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Health
SUBJECT:	General Rules and Regulations Governing the Practice of Medicine, General Rules and Regulations Governing the Practice of Osteopathy, Rules Governing the Practice of Dentistry, General Rules and Regulations Governing the Practice of Podiatry, General rules Governing the Practice of Optometry, Advanced Practice Nurses and Certificates of Fitness to Prescribe, and General rules Governing the Practice of a Physician Assistant
STATUTORY AUTHORITY:	Public Chapter 978 of the 110th General Assembly
EFFECTIVE DATES:	March 29, 2019 through September 25, 2019
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	This emergency rule is required by Public Chapter 978 of the 110th General Assembly. This emergency rule created minimum disciplinary standards required to be imposed by health-related licensing board and committees when there is a finding that a licensee engaged in inappropriate opioid prescribing.

REGULATORY FLEXIBILITY ANALYSIS

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

These rules do not overlap or conflict with other federal, state, or local government rules.

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

These rules were drafted for clarity, conciseness, and a lack of ambiguity.

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

These rules do not impact small businesses.

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

These rules do not impact small businesses.

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

These rules do not impact small businesses.

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

These rules do not impact small businesses.

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

These rules do not stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Department of Health (Various Prescribing Boards)

Rulemaking hearing date: TBD

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:**

   These rules do not impact small businesses.

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:**

   These rules do not require reporting or recordkeeping. They do not increase administrative costs.

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

   These rules do not impact small businesses.

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

   There is no less burdensome, less intrusive, or less costly alternative methods of achieving these rules' purpose.

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

   Federal: There are no comparable federal counterparts.

   State: T.C.A. § 63-1-126 requires licensing boards and committees to suspend the license of a healthcare practitioner who fails a urine drug screen and does not report to their peer assistance program.

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.**

   These rules do not impact small businesses.

Impact on Local Governments

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

This rule does not have a projected impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This is a new rule, required by Public Chapter 978 of the 110th General Assembly. This rule creates minimum disciplinary standards required to be imposed by health-related licensing boards and committees when there is a finding that a licensee engaged in inappropriate opioid prescribing.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

This rule is required by Public Chapter 978 of the 110th General Assembly.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

This rule will affect health-related licensing boards and those licensees who have been found by their board to have prescribed opioids inappropriately. This rule has the support of several professional associations who represent prescribers licensed in this state. The rule was crafted over the course of two public meetings with input from these associations.

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

There are none.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

This rule is not expected to alter local government revenues or expenditures.

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

Mary Katherine Bratton, Chief Deputy General Counsel, Tennessee Department of Health.

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

Mary Katherine Bratton, Chief Deputy General Counsel, Tennessee Department of Health

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

665 Mainstream Drive, Nashville, TN 37243, 615-741-1611, Mary.Bratton@tn.gov.

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

None.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-17-19
Rule ID(s): 8883-8889
File Date: 3/29/2019
Last Effective Day: 9/25/2019

Emergency Rule Filing Form

Emergency rules are effective from date of filing, unless otherwise stated in the rule, for a period of up to 180 days.

Agency/Board/Commission:	Tennessee Department of Health
Division:	
Contact Person:	Mary Katherine Bratton, Chief Deputy General Counsel
Address:	665 Mainstream Drive, Nashville, Tennessee
Zip:	37243
Phone:	(615) 741-1611
Email:	Mary.Bratton@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

Statement of Necessity:

These rules are being promulgated pursuant to 2018 Public Chapter 978, which was signed by the Governor on May 21, 2018 and which is now codified in T.C.A. § 63-1-162. The Task Force, created by T.C.A. § 63-1-162, is required to promulgate a rule for uniform minimum discipline across the prescribing boards. T.C.A. § 63-1-162(e) directs the Task Force to create such a rule by April 1, 2019. T.C.A. § 63-1-162(c) grants the Task Force authority to establish this rule by emergency action. Moreover, T.C.A. § 4-5-208(a)(5) permits an agency to promulgate an emergency rule where an enactment of the general assembly requires rules to be implemented within a prescribed period of time that precludes utilization of the rulemaking procedures required by Title 4, Chapter 5. Additionally, T.C.A. § 4-5-208 permits emergency rulemaking when there is an immediate danger to the public health, safety or welfare. The opioid epidemic is a danger to public health, and the promulgation of rules requiring minimum discipline, as agreed upon by the prescribing boards, can help to curb the excessive prescription of opioids by providing disciplinary measures tailored to address the particular problems involved in inappropriate prescribing of opioids.

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 make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0880-02	General Rules and Regulations Governing the Practice of Medicine
Rule Number	**Rule Title**
0880-02-.25	Minimum Discipline for Opioid Prescribing

Chapter Number	**Chapter Title**
1050-02	General Rules and Regulations Governing the Practice of Osteopathy
Rule Number	**Rule Title**
1050-02-.23	Minimum Discipline for Opioid Prescribing

Chapter Number	**Chapter Title**
0460-02	Rules Governing the Practice of Dentistry
Rule Number	**Rule Title**

0460-02-.15	Minimum Discipline for Opioid Prescribing

Chapter Number	Chapter Title
1155-02	General Rules and Regulations Governing the Practice of Podiatry
Rule Number	**Rule Title**
1155-02-.24	Minimum Discipline for Opioid Prescribing

Chapter Number	Chapter Title
1045-02	General Rules Governing the Practice of Optometry
Rule Number	**Rule Title**
1045-02-.18	Minimum Discipline for Opioid Prescribing

Chapter Number	Chapter Title
1000-04	Advanced Practice Nurses and Certificates of Fitness to Prescribe
Rule Number	**Rule Title**
1000-04-.11	Minimum Discipline for Opioid Prescribing

Chapter Number	Chapter Title
0880-03	General Rules Governing the Practice of a Physician Assistant
Rule Number	**Rule Title**
0880-03-.25	Minimum Discipline for Opioid Prescribing

RULES
OF
TENNESSEE BOARD OF MEDICAL EXAMINERS

CHAPTER 0880-02
GENERAL RULES AND REGULATIONS GOVERNING THE PRACTICE OF MEDICINE

TABLE OF CONTENTS

0880-02-.01	Definitions
0880-02-.02	Fees
0880-02-.03	Licensure Process-U.S. and Canada Medical School Graduates
0880-02-.04	Licensure Process-International Medical School Graduates
0880-02-.05	Licensure of Out-Of-State and International Applicants
0880-02-.06	Training Licenses and Licensure Exemptions
0880-02-.07	Application Review, Approval, Denial, Interviews and Conditioned, Restricted and Locum Tenens Licensure
0880-02-.08	Examination
0880-02-.09	Licensure Renewal and Reinstatement
0880-02-.10	Licensure Retirement/Inactivation and Reactivation
0880-02-.11	Officers, Records, Meeting Requests, Certificates of Fitness, Replacement Licenses, Consultants, Advisory Rulings, Declaratory Orders And Screening Panels
0880-02-.12	Licensure Discipline and Civil Penalties
0880-02-.13	Advertising
0880-02-.14	Specially Regulated Areas and Aspects of Medical Practice
0880-02-.15	Medical Records
0880-02-.16	Telemedicine Licensure and the Practice of Telemedicine
0880-02-.17	Consumer Right-To-Know Requirements
0880-02-.18	Supervision of Physician Assistants
0880-02-.19	Continuing Medical Education
0880-02-.20	Medical Professional Corporations and Medical Professional Limited Liability Companies
0880-02-.21	Office Based Surgery
0880-02-.22	Free Health Clinic, Inactive Pro Bono and Volunteer Practice Requirements
0880-02-.23	Tamper-Resistant Prescriptions
0880-02-.24	Medical Spa Registration
0880-02-.25	Minimum Discipline for Opioid Prescribing

0880-02-.01 DEFINITIONS. As used in this Chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

(1) Board - The Tennessee Board of Medical Examiners.

(2) Board's Administrative Office - The office of the administrator assigned to the Tennessee Board of Medical Examiners and housed within the Division.

(3) Board Designee - Any person who has received written delegation of authority from the Board to perform Board functions subject to review and ratification by the full Board where provided by these rules.

(4) Derogatory Information - As this term is used in T.C.A. § 63-6-210, shall mean wherever it appears in these rules any communication or information received during the licensure, renewal or reinstatement process which indicates either legal, ethical, competency, mental or physical problems which reflect in any manner not inconsistent with the Americans With Disabilities Act on the individuals fitness or competency to safely practice or continuing to safely practice medicine in Tennessee without restriction. Such communications or information include but are not limited to, conviction of a crime, malpractice lawsuits, loss or restriction of hospital privileges, licensure discipline in another state or country, previous licensure action either formal or informal in this state, ongoing investigation or prosecution of a disciplinary action in this or any other state or country and any physical/medical condition which is not otherwise ameliorated by compliance with physician orders, treatment program requirements or voluntary restrictions of the individual in compliance with the Americans With Disabilities Act.

(5) Division - The Tennessee Department of Health, Division of Health Related Boards, from which the Board receives administrative support.

0880-02-.24 MEDICAL SPA REGISTRATION.

(1) Any medical spa offering cosmetic medical services, as those terms are defined in T.C.A. §§ 63-1-153 and 63-6-105, in Tennessee must register with the Tennessee Board of Medical Examiners, prior to operation or within sixty calendar days of the effective date of this rule, by providing Board staff with the following:

(a) A completed Application for Registration of a Medical Spa along with the non-refundable Medical Spa Registration Fee required pursuant to Rule 0880-02-.02; and

(b) The name and physical address of the medical spa; and

(c) The name and Tennessee license number of the medical director or supervising physician responsible for services at the practice; and

(d) The name and physical address of the primary practice of the medical director or supervising physician; and

(e) Certification information of the medical director or supervising physician as required by T.C.A. § 63-1-153(b) and (c); and

(f) An attestation that the medical director or supervising physician registering the medical spa assumes and accepts responsibility for the cosmetic medical services provided at the medical spa.

(2) Registration is valid for twelve (12) months. Prior to expiration, the medical spa must complete a new Application for Registration of a Medical Spa and pay the registration fee.

(3) The medical director or supervising physician who is responsible for or supervises a medical spa is responsible for providing the Board with the information described in paragraph (1) of this rule; ensuring the annual registration of the medical spa; and complying with the signage and advertisement requirements contained in T.C.A. § 63-1-153.

(4) The medical director or supervising physician must be a medical doctor or osteopathic physician with an active Tennessee license and an active medical practice in Tennessee.

(5) Operation without current registration constitutes unprofessional conduct on the part of the medical director or any supervising physician providing services, including supervision services, at such unregistered medical spa and is grounds for disciplinary action by the licensing board of such physician.

Authority: *T.C.A. §§ 63-1-153, 63-6-101, and 63-6-105.* ***Administrative History:*** *Original rule filed July 31, 2018; effective October 29, 2018.*

0880-02-.25 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

RULES
OF
THE TENNESSEE BOARD OF OSTEOPATHIC EXAMINATION

CHAPTER 1050-02
GENERAL RULES AND REGULATIONS GOVERNING THE PRACTICE OF OSTEOPATHY

TABLE OF CONTENTS

1050-02-.01 Definitions
1050-02-.02 Fees
1050-02-.03 Licensure Process
1050-02-.04 Training
1050-02-.05 Application Review, Approval, Denial, Interviews and Conditioned, Restricted and Locum Tenens Licensure
1050-02-.06 Examination
1050-02-.07 Licensure Renewal and Reinstatement
1050-02-.08 Licensure Retirement and Reactivation
1050-02-.09 Officers, Records, Meeting Requests, Certificates of Fitness, Replacement Licenses, Consultants, Declaratory Orders and Screening Panels
1050-02-.10 Licensure Discipline and Civil Penalties
1050-02-.11 Advertising
1050-02-.12 Continuing Education Requirements
1050-02-.13 Specifically Regulated Areas and Aspects of Practice
1050-02-.14 Universal Precautions for the Prevention of HIV Transmission
1050-02-.15 The Utilization and Supervision of a Certified Nurse Practitioner or Licensed Physician Assistant
1050-02-.16 Consumer Right-To-Know Requirements
1050-02-.17 Telemedicine Licensure
1050-02-.18 Medical Records
1050-02-.19 Medical Professional Corporations and Medical Professional Limited Liability Companies
1050-02-.20 Free Health Clinic and Volunteer Practice Requirements
1050-02-.21 Office Based Surgery
1050-02-.22 Tamper-Resistant Prescriptions
1050-02-.23 Minimum Discipline for Opioid Prescribing.

1050-02-.01 DEFINITIONS. As used in this Chapter of Rules the following terms and acronyms shall have the following meanings ascribed to them:

(1) AOA - The American Osteopathic Association.

(2) Board - The Tennessee Board of Osteopathic Examination

(3) Board Administrative Office - The office of the administrator assigned to the Tennessee Board of Osteopathic Examination located at the 665 Mainstream Drive, Nashville, TN 37243.

(4) Board Consultant/Designee - Any person who has received delegation of authority from the Board to perform Board functions subject to review and ratification by the full Board where provided by these rules.

(5) COMLEX - The Comprehensive Osteopathic Medical Licensure Exam.

(6) COMSPEX - The Comprehensive Osteopathic Medical Special Purpose Exam.

(7) COMVEX - The Comprehensive Osteopathic Medical Variable Purpose Examination

(8) Division - The Tennessee Department of Health and Environment, Division of Health Related Boards, from which the Board receives administrative support.

(9) Endorsement/Reciprocity - The method of consideration for licensure for applicants previously licensed in another state.

(10) Examination - Unless otherwise stipulated, a written and/or oral examination specifically prepared and administered by the Board.

(Rule 1050-02-.21, continued)

(a) Each prescriber shall undertake adequate safeguards and security measures to ensure against loss, improper destruction, theft, or unauthorized use of the tamper-resistant prescriptions in the prescriber's possession.

(5) Use of Tamper-Resistant Prescriptions.

(a) Facsimile Prescription Transmission.

1. Prescriptions sent by facsimile transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, and quantity prescribed. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

(b) Electronic Prescription Transmission.

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§ 53-10-401 and 63-9-116. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

1050-02-.23 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(Rule 1050-02-.22, continued)

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

(Rule 1050-02-.22, continued)

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

RULES
OF
TENNESSEE BOARD OF DENTISTRY

CHAPTER 0460-02
RULES GOVERNING THE PRACTICE OF DENTISTRY

TABLE OF CONTENTS

0460-02-.01	Licensure Process - By Exam and By Criteria (Reciprocity)	0460-02-.08	Licensure Renewal
0460-02-.02	Dual Degree Licensure Process	0460-02-.09	Licensure Retirement and Reactivation
0460-02-.03	Limited and Educational Limited Licensure Process	0460-02-.10	Advertising
0460-02-.04	Licensure Exemption Process	0460-02-.11	Regulated Areas of Practice
0460-02-.05	Examinations	0460-02-.12	Dental Records
0460-02-.06	Specialty Certification	0460-02-.13	Free Health Clinic, Inactive Pro Bono and Volunteer Practice Requirements
0460-02-.07	Anesthesia and Sedation	0460-02-.14	Tamper-Resistant Prescriptions
		0460-02-.15	Minimum Discipline for Opioid Prescribing

0460-02-.01 LICENSURE PROCESS - BY EXAM AND BY CRITERIA (RECIPROCITY).

(1) The process for obtaining licensure by exam or by criteria (reciprocity) is as follows:

(a) An applicant shall obtain a Board application form from the Board Administrative Office, 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 activities necessary to accomplish the filing of the required documentation be completed prior to filing a licensure application and that all documentation be filed simultaneously.

(b) An applicant shall cause to be submitted directly, from a dental school, college or university duly accredited by the Commission on Dental Accreditation of the American Dental Association, to the Board Administrative Office a certificate of graduation containing the institution's Official Seal and which shows the following:

1. The applicant's transcript; and

2. The degree and diploma conferred, or a letter from the Dean of the educational institution attesting to the applicant's eligibility for the degree and diploma if the last term of dental school has not been completed at the time of application. However, no license shall be issued until official notification is received in the Board Administrative Office that the degree and diploma have been conferred.

(c) An applicant shall submit a signed "passport" style photograph taken within the preceding twelve (12) months.

(d) An applicant shall submit evidence of good moral character. Such evidence shall include at least two (2) letters attesting to the applicant's character from dental professionals on the signator's letterhead.

(e) An applicant shall submit proof of United States or Canadian citizenship or evidence of being legally entitled to live in the United States. Such evidence may include copies of birth certificates, naturalization papers, or current visa status.

(f) An applicant shall submit the required fees as provided in Rule 0460-01-.02 (1).

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

(Rule 0460-02-.14, continued)

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§ 53-10-401, 63-5-105, and 63-5-122. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

0460-02-.15 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(Rule 0460-02-.14, continued)

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(Rule 0460-02-.14, continued)

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

RULES
OF
THE TENNESSEE BOARD OF PODIATRIC MEDICAL EXAMINERS

CHAPTER 1155-02
GENERAL RULES AND REGULATIONS GOVERNING THE PRACTICE OF PODIATRY

TABLE OF CONTENTS

1155-02-.01	Definitions	1155-02-.15	Disciplinary Actions, Civil Penalties, Assessment of Costs, and Subpoenas
1155-02-.02	Scope of Practice	1155-02-.16	License
1155-02-.03	Necessity of Licensure	1155-02-.17	Change of Address and/or Name
1155-02-.04	Qualifications for Licensure	1155-02-.18	Mandatory Release of Patient Records
1155-02-.05	Procedures for Licensure	1155-02-.19	Board Meetings, Officers, Consultants, Records, Declaratory Orders, Advisory Rulings and Screening Panels
1155-02-.06	Fees	1155-02-.20	Consumer Right-To-Know Requirements
1155-02-.07	Application Review, Approval, Denial, Interviews	1155-02-.21	Podiatric Professional Corporations and Podiatric Professional Limited Liability Companies
1155-02-.08	Examinations	1155-02-.22	Advertising
1155-02-.09	Licensure Renewal	1155-02-.23	Tamper-Resistant Prescriptions
1155-02-.10	Reserved	1155-02-.24	Minimum Discipline for Opioid Prescribing
1155-02-.11	Retirement and Reactivation of License		
1155-02-.12	Continuing Education		
1155-02-.13	Professional Ethics		
1155-02-.14	Academic License		

1155-02-.01 DEFINITIONS - As used in this chapter and in chapters 1155-03 and 1155-04, the following terms and acronyms shall have the following meanings ascribed to them:

(1) Advertising - Includes, but is not limited to, business solicitation, with or without limiting qualifications, in a card, sign, or device issued to a person; in a sign or marking in or on any building, or in any newspaper, magazine, directory, or other printed matter. Advertising also includes business solicitations communicated by individual, radio, video, television broadcasting, direct mail or any other means designed to secure public attention.

(2) Advertisement - Informational communication to the public in any manner to attract public attention to the practice of a podiatrist or podiatry medicine.

(3) Applicant - Any individual seeking licensure by the Board who has submitted an official application and paid the application fee.

(4) American Podiatric Medical Association - When the acronym APMA appears in these rules, it is intended to mean American Podiatric Medical Association.

(5) Board - The Tennessee Board of Podiatric Medical Examiners.

(6) Board Administrative Office - The office of the administrator assigned to the Board located at 665 Mainstream Drive, Nashville, TN 37243.

(7) Board Designee - Any person who has received a written delegation of authority from the Board to perform Board functions subject to review and ratification by the full Board where provided by these rules.

(8) Closed Files - An administrative action which renders an incomplete or denied file inactive.

(9) Department - Tennessee Department of Health.

(10) Division - The Division of Health Related Boards, Tennessee Department of Health, from which the Board receives administrative support.

(Rule 1155-02-.22, continued)

(5) Use of Tamper-Resistant Prescriptions.

(a) Facsimile Prescription Transmission.

1. Prescriptions sent by facsimile transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, quantity prescribed, and the method by which the prescription has been transmitted.

(b) Electronic Prescription Transmission.

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document that the prescription was transmitted electronically in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§ 53-10-401, 63-3-106(1), and 63-3-127. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

1155-02-.24 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(Rule 1155-02-.23, continued)

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(Rule 1155-02-.23, continued)

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

RULES
OF
TENNESSEE BOARD OF OPTOMETRY

CHAPTER 1045-02
GENERAL RULES GOVERNING THE PRACTICE OF OPTOMETRY

TABLE OF CONTENTS

1045-02-.01	Fees
1045-02-.02	Licensure Process
1045-02-.03	Examinations
1045-02-.04	License Renewal
1045-02-.05	Continuing Education
1045-02-.06	Board Meetings, Members' Authority and Records
1045-02-.07	Diagnostic and Therapeutic Certification
1045-02-.08	Corporate or Business Names and Advertising
1045-02-.09	Ocular and Contact Lens Prescriptions and Office Equipment
1045-02-.10	Disciplinary Actions, Civil Penalties, Declaratory Orders, Screening Panels, Assessment of Costs, and Subpoenas
1045-02-.11	Scope of Practice
1045-02-.12	Primary Eye Care Procedures
1045-02-.13	Optometric Professional Corporations and Optometric Professional Limited Liability Companies
1045-02-.14	Optometric Records
1045-02-.15	Consumer Right-To-Know Requirements
1045-02-.16	Tamper-Resistant Prescriptions
1045-02-.17	Reserved
1045-02-.18	Minimum Discipline for Opioid Prescribing

1045-02-.01 FEES.

(1) The fees authorized by the Optometry Practice Act (T.C.A. §§ 63-8-101, et seq.) and other applicable statutes to be established in amount by the Board are established as follows:

(a)	Application Fee - A non-refundable fee to be paid each time an application for initial licensure is filed.	$250.00
(b)	Reinstatement Fee - A non-refundable fee to be paid each time an application for reinstating an expired license is filed.	$200.00
(c)	Duplicate Licensure	$25.00
(d)	Licensure Renewal Fee – A non-refundable fee to be paid biennially by all licensees except Inactive Volunteers. This fee also applies to licensees who reactivate a retired license or who reactivate an inactive license.	$275.00
(e)	Biennial State Regulatory Fee	$10.00
(f)	Inactive Volunteer Licensure Renewal Fee	$0.00

(2) All fees may be paid in person, by mail or electronically by cash, check, money order, or by credit and/or debit cards accepted by the Division. If the fees are paid by certified, personal or corporate check they must be drawn against an account in a United States Bank, and made payable to the Tennessee Board of Optometry.

Authority: *T.C.A. §§ 4-3-1011(b), 4-5-202, 4-5-204, 63-8-111, 63-8-112, 63-8-112(1), 63-8-115, 63-8-119, 9-4-5117, 63-8-128, and 63-8-133.* ***Administrative History:*** *Original rule filed May 15, 1981; effective July 22, 1981. Amendment filed October 13, 1983; effective November 14, 1983. Repeal and new rule filed November 30, 1990; effective January 14, 1991. Amendment filed August 2, 1995; effective October 16, 1995. Amendment filed December 11, 1998; effective February 23, 1999. Amendment filed September 13, 2002; effective November 27, 2002. Amendment filed June 10, 2004; effective August 24,*

(Rule 1045-02-.16, continued)

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber, may, but is not required to, document the means by which the prescription was transmitted.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§ 53-10-401, 63-8-112, and 63-8-126. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

1045-02-.17 RESERVED.

Authority: *T.C.A. §§ 63-8-113 and 63-8-125.* ***Administrative History:*** *Original rule filed August 18, 2014; effective November 16, 2014. A 60-day stay of the rule was filed by the Tennessee Department of Health's Board of Optometry on October 23, 2014. The new effective date was January 15, 2015. The Government Operations Committee filed a notice that 1045-02-.17 will not be included in the 2015 Omnibus Bill once it is passed by the 109th General Assembly. At that time, .17 will be eliminated from this chapter. Until that time, .17 will be effective beginning January 15, 2015. Rule expired on June 30, 2015 and reverted to reserved status.*

1045-02-.18 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is

(Rule 1045-02-.16, continued)

required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(Rule 1045-02-.16, continued)

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

RULES
OF
THE TENNESSEE BOARD OF NURSING

CHAPTER 1000-04
ADVANCED PRACTICE NURSES AND CERTIFICATES OF FITNESS TO PRESCRIBE

TABLE OF CONTENTS

1000-04-.01	Purpose and Scope
1000-04-.02	Definitions
1000-04-.03	Advanced Practice Nurse Certificate
1000-04-.04	Certificate of Fitness
1000-04-.05	Renewal of Certificate and Demonstration of Competency
1000-04-.06	Fees
1000-04-.07	Processing of Applications
1000-04-.08	Treatment of Pain
1000-04-.09	Prerequisites to Prescribing or Dispensing Medications
1000-04-.10	Tamper-Resistant Prescriptions
1000-04-.11	Minimum Discipline for Opioid Prescribing

1000-04-.01 PURPOSE AND SCOPE.

(1) Tennessee Code Annotated § 63-7-126 requires nurse practitioners, nurse anesthetists, nurse midwives, and clinical nurse specialists meeting certain qualifications to apply to the Board of Nursing for a certificate to practice as an advanced practice nurse including authorization to use the title "advanced practice nurse" or the abbreviation "APN." These rules implement this process and set forth the requirements for a registered nurse to hold himself/herself out as an advanced practice nurse.

(2) Certification by the Tennessee Board of Nursing as an advanced practice nurse shall authorize such person to represent him/herself as an advanced practice nurse under the appropriate category of nurse practitioner, nurse anesthetist, nurse midwife or clinical nurse specialist.

(3) The Nurse Practice Act, T.C.A. §§ 63-7-101, et seq., requires a certification process for a nurse practitioner to prescribe and/or issue legend drugs. These rules implement this certification process only and set forth the requirements a nurse must meet for certification as a nurse practitioner who prescribes and/or issues legend drugs.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 63-7-123, 63-7-126, and 63-7-207.* ***Administrative History:*** *Original rule filed April 5, 1982; effective May 20, 1982. Amendment filed November 4, 1985; effective December 4, 1985. Amendment filed December 30, 1994; effective March 18, 1995. Amendment filed June 26, 1997; effective September 8, 1997. Amendment filed March 25, 1999; effective June 8, 1999. Amendment filed October 26, 1999; effective January 9, 2000. Repeal and new rule filed May 28, 2004; effective August 11, 2004.*

1000-04-.02 DEFINITIONS.

(1) Advanced Practice Nurse (APN) - means a Tennessee licensed registered nurse who has a master's degree or higher in a nursing specialty and has national specialty certification as a nurse practitioner, nurse anesthetist, nurse midwife, or clinical nurse specialist. The four (4) recognized categories for advanced practice nurses are Clinical Nurse Specialist, Nurse Anesthetist, Nurse Midwife, and Nurse Practitioner.

(2) Clinical Nurse Specialist - means a Tennessee licensed registered nurse who has a master's degree or higher in a nursing specialty and has national specialty certification as a clinical nurse specialist.

(Rule 1000-04-.10, continued)

(a) A prescriber shall ensure that all handwritten, typed, or computer-generated prescription orders are issued on tamper-resistant prescriptions. Tamper-resistant prescriptions shall contain the following features:

1. Either a void or illegal pantograph or a watermark designed to prevent copying;

2. Either quantity check-off boxes with refill indicators or a uniform, non-white background color designed to prevent erasure or modification; and

3. Security features and descriptions listed on the prescriptions designed to prevent use of counterfeit forms.

(4) Security Measures and Recordkeeping.

(a) Each prescriber shall undertake adequate safeguards and security measures to ensure against loss, improper destruction, theft, or unauthorized use of the tamper-resistant prescriptions in the prescriber's possession.

(5) Use of Tamper-Resistant Prescriptions.

(a) Facsimile Prescription Transmission.

1. Prescriptions sent by facsimile transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, and quantity prescribed. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

(b) Electronic Prescription Transmission.

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§53-10-401, 63-7-123(b)(3), and 63-7-207. [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 25, 2009; effective through December 7, 2009. Public necessity rule filed June 25, 2009 expired; on December 8, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

1000-04-.11 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by

(Rule 1000-04-.10, continued)

prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during

(Rule 1000-04-.10, continued)

that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

(Rule 1000-04-.10, continued)

Authority: T.C.A. § 63-1-162.

RULES
OF
TENNESSEE BOARD OF MEDICAL EXAMINERS
COMMITTEE ON PHYSICIAN ASSISTANTS

CHAPTER 0880-03
GENERAL RULES GOVERNING THE PRACTICE OF A PHYSICIAN ASSISTANT

TABLE OF CONTENTS

0880-03-.01 Definitions
0880-03-.02 Scope of Practice
0880-03-.03 Necessity of License
0880-03-.04 Qualifications for Licensure
0880-03-.05 Procedures for Licensure
0880-03-.06 Fees
0880-03-.07 Application Review, Approval and Denial
0880-03-.08 Examinations
0880-03-.09 Licensure Renewal and Reinstatement of an Expired License
0880-03-.10 Range of Services/Supervision
0880-03-.11 Retirement and Reactivation of License
0880-03-.12 Continuing Education
0880-03-.13 Professional Ethics
0880-03-.14 Temporary License
0880-03-.15 Disciplinary Grounds, Actions, and Civil Penalties
0880-03-.16 License
0880-03-.17 Change of Name and/or Address
0880-03-.18 Free Health Clinic and Volunteer Practice Requirements
0880-03-.19 Committee Members, Officers, Consultants, Records, Declaratory Orders and Screening Panels
0880-03-.20 Advertising
0880-03-.21 Prescription Writing
0880-03-.22 Universal Precautions for the Prevention of HIV Transmission
0880-03-.23 Consumer Right-To-Know Requirements
0880-03-.24 Tamper-Resistant Prescriptions
0880-03-.25 Minimum Discipline for Opioid Prescribing

0880-03-.01 DEFINITIONS. As used in these rules, the following terms and acronyms shall have the following meaning ascribed to them:

(1) A.A.P.A. - American Academy of Physician Assistants.

(2) Advertising - Informational communication to the public in any manner to attract attention to the practice as a Physician Assistant. Includes, but is not limited to business solicitation, with or without limiting qualifications, in a card, sign, or device issued to a person; in a sign or marking, in or on any building; or in any newspaper, magazine, directory, or other printed matter. Advertising also includes business solicitations communicated by individual, radio, video, or television broadcasting or other means designed to secure public attention.

(3) A.M.A. - American Medical Association.

(4) Applicant - Any individual seeking licensure by the Committee who has submitted an official application and paid the application fee.

(5) A.R.C.-P.A. - The Accreditation Review Committee on Education for the Physician Assistant or its successor organization, which is the successor organization to C.A.A.H.E.P. for physician assistant education accreditation.

(6) Board - Tennessee Board of Medical Examiners.

(7) C.A.A.H.E.P. - The Commission on Accreditation of Allied Health Education Programs or its successor organization, which is the successor organization to C.A.H.E.A.

(8) C.A.H.E.A. - The Committee on Allied Health Education and Accreditation of the American Medical Association or its successor accrediting agency.

(9) Closed Files - An administrative action which renders an incomplete or denied file inactive.

(Rule 0880-03-.24, continued)

2. If a prescriber transmits a prescription order to a pharmacy by facsimile transmission, the prescriber or someone designated by the prescriber shall document in the patient's medical record the name of the drug, strength, and quantity prescribed. The prescriber may, but is not required to, document the means by which the prescription was transmitted.

(b) Electronic Prescription Transmission.

1. Prescriptions sent by electronic transmission are not required to be placed on tamper-resistant prescription paper.

2. If a prescriber transmits a prescription order to a pharmacy by electronic transmission, the prescriber shall document the prescription in the patient's file and in accordance with the applicable laws and rules for each of the prescribers' respective professions as well as applicable federal laws and rules. The prescriber, may, but is not required to, document the means by which the prescription was transmitted.

Authority: *Chapter 1035 of the Public Acts of 2008 and T.C.A. §§ 53-10-401, 63-19-104, and 63-19-107(2)(E). [effective October 1, 2008 for TennCare prescriptions and July 1, 2009 for non-TennCare prescriptions].* ***Administrative History:*** *Public necessity rule filed June 30, 2009; effective through December 12, 2009. Public necessity rule filed June 30, 2009 expired; on December 13, 2009, the rule reverted to its prior status. Emergency rule filed December 21, 2009; effective through June 19, 2010. Original rule filed March 22, 2010; effective June 20, 2010.*

0880-03-.25 Minimum Discipline for Opioid Prescribing.

(1) If the board or committee finds that its licensee has prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(2) Having made such a finding, the minimum discipline that the board or committee assesses shall include the following:

(a) Reprimand;

(b) Successful completion of a board or committee approved intensive continuing education course or program regarding treatment with opioids;

(c) A restriction against prescribing opioids for at least six (6) months, and until successful completion of the required continuing education;

(d) One or more Type A civil penalties;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the

(Rule 0880-03-.24, continued)

period in which the licensee is restricted from prescribing opioids.

(3) The prescribing boards and committee recognize that a higher level of minimum discipline is required for those licensees who have been disciplined for opioid-related prescribing violations but continue to violate the standard of care. As set out in paragraph (1) of this rule, the following findings are synonymous, though the boards or committee may have used one or more sets of language to describe a violation. If a licensee commits an order violation in which the prior order contains one or more of the following findings, the licensee has committed an opioid-related order violation for purposes of paragraph (5) of this rule:

(a) That the licensee had prescribed, dispensed, or administered opioids in a manner that constituted gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence;

(b) That the licensee engaged in a significant deviation or pattern of deviation from sound medical judgement related to the issuance of opioids;

(c) That the standard of care related to the issuance of opioids was violated;

(d) That the licensee had dispensed, prescribed or administered opioids not in the course of professional practice, or not in good faith to relieve pain and suffering or not to cure an ailment, physical infirmity or disease;

(e) That the licensee was unfit or incompetent by reason of negligence, habits or other cause related to the licensee's prescribing or issuance of opioids; or

(f) That the licensee violated the rules of the licensing entity with regard to prescribing or issuance of opioids.

(4) If within one (1) year from the date a licensee's opioid-prescribing privileges are reinstated, having been restricted by an opioid-related order, that licensee's board or committee finds that, during that year the licensee had prescribed, dispensed, or administered opioids in a manner that violates the board's or committee's statutes or rules (for example, by prescribing in a manner that constitutes gross healthcare liability or a pattern of continued or repeated health care liability, ignorance, negligence or incompetence), the board or committee shall make a finding that the licensee re-engaged in a significant deviation or pattern of deviation from sound medical judgement such that they are a repeat offender. For purposes of such a finding, sound medical judgment is the equivalent to the standard of care as defined in T.C.A. § 63-1-122.

(5) If the licensee commits an opioid-related order violation within one year of the opioid-related order, or if the licensee is found to be a repeat offender, the minimum discipline that the board or committee assesses shall include the following:

(a) Probation;

(b) Successful completion of a practice monitoring program which shall include at a minimum:

1. Board or committee approval of the monitor or monitoring program;

2. Quarterly reports to the board or committee which include the practice monitor's findings with regard to the licensee's:

(i) Non-opioid prescribing practices;

(Rule 0880-03-.24, continued)

(ii) medical record keeping;

(iii) pain management;

(iv) opioid treatment practices—where the practice monitoring is longer than the restriction against prescribing opioids; and

(v) compliance with the practice monitor's recommendations, including completion of any additional education recommended by the practice monitor;

(c) A restriction against prescribing opioids for twice the amount of time that was assessed in the initial board or committee order, and for no less than one (1) year;

(d) One or more Type A civil penalties totaling at least twice the amount that was assessed in the initial board or committee order;

(e) Proof to the licensee's board or committee that they have notified any physicians, podiatrists, advanced practice registered nurses, or physician assistants with whom they collaborate of the discipline; and

(f) Where the licensee is a physician or podiatrist, a restriction against collaborating with any advanced practice registered nurses or physician assistants for issuing opioids during the period in which the licensee is restricted from prescribing opioids.

(6) Nothing in this rule shall prohibit the board or committee from taking action in excess of the minimum disciplinary action outlined herein. Each case shall be judged independently and may result in additional discipline including other restrictions or a higher level of discipline, including revocation, where appropriate. Further, nothing in this rule shall prohibit the board or committee from taking disciplinary action against a licensee based on a finding that the licensee violated the practice act in manners additional to those outlined in paragraph (1) above, suggesting a need for a higher level of discipline.

Authority: T.C.A. § 63-1-162.

* 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)
Michael Wieting, D.O.	X				
Mark Young, APRN	X				
John Hale, M.D.	X				
Greg King, P.A.	X				
Ramesh B. Pavuluri. D.P.M.	X				
Thomas Wiliams, DDS	X				

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

Date: 3/28/19

Signature: Mary Katherine Bratton

Name of Officer: Mary Katherine Bratton

Title of Officer: Chief Deputy General Counsel
Department of Health

Subscribed and sworn to before me on: 3-28-19

Notary Public Signature: Suzanne Mechkowski

My commission expires on: My Commission Expires January 26, 2021

SUZANNE MECHKOWSKI STATE OF TENNESSEE NOTARY PUBLIC SUMNER COUNTY

Agency/Board/Commission: General Rules and Regulations Governing the Practice of Medicine, General Rules and Regulations Governing the Practice of Osteopathy, Rules Governing the Practice of Dentistry, General Rules and Regulations Governing the Practice of Podiatry, General Rules Governing the Practice of Optometry, Advanced Practice Nurses and Certificates of Fitness to Prescribe, and General Rules Governing the Practice of a Physician Assistant.

Rule Chapter Number(s): 0880-02, 1050-02, 0460-02, 1155-02, 1045-02, 1000-04, and 0880-03

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.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

3/29/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/29/2019

Effective for: 180 *days

Effective through: 9/25/2019

** 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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SECRETARY OF STATE
DIVISION OF PUBLIC SERVICES

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	University of Memphis
SUBJECT:	Student Housing
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 4-5-102(12)(B)(iv)(*b*)
EFFECTIVE DATES:	June 16, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	Per Tennessee Code Annotated, Section 4-5-102(12)(B)(iv)(*b*), agency matters related to the housing of students must be promulgated as rules. The proposed rule addresses matters related to eligibility for housing, housing contracts and fees, late payment charges, and appeals of housing decisions.

Regulatory Flexibility Addendum

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

The rule is not anticipated to have an impact on small business.

Impact on Local Governments

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

The rule is not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Per Tenn. Code Ann. § 4-5-102(12)(B)(iv)(b) agency matters related to the housing of students must be promulgated as rules. These rules address matters related to eligibility for housing, housing contracts and fees, and appeals of housing decisions.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Per Tenn. Code. Ann. § 4-5-102(12)(B)(iv)(b) agency matters related to the housing of students must be promulgated as rules. This requirement was further stated in State Board of Regents of University v. Gray, 561 S.W.2d 140 (Tenn. 1978).

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The individuals directly affected by this rule are the students attending University of Memphis who elect to reside in University housing. The rule does not make any substantive changes to how housing has been historically administered but rather explicitly delineates current practice, and, therefore, the University does not anticipate any objection to the rule.

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

State Board of Regents of University v. Gray, 561 S.W.2d 140 (Tenn. 1978).

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

There will be no probable increase or decrease in state and local government revenues and expenditures resulting from this new rule.

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

Dr. Darrell C. Ray, Vice President for Student Affairs

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

Dr. Darrell C. Ray, Vice President for Student Affairs

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Dr. Darrell C. Ray, Vice President for Student Affairs, 235 Administration Building, Memphis, TN 38152, 901-678-2114, dcray5@memphis.edu

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

None

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Nashville, TN 37243
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Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-12-19
Rule ID(s): 8867
File Date: 3/18/19
Effective Date: 6/16/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission:	University of Memphis
Division:	
Contact Person:	Dr. Darrell Ray
Address:	253 Administration Building, Memphis, TN
Zip:	38152
Phone:	901-678-2114
Email:	Dcray5@memphis.edu

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0240-10-02	Student Housing
Rule Number	**Rule Title**
0240-10-02-.01	Definitions
0240-10-02-.02	Eligibility
0240-10-02-.03	Residence Hall Contracts
0240-10-02-.04	Installment Payment Plan
0240-10-02-.05	Termination, Cancellation and Refunds
0240-10-02-.06	Conduct and Right to Enter
0240-10-02-.07	Appeals

Rules of
University of Memphis

Chapter 0240-10-02
Student Housing
New Chapter

Table of Contents is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.01 Definitions
0240-10-02-.02 Eligibility
0240-10-02-.03 Housing Contracts
0240-10-02-.04 Installment Payment Plan
0240-10-02-.05 Termination, Cancellation and Refunds
0240-10-02-.06 Conduct and Right to Enter
0240-10-02-.07 Appeals

0240-10-02-.01 Definitions is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.01 Definitions

(1) Residence hall. Any University of Memphis ("the University") managed or affiliated student residence facility, including traditional residence buildings and apartments. They do not include individual fraternity or sorority housing.

(2) Resident(s). Any University student who has executed a Housing Contract to live in a residence hall and received an assignment.

(3) Student(s). A person admitted, enrolled or registered for study at the University, either full-time or part-time, pursuing undergraduate, graduate, or professional studies, as well as non-degree seeking students.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D).

0240-10-02-.02 Eligibility is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.02 Eligibility

(1) To be eligible to reside in University residence halls students must be fully admitted to the University or conditionally admitted students in a degree program at the University.

(2) Applicants for Graduate and Student Family Housing must be either:

(a) married and/or a single parent (have legal custody of a dependent); or

(b) a single graduate student.

(3) All students shall have an equal opportunity to reside in student residence halls regardless of race, gender, marital status, creed, color, national origin, or disability.

(4) No person who is registered, or required to register, as a sex offender will be eligible to reside in University residence halls.

(5) All students under the age of twenty-two (22) who reside in University residence halls must provide proof of adequate immunization against meningococcal disease as required by state law unless they have a valid exemption.

(6) Students who fail to provide proof of adequate immunization will not be allowed to reside in University residential halls unless they have a valid exemption.

(7) Any exceptions to the eligibility requirements must be approved by the Director of Residence Life or their designee.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D); T.C.A.§ 49-7-124; T.C.A. § 49-7-162.

0240-10-02-.03 Housing Contracts is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.03 Housing Contracts

(1) To live in University residence halls, a completed application must be submitted. Receipt of the housing application does not guarantee assignment to any residence hall and the Director of Residence Life reserves the right to refuse any housing application.

(2) A student who applies to reside in a residence hall shall, as a condition to residing in the residence hall, sign a Housing Contract prepared by the University that establishes the terms and conditions of the student's occupancy of the residence hall.

(3) The Housing Contract, which will be in a paper or electronic format, will address the following non-exclusive list of subjects:

(a) Term (length) of the agreement;

(b) Cancellation of the agreement;

(c) Amounts, billing, payment, and refunds of housing fees, security; deposits, and damage and cleaning fees;

(d) Assignment and reassignment of rooms;

(e) Policies and procedures governing the use and safety of the residence hall and conduct within the residence hall;

(f) Rights of entry to rooms;

(g) Loss of or damage to the student's personal property;

(h) Loss of or damage to University property;

(i) Alterations, additions, or improvements to rooms;

(j) Animals;

(k) Prohibited activities;

(l) Visitation;

(m) Prohibition on assignment and subleasing by the student;

(n) Termination of the agreement by either the student or the University, and options for the student to appeal the termination; and/or

(o) Other reasonable and necessary subjects determined by the Director of Residence Life and University leadership.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D).

0240-10-02-.04 Installment Payment Plan is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.04 Installment Payment Plan

(1) Students may voluntarily enroll in the Installment Payment Plan (IPP) at the beginning of each semester.

(2) Students enrolled in this plan shall be assessed an IPP administrative fee of no greater than $50 for each semester enrolled in the plan. This charge shall be due and payable at registration.

(3) All financial aid awarded must first be applied toward payment of mandatory fees. The remaining balance after financial aid and discounts are applied will be divided into equal payments with the final payment due the first day of the last month of the applicable term.

(4) A late payment charge in the amount of $25 will be assessed on each installment that is not received by the University on or before the due date.

(5) Request for readmittance to the University will be denied to any student who participated in the IPP and who left the University without paying all charges pursuant to the program. Students will not be eligible for readmittance until all delinquent charges and interest on the charges are paid in full.

Authority: T.C.A. § 49-8-113; T.C.A. § 49-8-203(a)(1)(D).

0240-10-02-.05 Termination, Cancellation and Refunds is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.05 Termination, Cancellation and Refunds

(1) The University may terminate any Housing Contract in the event of any of the following nonexclusive reasons:

(a) Disciplinary action or violation of University policy;

(b) Withdrawal from the University;

(c) Failure to maintain eligible student status;

(d) Violation of any term of the Housing Contract;

(e) Violation of any applicable law or University rule, policy or procedure; or

(f) Change in marital or familial status.

(2) Residents may terminate their Housing Contract in accordance with the contract provisions.

(3) Residents whose Housing Contract is subject to termination will receive notice in writing of the reasons for termination and be given an opportunity to respond.

(4) Any resident who fails to make timely payment of all fees due under the terms of the Housing Contract will be liable for all expenses of collection, including court costs and attorneys' fees.

(5) Refunds will be made consistent with University policies or procedures related to refunds of student fees.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D).

0240-10-02-.06 Conduct and Right to Enter is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.06 Conduct and Right to Enter

(a) In addition to the terms of the Housing Contract, residents must also comply with all University of Memphis published policies including the Code of Student Conduct. Violations of the contract and the Code of Student Conduct may result in termination of the Housing Contract.

(b) Residents are responsible for the conduct of their guests. It is the responsibility of the resident to make sure that the guest understands and abides by all Housing and University regulations. If a guest is involved in any violations of University or Housing regulations, the hosting resident, as well as the guest, may be subject to disciplinary action, including termination of the Housing Contract.

(c) The University reserves the right to enter any residence hall unit or apartment at all reasonable times to inspect for maintenance, health, safety or emergency purposes. Searches may be authorized anytime there is reasonable cause to believe that there is a health or safety concern or in accordance with federal and state law.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D).

0240-10-02-.07 Appeals is added to Chapter 0240-10-02 Student Housing and shall read as follows:

0240-10-02-.07 Appeals

(a) Residents may appeal the termination of the Housing Contract to the Director of Residence Life or their designee by filing a written appeal within two (2) business days of the notice of termination.

(b) Within two (2) business days of receipt of the appeal, the Director of Residence Life or their designee will notify the resident of the decision in writing to their official University email address or other provided email address. The decision of the Director of Residence Life or their designee is final.

Authority: T.C.A. § 4-5-102(12)(E)(ii); T.C.A. § 49-8-203(a)(1)(D).

* 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)
G. Douglas Edwards	✓				
Marvin Ellison	✓				
Alan Graf, Jr.	✓				
Cato Johnson	✓				
R. Brad Martin	✓				
David North	✓				
Carol Roberts				✓	
David Kemme	✓				
Susan Springfield	✓				
Drew Gilmore					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the University of Memphis Board of Trustees on 12/4/18, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: 2/5/19

Signature: Melanie Murry

Name of Officer: Melanie Murry

Title of Officer: University Counsel/Board Secretary

Subscribed and sworn to before me on: 2/5/2019

Notary Public Signature:

My commission expires on: 09/30/2022

BRANDIN MARTIN STATE OF TENNESSEE NOTARY PUBLIC SHELBY COUNTY

Agency/Board/Commission: University of Memphis

Rule Chapter Number(s): Chapter 0240-10-02

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

3/1/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/18/19

Effective on: 6/16/19

Tre Hargett
Secretary of State

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G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	University of Memphis
SUBJECT:	Student Immunization Requirements
STATUTORY AUTHORITY:	Tennessee Code Annotated, Sections 49-7-124(g) and 49-7-125
EFFECTIVE DATES:	June 16, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	In compliance with Tennessee state law, the University has reviewed its immunization requirements and prepared a comprehensive immunization rule. This rule describes the requirements for immunizations for specific diseases as mandated by state law or as deemed necessary for specific disciplines. The rule also details applicable exemptions. The rule was developed in consultation with the Tennessee State Department of Health.

Regulatory Flexibility Addendum

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

The rule is not anticipated to have an impact on small business.

Impact on Local Governments

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

The rule is not anticipated to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

In compliance with Tennessee state law, the University has reviewed its immunization requirements and prepared a comprehensive immunization rule. This rule describes the requirements for immunizations for specific diseases as mandated by state law or as deemed necessary for specific disciplines. The rule also details applicable exemptions. The rule was developed in consultation with the Tennessee State Department of Health.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. 49-7-124(g) requiring that immunization requirements be developed in consultation with the department of health; TCA 49-7-125 which details requirements for Hepatis B waivers.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

University of Memphis students are the most directly affected by this rule as it governs their ability to be admitted to the University and to reside in University housing. These rules are consistent with the rules that were in effect under the governance of the Tennessee Board of Regents and the University is unaware of any persons or organizations that would object to this rule. The rule was reviewed by the Tennessee Department of Health and the Department's recommendations were incorporated.

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

None

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

None

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

Dr. Darrell C. Ray, Vice President for Student Affairs and Dr. Jane Clement, Director of Health Services

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

Dr. Darrell C. Ray, Vice President for Student Affairs and Dr. Jane Clement, Director of Health Services

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Dr. Darrell C. Ray, Vice President for Student Affairs, 235 Administration Building, Memphis, TN 38152, 901-678-2114, dcray5@memphis.edu

Dr. Jane Clement, Director of Health Services, 214 Wilder Tower, Memphis, TN 38152, 901-678-2068, jclement@memphis.edu

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

None

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Nashville, TN 37243
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Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-11-19
Rule ID(s): 8866
File Date: 3/18/19
Effective Date: 6/16/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission:	University of Memphis
Division:	
Contact Person:	Dr. Darrell Ray, Vice President of Student Affairs
Address:	253 Administration Building, Memphis, TN
Zip:	38152
Phone:	901-678-2114
Email:	Dcray5@memphis.edu

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0240-10-01	Student Immunization Requirements
Rule Number	**Rule Title**
0240-10-01-.01	Purpose
0240-10-01-.02	General Exemptions
0240-10-01-.03	Measles, Mumps, Rubella (MMR)
0240-10-01-.04	Varicella (Chicken Pox)
0240-10-01-.05	Meningococcal Disease
0240-10-01-.06	Hepatitis B
0240-10-01-.07	College of Nursing and Allied Health Professions
0240-10-01-.08	Proof of immunization

Rules of
University of Memphis

Chapter 0240-10-01
Student Immunization Requirements
New Chapter

Table of Contents is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.01 Purpose
0240-10-01-.02 General Exemptions
0240-10-01-.03 Measles, Mumps, Rubella (MMR)
0240-10-01-.04 Varicella (Chicken Pox)
0240-10-01-.05 Meningococcal Disease
0240-10-01-.06 Hepatitis B
0240-10-01-.07 College of Nursing and Allied Health Professions
0240-10-01-.08 Proof of immunization

0240-10-01-.01 Purpose is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.01 Purpose

(1) The purpose of this section is to establish a uniform policy for immunization requirements for students of the University of Memphis ("the University"). These rules are subject to any superseding federal or state law and are not to be construed as limiting the University in other areas.

Authority: T.C.A. § 49-8-203(a)(1)(E).

0240-10-01-.02 General Exemptions is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.02 General Exemptions

(1) The following students are exempted from all immunization requirements:

(a) Students enrolling in a course of study that is exclusively online and does not involve any experiential component.

(b) Students enrolled in a dual enrollment program offered on the site of a local education authority or secondary school.

(c) Students may be exempted where a physician licensed by the Board of Medical Examiners, the Board of Osteopathic Examiners, or a health department certifies in writing that a particular vaccine is contraindicated for one (1) of the following reasons:

1. The student meets the criteria for contraindication set forth in the manufacturer's vaccine package insert; or

2. The student meets the criteria for contraindication published by the Centers for Disease Control (CDC) or the Advisory Committee on Immunization Practices (ACIP); or

3. In the best professional judgment of the physician, based upon the student's medical condition and history, the risk of harm from the vaccine outweighs the potential benefit.

(d) Where a parent or guardian, or, in the case of an adult student, the student, provides the University with a written statement, affirmed under the penalties of perjury, that the vaccination conflicts with the religious tenets and practices of the parent or guardian or, in the case of an adult student, the student.

(e) Any other regulatory, statutory, or legal exemption.

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. § 49-7-124(c).

0240-10-01-.03 Measles, Mumps, Rubella (MMR) is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.03 Measles, Mumps, Rubella (MMR)

(1) General requirement: All full-time students admitted to the University must provide proof of immunization for measles, mumps, and rubella prior to class registration.

(2) Exemptions: In addition to the general exemptions in 0240-10-01-.02, the following students are exempted
from the MMR immunization requirement:

(a) Students born before January 1, 1957;

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. 49-7-124(g).

0240-10-01-.04 Varicella (Chicken Pox) is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.04 Varicella (Chicken Pox)

(1) General requirement: All full-time students admitted to the University must provide proof of immunization for varicella prior to class registration.

(2) Exemptions: In addition to the general exemptions in 0240-10-01-.02, the following students are exempted from the Varicella immunization requirement

(a) Students born before January 1, 1980;

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. § 49-7-124(g).

0240-10-01-.05 Meningococcal Disease is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.05 Meningococcal Disease

(1) All students under the age of twenty-two (22) who reside in University residential facilities must provide proof of adequate immunization against meningococcal disease as required by state and/or federal law. Students who fail to provide proof of adequate immunization will not be allowed to move into University residence halls unless they have a valid exemption.

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. § 49-7-124(g).

0240-10-01-.06 Hepatitis B is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.06 Hepatitis B

(1) Hepatitis B immunizations are not required but are strongly recommended. All new incoming students will be provided with information concerning hepatitis B disease in accordance with state law and regulation.

(2) During the registration process each new incoming student will complete a waiver form indicating receipt of the information and acknowledging that the University has provided the information required in this section.

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. § 49-7-125.

0240-10-01-.07 College of Nursing and Allied Health Professions is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.07 College of Nursing and Allied Health Professions

(1) All students admitted into the College of Nursing or any allied health professions program must also have the following vaccinations in accordance with current Center for Disease Control (CDC) guidelines, subject to immunization exemptions:

(a) tetanus, diphtheria, pertussis (Tdap)

(b) polio

(c) influenza

(d) hepatitis B

(d) any other immunization required for healthcare personnel as issued by the CDC.

Authority: T.C.A. § § 49-8-203(a)(1)(E), T.C.A. § 49-7-124.

0240-10-01-.08 Proof of immunization is added to Chapter 0240-10-01 Student Immunization Requirements and shall read as follows:

0240-10-01-.08 Proof of immunization

(1) Proof of immunization may include:

(a) Completed Certificate of Immunization form signed by a health care provider;
(b) Official health department or medical provider immunization card or shot record;
(c) Military form DD214;
(d) Active Military – ID must be provided;
(e) Official documentation from a prior college or university; or
(f) Any other proof deemed appropriate by the Student Health Center and allowed by state law or regulation.

Authority: T.C.A. § 49-8-203(a)(1)(E), T.C.A. § 49-7-124(g).

* 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)
G. Douglas Edwards	✓				
Marvin Ellison	✓				
Alan Graf, Jr.	✓				
Cato Johnson	✓				
R. Brad Martin	✓				
David North	✓				
Carol Roberts				✓	
David Kemme	✓				
Susan Springfield	✓				
Drew Gilmore					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the University of Memphis Board of Trustees on 12/4/18, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: 2/5/19

Signature: Melanie Murry

Name of Officer: Melanie Murry

Title of Officer: University Counsel/Board Secretary

Subscribed and sworn to before me on: 2/5/2019

Notary Public Signature:

My commission expires on: 04/30/2022

BRANDI N MARTIN
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY

Agency/Board/Commission: University of Memphis

Rule Chapter Number(s): Chapter 0240-10-01

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

3/1/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/18/19

Effective on: 6/16/19

Tre Hargett
Secretary of State

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ADMIN. RULES

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Wildlife Resources Agency
DIVISION:	Boating and Law Enforcement Division
SUBJECT:	Rules and Regulations for Boating Certificates – Vessel Registration and Certification of Number Fees
EFFECTIVE DATES:	June 27, 2019 through June 30, 2020
FISCAL IMPACT:	Increase state revenue to the Wildlife Resources Fund by approximately $681,000 each year.
STAFF RULE ABSTRACT:	Pursuant to Tennessee Code Annotated, Section 69-9-207, the agency is amending this rule to adjust the boat registration fees to account for the increase in the consumer price index CPI since the last adjustment 10 years ago.

Public Hearing Comments

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

[X] There were no public comments to the above-described rule.

[ ] Attached hereto are the responses to public comments.

Regulatory Flexibility Addendum

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

There are no businesses, small or otherwise, that would bear the cost of or directly benefit from the proposed rule.

Impact on Local Governments

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

The Agency does not believe that the rule amendment/repeal will have any impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Pursuant to Tenn. Code Ann. § 69-9-207, the Agency is amending this rule to adjust the boat registration fees to account for the increase in the consumer price index (CPI) since the last adjustment 10 years ago.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

There are no federal or state laws mandating this rule repeal or amendment.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Boat owners registering their boats in the State of Tennessee will be impacted by this rule.

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

No Attorney General Opinion or judicial ruling directly relating to the rule has been identified.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The proposed amendment to boat registration fees will increase state revenue to the Wildlife Resources Fund by approximately $681,000 each year.

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

Chris Richardson, TWRA, PO Box 40747, Nashville, TN 37204; 615-308-0477; Chris.Richardson@tn.gov

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

Chris Richardson, Asst. Director, TWRA, will explain the rule at the scheduled meeting of the Government Operations Committee

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Chris Richardson, TWRA, PO Box 40747, Nashville, TN 37204; 615-308-0477; Chris.Richardson@tn.gov

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

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Nashville, TN 37243
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For Department of State Use Only

Sequence Number: 03-18-19
Rule ID(s): 8890
File Date: 3/29/2019
Effective Date: 4/27/2019

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Wildlife Resources Agency
Division:	Boating and Law Enforcement Division
Contact Person:	Chris Richardson
Address:	PO Box 40747, Nashville, TN
Zip:	37204
Phone:	615-308-0477
Email:	chris.richardson@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1660-02-01	RULES AND REGULATIONS FOR BOATING CERTIFICATES
Rule Number	**Rule Title**
1660-02-01-.03	FEES FOR VESSEL REGISTRATION AND CERTIFICATE OF NUMBER.

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Amendment

1660-02-01-.03 is amended by increasing the fees to register a vessel

1660-02-01-.03 FEES FOR VESSEL REGISTRATION AND CERTIFICATE OF NUMBER.
The fee to be collected for issuance of a vessel certificate of number or registration shall be as follows:

Vessel Fee Category	1 year	2 years	3 years
16 feet and under	$~~13~~ 15	$~~24~~ 28	$~~35~~ 41
Over 16 feet to less than 26 feet	~~25~~ 29	~~48~~ 56	~~71~~ 83
26 feet to less than 40 feet	~~38~~ 44	~~72~~ 84	~~107~~ 125
40 feet and over	~~51~~ 59	~~97~~ 113	~~142~~ 166
Dealer / Manufacturer	~~32~~ 37	~~64~~ 75	~~95~~ 111
Duplicate	~~6~~ 7		
Consignment:			
16 feet and under	~~13~~ 15	~~24~~ 28	~~35~~ 41
Over 16 feet to less than 26 feet	~~25~~ 29	~~48~~ 56	~~71~~ 83
26 feet to less than 40 feet	~~38~~ 44	~~72~~ 84	~~107~~ 125
40 feet and over	~~51~~ 59	~~97~~ 113	~~142~~ 166

Authority: *T.C.A. §§ 69-9-207 and 70-1-206.* ***Administrative History:*** *Original rule filed July 31, 1998; effective October 14, 1998. Amendment filed April 3, 2008; effective June 17, 2008.*

*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)
Angie Box					
Jeff Cook					
Bill Cox					
Dennis Gardner					
Kurt Holbert					
Connie King					
Brian McLerran					
Tony Sanders					
James Stroud					
Bill Swan					
Kent Woods					
Jamie Woodson					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Fish and Wildlife Commission on 01/18/19, 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: *11/09/18*

Rulemaking Hearing(s) Conducted on: (add more dates). *01/18/19*

KIMBERLY K. WHITE
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

Date: 1/18/19

Signature: Ed Carter

Name of Officer: Ed Carter

Title of Officer: Executive Director

Subscribed and sworn to before me on: 1/18/19

Notary Public Signature: Kimberly K. White

My commission expires on: 11/8/2022

Agency/Board/Commission: Tennessee Wildlife Resources Agency

Rule Chapter Number(s): 1660-02-01-.03

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

3/1/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/29/2019

Effective on: 4/27/2019

Tre Hargett
Secretary of State

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G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Wildlife Resources Agency
DIVISION:	Director's Office
SUBJECT:	Public Record Requests
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 10-7-503
EFFECTIVE DATES:	June 6, 2019 through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	Pursuant to Tennessee Code Annotated, Section 10-7-503(9)(2), these rulemaking hearing rules establish a written public records policy designating the public records request coordinator, address the process for making records requests, and addressing the process for responding to records requests. NOTE: Rule not submitted in redline form.

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

[X] There were no public comments to the above-described rule.

[ ] Attached hereto are the responses to public comments.

Regulatory Flexibility Addendum

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

There are no businesses, small or otherwise, that would bear the cost of or directly benefit from the proposed rule.

Impact on Local Governments

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

The Agency does not believe that the rule amendment/repeal will have any impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Pursuant to Tenn. Code Ann. § 10-7-503(g)(2), these rules establish a written public records policy designating the public records request coordinator, address the process for making records requests, and addressing the process for responding to records requests.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Tenn. Code Ann. § 10-7-503 mandates the promulgation of these rules.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Any person submitting a public records request to the Agency will be affected by these rules.

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

No Attorney General Opinion or judicial ruling directly relating to the rule has been identified.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The fiscal impact to state and local government is minimal.

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

Chris Richardson, TWRA, PO Box 40747, Nashville, TN 37204; 615-308-0477; Chris.Richardson@tn.gov

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

Chris Richardson, Asst. Director, TWRA, will explain the rule at the scheduled meeting of the Government Operations Committee

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Chris Richardson, TWRA, PO Box 40747, Nashville, TN 37204; 615-308-0477; Chris.Richardson@tn.gov

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

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-07-19
Rule ID(s): 8850
File Date: 3/8/19
Effective Date: 6/6/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Wildlife Resources Agency
Division:	Director's Office
Contact Person:	Chris Richardson
Address:	PO Box 40747, Nashville, TN
Zip:	37204
Phone:	615-308-0477
Email:	chris.richardson@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1660-03-02	Rules and Regulations Governing Public Record Requests
Rule Number	**Rule Title**
1660-03-02-.01	Policy
1660-03-02-.02	Public Record Requests
1660-03-02-.03	Responding to Requests

RULES
OF
TENNESSEE WILDLIFE RESOURCES AGENCY
ADMINISTRATION

CHAPTER 1660-03-02
RULES AND REGULATIONS GOVERNING PUBLIC RECORDS REQUESTS

TABLE OF CONTENTS

1660-03-02-.01 Policy
1660-03-02-.02 Public Record Requests
1660-03-02-.03 Responding to Requests

1660-03-02-.01 POLICY

(1) The Tennessee Public Records Act ("TPRA") provides that all state, county and municipal records shall, at all times during business hours, be open for personal inspection by any citizen of this state, and those in charge of the records shall not refuse such right of inspection to any citizen, unless otherwise provided by state law. Accordingly, the public records of the Agency are presumed to be open for inspection unless an exemption is otherwise provided by law. Personnel of the Agency shall provide access and assistance in a timely and efficient manner to persons requesting access to public records. None of the provisions of this rule shall be used to hinder access to open public records; however, the integrity and organization of public records, as well as the efficient and safe operation of the Agency shall be protected as provided by current law. Concerns about the provisions or enforcement of this rule should be addressed to the Agency's Public Records Request Coordinator.

(2) Definitions:

(a) "Records custodian" means the office, official or employee lawfully responsible for the direct custody and care of a public record. The records custodian is not necessarily the original preparer or receiver of the record.

(b) "Public records" mean all documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental agency.

(c) "Public records request coordinator" means the individual, or individuals, responsible for ensuring public record requests are routed to the appropriate records custodian and are fulfilled in accordance with the TPRA. The public records request coordinator may also be a records custodian.

(d) "Redacted record" means a public record otherwise open for public inspection from which protected or confidential information is removed or obscured prior to release or inspection.

(e) "Requestor" means the person requesting access to a public record, whether inspection or duplication.

Authority: *T.C.A. §§ 69-9-209; 70-1-206; and 10-7-503.*

1660-03-02-.02 PUBLIC RECORD REQUESTS

(1) All public record requests shall be made to the Public Records Request Coordinator ("PRRC") or his/her designee in order to ensure public record requests made pursuant to the TPRA are routed to the appropriate records custodian and fulfilled in a timely manner.

(2) Requests for inspection may be made at the Agency's administrative offices located at 5107 Edmondson Pike, Nashville, Tennessee 37211 between the hours of 8:00 am and 4:30 pm. C.S.T.,

Monday through Friday excepting holidays. Requests may also be made via phone, fax, email or web submissions.

(3) Requests for copies and/or inspection and copies may be made via phone, fax, email, or web submissions in addition to being mailed or hand delivered to the Agency's administrative offices. If mailed, those should be addressed to the Public Records Request Coordinator c/o Legal Division, Tennessee Wildlife Resources Agency, 5107 Edmondson Pike, Nashville, Tennessee 37211.

Authority: *T.C.A. §§ 69-9-209; 70-1-206; and 10-7-503.*

1660-03-02-.03 RESPONDING TO REQUESTS

(1) Public Record Request Coordinator

(a) The PRRC shall review public record requests and make an initial determination of the following:

1. If the records requested are described with sufficient specificity to identify them; and

2. If the governmental entity is the custodian of the records requested.

(b) The PRRC shall acknowledge receipt of the request and take the following appropriate action(s):

1. Advise the requestor of the following:

(i) Provision of proof of state citizenship;

(ii) Fees for reproduction and labor, if applicable;

(iii) Waivers of fees, if applicable; and

(iv) Aggregation of multiple requestors.

2. The Agency may deny the request in writing if the following applies:

(i) The requestor is not a Tennessee citizen;

(ii) The request lacks specificity;

(iii) An exemption exists that makes the record not subject to disclosure under the TPRA; or

(iv) The Agency is not the custodian of the requested records. If the records relate to another governmental entity and the PRRC is aware of the correct governmental entity, the PRRC will advise the requestor of the correct governmental entity and PRRC for that entity, if known.

3. If appropriate, the PRRC may contact the requestor to see if request can be narrowed.

4. The PRRC shall forward the records request to the appropriate records custodian and help facilitate the production of the records.

(2) The designated PRRC for the Tennessee Wildlife Resources Agency will be the attorney(s) in the Legal Division for the Agency.

(3) Contact information for questions about the TPRA process:

Public Records Request Coordinator
Attention: Legal Division
5107 Edmondson Pike
Nashville, TN 37211
Telephone: 615-781-6606
Fax: 615-781-5264
E-mail: TWRA.RecordReq@tn.gov

(4) Records Custodian

(a) Upon receiving a public records request, the request shall be forwarded to the PRRC for review.

(b) If it is not practicable to promptly provide requested records because additional time is necessary to determine whether the requested records exist, to gain access to records, to determine whether the records are open, or for other similar reasons, then the PRRC shall, within seven (7) business days from the date of receipt of the request, inform the requestor if the records can be released, and if so, provide a reasonable time for production of such records.

(c) The Agency will provide existing records made in the normal course of business that are subject to disclosure pursuant to the Open Records Act; however the Agency is not required to create records in response to any request, including but not limited to summaries, spreadsheets, lists, etc.

(d) If it is determined that production of records should be segmented because the records request is for a large volume of records or additional time is necessary to prepare the records for access, the PRRC shall notify the requestor that production of the records will be in segments and that a records production schedule will be provided as expeditiously as practicable. If appropriate, the PRRC should contact the requestor to see if request can be narrowed.

(e) If additional pertinent records are discovered that were inadvertently omitted from the original records production, the records custodian will inform the PRRC, who will contact the requestor concerning the omission and produce the records as quickly as practicable.

(5) Redaction

(a) If a record contains confidential information or information that is not open for public inspection, the records custodian shall prepare a redacted copy prior to providing access. The records custodian shall coordinate with the Agency's Legal Division/PRRC for review and redaction of records.

(6) Confidential Records

(a) Records that are created on the Agency's REAL system and that are populated and updated using information from the state's drivers' license database are considered confidential pursuant to § 18 USC 2721 and Tenn. Code Ann. § 55-25-101 et seq. Such records are not subject to the Open Records Act, and shall only be disclosed in accordance with exemptions provided for in federal and state law.

(7) Inspection of Records

(a) There is no charge for inspection of open public records.

(b) The location for inspection of records within the offices of the Agency shall be specified by the records custodian.

(c) The PRRC may require an appointment for inspection or may require inspection of records at an alternate location under reasonable circumstances.

(8) Reproduction of Records

(a) Copies will be available for pickup at the location specified by the records custodian.

(b) Upon payment for costs of postage, copies will be delivered to the requestor's home address by US Postal Service.

(c) A requestor may be allowed to make copies of records with personal equipment including but not limited to a cellphone equipped with a camera but only after such records have been inspected and properly redacted, if necessary.

(d) In order to alleviate costs, copies of records may be provided via electronic transmission via email.

(9) Fees and Charges

(a) Prior to producing copies of records, requestors will be provided with an estimate of the charges, itemized by per page costs, labor, as well as other media that has been reproduced, to be assessed.

(b) When fees for copies and labor do not exceed $10.00 the fees will be waived.

(c) The Agency shall assess charges for the copying and labor based on the most current version of the Schedule of Reasonable Charges, issued by the Office of Open Records Counsel, which can be found on the Comptroller's website at: http://www.comptroller.tn.gov/openrecords/forms.asp.

(d) Payment is to be made by cash, cashier's check, money order, or credit card. The cashier's check or money order shall be made payable to the Tennessee Wildlife Resources Agency and must be delivered to the agency sales office at TWRA Agency Sales Division, Ray Bell Region II Office Building 5105 Edmondson Pike PO Box 41489 Nashville, TN 37204.

(e) Payment in advance will be required whenever reproduction costs are estimated to exceed $10.00.

Authority: *T.C.A. §§ 69-9-209; 70-1-206; and 10-7-503.*

* 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)
Angie Box					
Jeff Cook					
Bill Cox					
Dennis Gardner					
Kurt Holbert					
Connie King					
Brian McLerran					
Tony Sanders					
James Stroud					
Bill Swan					
Kent Woods					
Jamie Woodson					

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Fish and Wildlife Commission on 01/18/19, 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: *11/09/18*

Rulemaking Hearing(s) Conducted on: (add more dates). *01/18/19*

KIMBERLY K. WHITE
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

Date: 1/18/19

Signature: Ed Carter

Name of Officer: Ed Carter

Title of Officer: Executive Director

Subscribed and sworn to before me on: 1/18/19

Notary Public Signature: Kimberly K. White

My commission expires on: 11/8/2022

Agency/Board/Commission: Tennessee Wildlife Resources Agency

Rule Chapter Number(s): 1660-03-02

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

2/25/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/8/19

Effective on: 6/6/19

Tre Hargett
Secretary of State

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ADMINISTRATIVE SERVICES

Public Hearing Comments

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Environment and Conservation
DIVISION:	Office of General Counsel
SUBJECT:	Access to Public Records
STATUTORY AUTHORITY:	Tennessee Code Annotated section 10-7-503(9) provides that "[n]o later than January 1, 2019, state governmental entities shall promulgate rules regarding public records .. .. "
EFFECTIVE DATES:	June 4, 2019 through June 30, 2020
FISCAL IMPACT:	The rulemaking will only affect the Department's revenues. The impact is estimated to be minimal. The primary change that might affect the Department's budget is increasing the fee waiver from $10 to $50. Also, allowing people to make copies of records with personal equipment allows them to avoid paying fees for producing records. It is difficult to predict the fiscal impact of this change without knowing how requestors will respond to this rule change.
STAFF RULE ABSTRACT:	The purpose of this rulemaking hearing rule is to broaden Rule 0400-01-01-.01 for managing public records to incorporate all of the elements required by Tennessee Code Annotated section 10-7-503(9). The Department had previously adopted a public records policy effective June 30, 2017. The proposed rule incorporates the required elements of the existing policy, and also addresses aggregation of multiple records requests, copying of records with personal equipment, and sufficient identification of records.

Public Hearing Comments

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

Comment: Please extend the comment period to January 2019 and convene a committee of experts to advise the Department on this rulemaking.

Response: The Department has a statutory deadline to promulgate these rules "[n]o later than January 1, 2019." Tenn. Code Ann. § 10-7-503. Accordingly, there is neither time to extend the deadline nor time to form an advisory committee reflecting the full spectrum of public records requestors.

The Department complied with the statutory rulemaking hearing timeframe and took extra efforts to ensure that interested persons were aware of the rulemaking in a timely manner. In particular, the Department notified the commenter via electronic mail on October 10, 2018, at the outset of the rulemaking process, and the commenter submitted 27 pages of detailed written comments, indicating that it had sufficient time to comment. The Department has carefully reviewed and considered the comments submitted for this rulemaking, including the commenter's. The Department is also open to dialogue with the stakeholders relative to public records issues in the future.

Comment: Some commenters requested in writing prior to the hearing, and orally at the hearing, that the Commissioner be present at the rulemaking hearing.

Response: Because this is a large department with many duties and responsibilities, the Commissioner conducts business primarily through her designated staff. This rulemaking is being undertaken by the Office of General Counsel. The Department's General Counsel, who has personally advised the Commissioner on this rulemaking, was present at the hearing and heard the testimony presented. The Department's General Counsel also met with representatives of the commenters.

Comment: The Department should include language in the rule that addresses retention of emails.

Response: The Department currently employs 2,796 (as of December 6, 2018) staff, most of whom send and/or receive dozens of electronic mail messages each day. In order to manage this enormous volume of data, the State has a 90-day email retention policy, after which emails are deleted unless retained under a litigation hold. The commenter did not specify the manner in which email retention should be addressed in these rules, and the Department believes the issue is adequately addressed through existing practice.

Comment: The public records request form omits discussion of helping a requestor and does not address the fee waiver.

Response: The request form developed by the Office of Open Records Counsel (OORC) is the form required by Tenn. Code Ann. § 10-7-503(a). The Department can make this information available on the Department's website.

Paragraph (1) Purpose

Comment: The Department must state that the Act is to be interpreted broadly to ensure disclosure of public records and its records are "presumed open for inspection."

Response: This provision has been added to paragraph (1) of the rule.

Comment: Please delete "confidentiality" from the list of items that must be protected in paragraph (1) of the rule. *See generally* Tenn. Code Ann. § 10-7-504.

Response: The requested change will not be made because the Department is obligated to protect the confidentiality of documents that are exempt from disclosure.

Paragraph (3) Requesting Access to Public Records

Comment: Allowing the Department to require proof of citizenship to inspect and receive copies of records shuts down access and discourages citizens to request records, because they have to prove something. The commenter recommends not requiring proof of citizenship unless there is a plausible reason to think the person is not a citizen and then only for large requests. The commenter also suggests adding a rule that states the Department will not deny records to journalists who work for a Tennessee news organization.

Response: The Department has amended the final rule so that proof of citizenship is not mandatory but rather may be required as provided under Tennessee law. The Department generally waives proof of citizenship for most media requests and for out-of-state requestors researching the environmental status of property in Tennessee.

Comment: The proposed rule creates a "vetting" process that would precede a formal public records request and exist outside of the procedures and policies established by the Act. This allows the Department to control the contents of a citizen's request. The commenter proposes the following language:

> The Department is not required to sort through files to compile information or to create or recreate a record that does not exist. Any request for inspection or copying of a public record shall be sufficiently detailed to enable the department to identify the specific records to be provided for inspection and copying. [] To the extent a request submitted to the Department is not sufficiently detailed, Department staff will work with the requestor to clarify the request.

Response: It appears that the commenter may misunderstand the intent of the draft rule. The Department did not create a vetting process, but was instead offering to assist people in developing records requests. The proposed rule states that the requestor "may" seek such assistance before submitting a request. Nonetheless, the Department will clarify in the final rule that the purpose of this provision is to assist potential requestors. The final sentence refers to what should be done after a public records request is made, and is addressed in subpart (4)(a)2(iii) of this rule.

Comment: Two commenters stated the proposed changes hamper the rights of citizens "acting as attorneys" by restricting their communication with records custodians and Department staff. Such conduct is already governed by the Tennessee Rules of Professional Conduct. The proposed rule imposes additional restrictions on speech between attorneys and Department staff based on their occupation.

Response: The rule has been amended to notify attorneys that the Office of General Counsel represents the Department in matters related to public records requests. We expect that attorneys will comply with their ethical obligations under RPC 4.2, which provides, in relevant part:

> In representing a client, a lawyer shall not communicate about the subject of the representation with a person the lawyer knows to be represented by another lawyer in the matter, unless the lawyer has the consent of the other lawyer or is authorized to do so by law or a court order.

Paragraph (4) Responding to Public Records Requests

Comment: The Act obligates the Department to assist a requestor in appropriately narrowing their request. The rule must be amended to indicate that the Department will assist requestors to clarify their requests if they are not sufficiently specific.

Response: This comment overlooks subpart (4)(a)(2)(iii), which includes a provision for narrowing requests after submission. This subpart has been further amended to indicate that the PRRC will contact requestors for "clarification" of their requests if appropriate.

Comment: Where a public records request seeks documents stored electronically, the Department almost never would be required to sort through its files. Instead, the Department need only work with the requestor to tailor appropriate search terms that would produce the responsive records.

Response: It appears that the commenter may not be aware of the Department's burden of gathering and reviewing electronic records. The Department has many separate local and shared drives across the state where data are stored. Moreover, not all electronic records are searchable, particularly if documents have been scanned. Electronic mail is retained in individual Outlook folders for each Department staff member. Electronic mail searches are slow and cumbersome, and almost always require review for privileged or confidential information. Searches for emails that are more than 90-days old require the Department to determine whether the record custodian was on a litigation hold, and if so, the Department must then retrieve emails that are older than 90 days from a separate State agency before they can be searched. While search terms are certainly appreciated, if such search terms are required, this may indicate that the requestor has failed to provide sufficient detail to enable the Department to identify the specific records for inspection of copying as required under Tenn. Code Ann. § 10-7-503(a)(4).

Comment: The Department should clarify why there are outward and inward facing databases.

Response: This comment does not appear to be related to the public records rule. The Department is not required to maintain online public databases; however, in the interest of transparency the Department does so to promote public access to records of significant public interest. Nearly all of the records the Department uploads to its online databases are accessible by the public. Department staff routinely upload final documents such as NOVs, notices of deficiency, permit applications, draft permits for public comment, public comments, final permits, correspondence with regulated entities, inspection reports, monitoring reports, and more to its public online databases. Documents in the online databases that are not readily accessible to the public may be confidential, draft records, internal communications, or routine documents that are not likely to have significant public interest. Otherwise, public records are accessible through the procedures outlined in this rulemaking.

Comment: Commenters addressed Rule 0400-01-01-.01(4)(c)(2). They stated that the rule conflicts with federal environmental laws by restricting disclosure provisions and limiting public access to records, expands the confidentiality exemptions beyond those assigned to the Department, and burdens local governments who provide stormwater infrastructure information.

Response: This is not a proposed rule, but instead an existing rule that has previously undergone public notice and comment, review by the Office of the Attorney General, and review by the General Assembly. The rule was promulgated in response to enactment of Tenn. Code Ann. § 10-7-504(a)(21).

This rule applies to Department records, not to local government records.

Comment: Rule 0400-01-01-.01(4)(c) is overbroad and unduly restricts public access to important state records. Please omit 0400-01-01-.01(4)(c)(1) or, in the alternative, list each source of confidentiality.

Response: The Department is prohibited from providing public access to records designated as confidential by law. *See generally* Tenn. Code Ann. § 10-7-504. Repeating this prohibition in the rules does not broaden this prohibition, but helps to ensure that Department records custodians and requestors are reminded of this requirement. The primary statutory citation for confidentiality is already referenced in the rule and will be retained. Both judicial opinions and opinions of the OORC have added other bases for confidentiality, particularly attorney-client privilege. These sources of law are available to members of the public and will not be added to the rule.

Comment: Please add the Model Policy provision which states, "Whenever a redacted record is provided, a records custodian should provide the requestor with the basis for redaction. The basis given for redaction shall be general in nature and not disclose confidential information."

Response: The Department agrees, and has changed the final rule accordingly. The Department does not interpret this requirement as imposing a level of detail approaching what would be expected in a privilege log in litigation discovery.

Comment: The Department should include language in the rule that addresses retention of confidential and redacted records. The commenter proposes the following language as part of Proposed Rule 0400-01-01-.01(4)(c):

> If a record is not produced or is redacted prior to public inspection, the Department will maintain a copy of the record until the period for judicial review has ended. This duty to preserve materials withheld by the Department shall override a document retention schedule that would otherwise apply, unless the preservation period is longer.

Response: There is no requirement in the model policy to retain confidential and redacted records. The Department thinks there is ample protection under the law for records that may be related to a claim or controversy. Moreover, the mere withholding of records or redaction of public records does not create a reasonable anticipation of litigation. These records will continue to be preserved under the applicable RDAs.

Comment: Charging for inspection when a copy of a record is made in order to redact confidential information conflicts with the Tennessee Law 10-7-503(a)(7)(A)(i) that states a governmental entity may not charge to view a public record. The Department should bear the cost of printing copies for redaction if they choose not to use electronic redaction technology.

Response: The rule has been amended to reflect statutory language regarding this matter.

Paragraph (6) Copies of Records

Comment: Several comments insisted that the Department should allow requestors to use personal equipment, particularly cell phones, to take pictures of records or otherwise makes copies. One commenter proposed that the Department use the following language, "A requestor will be allowed to make copies of records with personal equipment so long as the use of personal equipment would not damage the records."

Response: The Department has changed the final rule to allow people inspecting records to take pictures with their cell phones and other devices. However, in order to protect the integrity of Department documents, the Department will not allow the use of personal equipment such as scanners and portable copiers that require physical contact with the record to make a copy.

The Department has relatively few records inspections because key documents are posted online. Moreover, the Department continues to increase efforts to create, receive, and maintain records in electronic form. Accordingly, inspections may be conducted on a Department computer. Although the rule will allow inspectors to take pictures of the computer screen, it will prohibit the insertion of devices into the computer to avoid the risk of infection. Also, copying records onto a disk or jump drive constitutes making a copy of records, not merely inspecting the records, so charges for production costs might apply.

Paragraph (7) Fees and Charges and Procedures for Billing and Payment

Comment: The Department must include a fee waiver provision that is consistent with the Model Policy and in the public interest. The commenter proposes the following language:

...

2. Upon written request, the Department may provide the requested copies of public records without charge if the Commissioner determines that the reduction is for the public good.

Response: There is no legal requirement to include a public interest waiver, and the rules already include an option to reduce "any part of the fees calculated under these rules" if doing so is in the public interest. This public interest fee reduction will be retained as proposed and the requested change will not be made.

The Department places a large volume of its public records online in multiple databases, including a Department-wide enforcement database, water permits dataviewer, water resources mapviewer (water quality assessment), groundwater protection (septic) dataviewer, air pollution control & inspections dataviewer, certified asbestos professionals, Exceptional Tennessee Waters, solid waste management dataviewer, rare species dataviewer, and the hydrologic determinations mapviewer. See https://www.tn.gov/environment/about-tdec/tdec-dataviewers.html. The Department has expended significant effort to develop and maintain these databases to provide timely, effective, and free access to records of significant public interest.

The Department receives more than 1,500 records requests each year and expends significant staff resources responding to multiple and extensive public records requests. Many such requests are submitted by organizations who assert they are acting in the public interest, including those who are seeking records for litigation purposes. Those organizations may also have segments of the public that oppose their interest. Accordingly, in most cases the Department will assess costs associated with records requests; however, the Department will consider a reduction of costs for those requests that appear to be in the overall public interest.

Comment: The Department's waiver of production costs under paragraph (7) states the department shall waive production costs that are under $10. This should be increased to $50 to reduce the burden on requestors.

Response: The Department has amended the fee waiver to reflect $50 as requested in the comment, and will maintain the waiver for the first hour of staff time.

The Department notes that the rule as originally proposed provided for both one free hour of staff time (which almost always exceeds $10) and $10 in production costs. Most records requests already fall within these two fee waivers because the Department attempts to provide documents electronically if possible. Consistent with this practice, paragraph (6) of the rule has been further clarified to specifically state that the Department will provide documents electronically to reduce costs and response time.

Regulatory Flexibility Addendum

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

(1) The 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 proposed rule is not likely to affect small businesses as it reflects the Department's current policy and practice regarding public records. The proposed rule will likely reduce the costs for citizens to obtain public records due to the proposed increase in the Department's fee waiver amount.

(2) The projected reporting, recordkeeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.

The proposed rule does not impose reporting, recordkeeping, or other administrative costs to small businesses.

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

The proposed rule is not likely to affect small businesses as it reflects the Department's current policy and practice regarding public records. The proposed rule will likely reduce the costs for citizens to obtain public records due to the proposed increase in the Department's fee waiver amount.

(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 is not likely to affect small businesses as it reflects the department's current policy and practice regarding public records. The proposed rule will likely reduce the costs for citizens to obtain public records due to the proposed increase in the Department's fee waiver amount.

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

All State agencies are required to promulgate rules by January 1, 2019, regarding access to their public records. The Department's rules are based on the model open records policy of the Office of Open Records Counsel and existing Department policy.

This rule is comparable to federal agency rules implementing the Freedom of Information Act.

(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 proposed rule is not likely to affect small businesses as it reflects the department's current policy and practice regarding public records. The proposed rule will likely reduce the costs for citizens to obtain public records due to the proposed increase in the Department's fee waiver amount.

Impact on Local Governments

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

The Department anticipates that these amended rules will not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

The purpose of this rulemaking is to broaden Rule 0400-01-01-.01 for managing public records to incorporate all of the elements required by Tennessee Code Annotated section 10-7-503(g). The Department had previously adopted a public records policy effective June 30, 2017. The proposed rule incorporates the required elements of the existing policy, and also addresses aggregation of multiple records requests, copying of records with personal equipment, and sufficient identification of records.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Tennessee Code Annotated section 10-7-503(g) provides that "[n]o later than January 1, 2019, state governmental entities shall promulgate rules regarding public records...."

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee citizens are most directly affected by this rule. Tennessee law requires the Tennessee Department of Environment and Conservation to adopt rules regarding public records.

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

While there are attorney general opinions interpreting various portions of the TPRA, the Department is not aware of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

The rulemaking will only affect the Department's revenues. The impact is estimated to be minimal. The primary change that might affect the Department's budget is increasing the fee waiver from $10 to $50. Also, allowing people to make copies of records with personal equipment allows them to avoid paying fees for producing records. It is difficult to predict the fiscal impact of this change without knowing how requestors will respond to this rule change.

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

Brian Clifford
Office of General Counsel
Tennessee Department of Environment and Conservation
(615) 532-0131
Brian.Clifford@tn.gov

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

Mallorie Kerby
Assistant General Counsel
Office of General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Office of General Counsel Tennessee Department of Environment and Conservation William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 2nd Floor Nashville, Tennessee 37243 (615) 532-0108 Mallorie.Kerby@tn.gov

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

The Department is not aware of any requests.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-05-19
Rule ID(s): 9818
File Date: 3/6/19
Effective Date: 6/4/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Environment and Conservation
Division:	Office of General Counsel
Contact Person:	Brian Clifford
Address:	William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 2nd Floor Nashville, Tennessee
Zip:	37243
Phone:	(615) 532-0131
Email:	Brian.Clifford@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0400-01-01	Fees and Charges for Certain Departmental Services
Rule Number	**Rule Title**
0400-01-01-.01	Access to Department of Environment and Conservation Public Records

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Chapter 0400-01-01
Fees and Charges for Certain Departmental Services

Amendments

Chapter 0400-01-01 Fees and Charges for Certain Departmental Services is amended by deleting the Chapter title and giving it a new title to read as follows:

Public Records and Fees and Charges for Certain Departmental Services

Authority: T.C.A. §§ 4-5-201, et seq., 10-7-503; 10-7-504(a)(21); 11-1-101; 11-1-108; and 68-203-103.

The Table of Contents to Chapter 0400-01-01 Fees and Charges for Certain Departmental Services is amended by deleting the title of Rule 0400-01-01-.01 in its entirety and substituting instead the following:

0400-01-01-.01 ~~Access to Department of Environment and Conservation~~ Public Records

Authority: T.C.A. §§ 4-5-201, et seq., 10-7-503; 10-7-504(a)(21); 11-1-101; 11-1-108; and 68-203-103.

Rule 0400-01-01-.01 Access to Department of Environment and Conservation Public Records is amended by deleting it in its entirety and substituting instead the following:

0400-01-01-.01 ~~Access to Department of Environment and Conservation~~ Public Records

(1) Purpose

The purpose of this rule is to establish the process by which the Department will provide access to its public records pursuant to the TPRA. Personnel of the Department shall provide timely access and assistance to persons requesting to inspect or receive copies of public records. No provision of these rules shall be used to hinder access to the Department's public records. The public records of the Department are presumed to be open for inspection unless otherwise provided by law. However, the confidentiality, integrity, and organization of records, as well as the efficient and safe operation of the Department, shall be protected.

(2) Definitions

"Department" means the Tennessee Department of Environment and Conservation.

"OORC" means the Tennessee Office of Open Records Counsel.

"Public records" means all documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental agency. Public records do not include the device or equipment, including, but not limited to, a cell phone, computer, or other electronic or mechanical device or equipment, that may have been used to create or store a public record.

"Public Records Request Coordinator" and "PRRC" mean the individual designated by this rule who has the responsibility to ensure public record requests are routed to the appropriate records custodian and are fulfilled in accordance with the TPRA. The Public Records Request Coordinator may also be a records custodian. The term also includes the Public Records Request Coordinator's designee.

"Records custodian" means the office, official, or employee lawfully responsible for the direct custody and care of a public record. The records custodian is not necessarily the original preparer or receiver of the record.

"Requestor" means a person seeking access to a public record, whether it is for inspection or duplication.

"TPRA" means public records laws compiled in T.C.A. Title 10, Chapter 7, Part 5, often referred to as the Tennessee Public Records Act.

(3) Requesting Access to Public Records

(a) Except as described in this subparagraph, public records requests shall be submitted to the PRRC to ensure the requests are routed to the appropriate records custodian and fulfilled in a timely manner. Public records requests may be submitted to the PRRC using the contact information set forth in part (4)(a)3 of this rule. However, if a requestor submits a public records request directly to a records custodian, the records custodian may fulfill the request without submitting the request, response, or records through the PRRC if:

1. Responding will not incur charges under this rule or the Schedule of Reasonable Charges issued by the OORC; and

2. The records custodian is reasonably certain that the information or records are not confidential.

(b) Requests for inspection only may be made orally to a records custodian or the PRRC or submitted in writing using the Public Records Request Form, found in paragraph (8) of this rule, or a substantially similar form provided by the Department, completed in accordance with the instructions, and submitted to the PRRC. If the request is made orally, as a best practice, the PRRC should request a mailing or electronic mailing address from the requestor for providing any written communication required under the TPRA.

(c) Requests for copies, or requests for inspection and copies, shall be made in writing using the Public Records Request Form, found in paragraph (8) of this rule, or substantially similar form, completed in accordance with the instructions therein, and submitted to the PRRC.

(d) The Department may require any person making a request to view or make a copy of a public record to present a government-issued photo identification, if the person possesses photo identification, that includes the person's address. If a person does not possess photo identification, the Department may require other forms of identification acceptable to the Department.

(e) The Department is not required to sort through files to compile information or to create or recreate a record that does not exist. Any request for inspection or copying of a public record shall be sufficiently detailed to enable the Department to identify the specific records to be provided for inspection and copying. A potential requestor who is uncertain of either how to sufficiently identify records or if certain records exist may contact the PRRC or other appropriate Department personnel for assistance prior to submitting a records request. The Office of General Counsel represents the Department in matters related to public records requests.

(4) Responding to Public Records Requests

(a) Public Records Request Coordinator

1. The PRRC, or a records custodian fulfilling a request in accordance with subparagraph (3)(a) of this rule, shall review public record requests and make an initial determination of the following:

(i) If the requestor identified himself or herself as a Tennessee citizen;

(ii) If the records requested are described with sufficient detail to enable the Department to identify the specific records that are to be provided; and

(iii) If the Department is the custodian of the records.

2. The PRRC shall acknowledge receipt of the request and take any of the following appropriate action(s):

(i) Advise the requestor of the requirements of this rule for obtaining public records, if the requirements have not been met.

(ii) Deny the request in writing using the Public Records Request Response Form developed by the OORC (the "Response Form"), or a substantially similar form, providing the appropriate ground, including but not limited to the following:

(I) The requestor is not, or has not presented evidence of being, a Tennessee citizen.

(II) The request lacks sufficient detail to identify the specific records to be provided for inspection or copying.

(III) An exemption or other law makes the record not subject to disclosure under the TPRA. The specific exemption or other law will be provided to the requestor in accordance with the TPRA.

(IV) The Department is not the custodian of the requested records.

(V) The records do not exist.

(iii) Contact the requestor to discuss modification or clarification of the request.

(iv) Forward the records request to the appropriate records custodian in the Department.

(v) If requested records are in the custody of a different governmental entity, and the PRRC knows the correct governmental entity, advise the requestor of the correct governmental entity and PRRC for that entity if known.

3. (i) The title of the PRRC is "Tennessee Department of Environment and Conservation, Public Records Request Coordinator." The PRRC's contact information is:

Tennessee Department of Environment and Conservation
312 Rosa L. Parks Ave., 2nd floor
Nashville, TN 37243
615-532-0109
TDEC.Public.Records.Request@tn.gov
https://www.tn.gov/environment/contacts/public-records-request.html

(ii) Any changes to the contact information will be posted on the Department's website.

(b) Records Custodian

1. Upon receiving a public records request for inspection or copies, a records custodian shall promptly make the requested public records available in accordance with T.C.A. § 10-7-503. If the records custodian is uncertain as to whether an applicable exemption or other law would apply to make requested records confidential, the records custodian shall consult with the PRRC.

2. If it is not practicable for the records custodian to promptly provide the requested records because additional time is necessary to determine whether the requested records exist; to search for, retrieve, or otherwise gain access to records; to determine whether the records are subject to confidentiality requirements; to redact records; or for other similar

reasons, then a records custodian shall contact the PRRC to discuss the reason(s). The PRRC shall send the requestor a completed Response Form within seven business days from the date the Department received the request and provide the reason(s) additional time is needed to respond to the request.

3. If the Department intends to deny a public record request, the records custodian shall coordinate with the PRRC. If the PRRC determines that grounds for denial exist, the PRRC shall deny the request in writing as provided in subpart (a)(2)(ii) of this paragraph using the Response Form.

4. If a records custodian reasonably determines production of records should be segmented because the records request is for a large volume of records, or additional time is necessary to prepare the records for access, the Department shall use the Response Form, to notify the requestor that production of the records will be in segments and that a records production schedule will be provided as expeditiously as practicable. If the Department deems it appropriate, the PRRC may contact the requestor to see if the request can be narrowed.

5. If a records custodian discovers records that existed at or before the time of the records request and that are responsive to the records request but were omitted from the Department's response to the records request, the Department shall contact the PRRC to explain the omission, and the PRRC shall contact the requestor concerning the omission and produce the records as quickly as practicable.

(c) Confidential Records and Redaction

1. Records that are designated by law as confidential, including but not limited to records designated as confidential under T.C.A. § 10-7-504, shall not be open for public inspection.

2. **In accordance with T.C.A. § 10-7-504(a)(21)(A)(i), the following records, and any other records determined by the Department to** ~~be described by such subdivision~~ allow a person to identify areas of structural or operational vulnerability of a utility service provider or permit unlawful disruption to, or interference with, the services provided by a utility service provider, **shall be treated as confidential and shall not be open for public inspection:**

~~(a)~~(i) **The latitude and longitude coordinates of public water system wells, intakes, water mains, water tanks, valves and GIS analyses derived from these data;**

~~(b)~~(ii) **Records pertaining to the delineation of source water protection areas; and**

~~(c)~~(iii) **Records pertaining to well head protection areas and inventories of significant potential contaminant sources.**

3. If a record contains confidential information or information that is not open for public inspection, the Department shall prepare a redacted copy prior to providing access to the record. However, if the entire record is confidential, then it shall not be deemed a public record and shall not be produced. Whenever a redacted record is provided, the PRRC should provide the requestor with the basis for redaction, which shall be general in nature and not disclose confidential information. The redaction of confidential information shall not constitute the creation of a new record. Costs associated with redacting records, including the cost of copies and staff time to provide redacted copies, shall be borne as provided by law.

(5) Inspection of Records

(a) The Department will not charge for inspection of the Department's public records.

(b) The PRRC or records custodian shall promptly respond to a public records request for inspection.

The time and location for inspection of records within the offices of the Department should be coordinated with the PRRC or records custodian.

(6) Copies of Records

(a) The PRRC or records custodian shall promptly respond to a public records request for copies.

(b) Copies will be available for pickup at a location specified by the records custodian or PRRC.

(c) If records are available in electronic form and the requestor agrees, the Department may provide such records via electronic mail, a web-based sharing platform, or other means to reduce costs and delivery time. Otherwise, copies will be shipped to the requestor's address.

(d) A requestor may make copies of public records with personal equipment, if the equipment does not require contact with the record. However, the Requestor shall not connect any personal equipment directly to a Department computer, including, but not limited to, utilizing a flash drive, in order to make copies of public records.

(7) Fees and Charges and Procedures for Billing and Payment

~~(1)~~(a) Production Costs

Upon a request for records under ~~Tennessee's Public Records Act, T.C.A. §§ 10-7-501, et seq.,~~ the TPRA, the Department shall charge the ~~requesting party~~ requestor a reasonable charge for production costs, including labor, duplication, and delivery, based on the most current Schedule of Reasonable Charges issued by the ~~Office of Open Records Counsel~~ OORC, available at the website of the OORC ~~Open Records Counsel in the Comptroller's Office~~. If a public record has commercial value as that term is described by T.C.A. § 10-7-506(c), the Department shall charge the requestor an additional fee in accordance with the procedure set out in Rule 0400-40-01-.02.

~~(2)~~(b) Payment of Production Costs

The Department shall provide the ~~requesting party~~ requestor an estimate of the production costs, including labor, duplication, and delivery, before the initial production of the requested records ~~documents~~. The Department shall require the ~~requesting party~~ requestor to provide full payment of the production costs, including postage if applicable, before copies of the requested records are delivered or otherwise made available.

~~(3)~~(c) Waiver of Production Costs.

~~(a)~~1. The Department shall waive the production cost if the total production cost, including labor, duplication, and delivery, is less than ~~ten dollars ($10)~~ $50.

~~(b)~~2. When the ~~requesting party~~ requestor is a federal, state, or local government agency, the Department may ~~provide~~ produce the requested copies of public records without charge if the Commissioner determines that ~~such reduction~~ the production is in the best interest of the public. A request made by a federal, state, or local government agency on behalf of a citizen under the ~~Tennessee Public Records Act~~ TPRA shall be treated as a request by a citizen and charged accordingly.

3. The Department will not charge for the first hour of labor for each request unless the requests are aggregated as provided in subparagraph (e) of this paragraph.

~~(4)~~(d) Reduction of Fees.

The Commissioner may reduce any part of the fees calculated under these rules upon ~~a~~ the Commissioner's determination that ~~such~~ the reduction is in the best interest of the public.

(e) Aggregation of Frequent and Multiple Requests

1. The Department will aggregate requests for inspection or copies of records in accordance with the Reasonable Charges for Frequent and Multiple Request Policy promulgated by the OORC when four or more requests are received within a calendar month either from a single individual or from a group of individuals deemed by the Department to be working in concert.

2. Records requests will be aggregated at the Department level.

3. The PRRC is responsible for making the determination that a group of individuals is working in concert. The PRRC or the records custodian will inform the individuals that they have been deemed to be working in concert and that they have the right to seek review from the OORC.

4. Public records requests involving routinely released and readily accessible records may be excluded from aggregation. However, a requestor will be encouraged to search for such records online prior to submitting a public records request.

5. Once a requestor makes four or more requests in a calendar month, the Department is no longer required to deduct one hour from the labor cost. The Department will deduct one hour of labor cost for each of the first three requests in a calendar month.

(8) Public Records Request Form

PUBLIC RECORDS REQUEST

The Tennessee Public Records Act (TPRA) grants Tennessee citizens the right to access records made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental entity that exist at the time of the request. The TPRA does not require records custodians to compile information or create or recreate records that do not exist.

Many of the Department's public records are available via online data viewers or public notice web pages. Potential requestors are encouraged to check these online sources for the availability of desired public records before submitting a public records request.

To: Public Records Request Coordinator, Tennessee Department of Environment and Conservation, 312 Rosa L. Parks Ave., 2nd floor, Nashville, TN 37243 or email to: TDEC.Public.Records.Request@tn.gov

From: _____

Requestor's Name and Contact Information

Is the requestor a Tennessee citizen? ☐ Yes ☐ No

Request: ☐ Inspection

☐ Copy/Duplicate

If costs for copies are assessed, the requestor has a right to receive an estimate. Do you wish to waive your right to an estimate and agree to pay copying and production costs in an amount not to exceed $_____? If so, initial here: _____.

Delivery preference: ☐ On-Site Pick-Up ☐ USPS First-Class Mail
☐ Electronic ☐ Other: _____

Records Requested:

Provide a detailed description of the record(s) requested, including: (1) type of record; (2) timeframe or dates for the records sought; and (3) subject matter or key words related to the records. Under the TPRA, record requests must be sufficiently detailed to enable a governmental entity to identify the specific records sought. As such, your record request must provide enough detail to enable the records custodian responding to the request to identify

the specific records you are seeking.

_____

_____

_____

_____

_____

Signature of Requestor and Date Submitted

CN-[ ]

Authority: T.C.A. §§ 4-5-201, et seq., 10-7-503; 10-7-504(a)(21); 11-1-101; 11-1-108; and 68-203-103.

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner on 12/27/2018, 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: *(10/01/18)*

Rulemaking Hearing(s) Conducted on: (add more dates). *(11/28/18)*

Date: December 27, 2018

Signature: Shari Meghreblian, PhD

Name of Officer: Shari Meghreblian, PhD

Title of Officer: Commissioner

KATI HICKS STATE OF TENNESSEE NOTARY PUBLIC DAVIDSON COUNTY

Subscribed and sworn to before me on: December 27, 2018

Notary Public Signature: Kati Hicks

My commission expires on: 9/6/22

Agency/Board/Commission: Commissioner of the Tennessee Department of Environment and Conservation

Rule Chapter Number(s): 0400-01-01

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

2/25/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/6/19

Effective on: 6/4/19

Tre Hargett
Secretary of State

2019 MAR -6 PM 12:21
SECRETARY OF STATE
FILED

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Tennessee Public Utility Commission
DIVISION:	Legal
SUBJECT:	Access to Public Records
STATUTORY AUTHORITY:	Public Chapter 712 of the Public Acts of 2018 amended the Tennessee Public Records Act at Tenn. Code Ann. § 10-7-503(9) to require state governmental entities to promulgate rules concerning access to public records.
EFFECTIVE DATES:	June 2, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	On April 10, 2017, the Commission established a written public records policy, which these rules will replace. Public Chapter 712 of the Public Acts of 2018 amended the Tennessee Public Records Act at Tenn. Code Ann. § 10-7-503(9) to require state governmental entities to promulgate rules concerning access to public records. First, this rulemaking deletes Rule 1220-01-01-.07, Requests for Public Information and Copying Charges, because it is outdated and does not comply with Tenn. Code Ann. § 10-7-503(9). Next, the new rules, 1220-01-04-.01 through .09, Access to Public Records, comply with the requirements of Tenn. Code Ann.§ 10-7-503(9). A summary, in pertinent part, is as follows: • The purpose of the rules is to provide timely and efficient access to public records of the Commission while at the same time preserving the confidentiality of confidential records or information as provided in state and federal law. • Public records requests shall be made to the public records request coordinator (PRRC) and the rule provides the contact information for doing so.

• Requests for copies shall be made in writing to the PRRC, and that requests for inspection only may be made verbally or in writing.

• When responding to public records requests, the rules require that requested records be made available promptly or that the PRRC respond within seven business days that more time is needed to respond, production of records shall be segmented in installments, or that the request is being denied in whole or in part because of an applicable exemption.

• Records that contain confidential or privileged information will be redacted and the requester will be informed of basis for the redaction.

• There is no charge for inspection of records and, so long as it does not compromise the integrity or organization of the records, a requester will be permitted to make copies or video using a camera or cell phone during the inspection.

• Inspection of records shall take place during office hours at the Commission's offices in Nashville, and the PRRC may require an appointment for inspection.

• A requester may use a personal camera or cell phone to take a photograph of a public record so long as the organization and integrity of the record is maintained.

• An itemized estimate of the fees for producing copies and labor charges, as applicable, will be provided to the requester before the records will be produced. Pre-payment is required. Fees and charges are based on the "Schedule of Reasonable Charges" established by the Tennessee Office of Open Records Counsel.

• Aggregation of frequent or multiple requests when 4 or more requests are received within a calendar month. Fees associated with aggregated requests will not be waived.

• After a failure to inspect/view records within 15 days of receiving notice that the records are available, or 2 missed appointments to view the records, the Commission will not comply with any requests from the requester for a period of 6-months.

• If after agreeing to pay an estimated cost for production of copies, a requester fails to pay for requested copies, the Commission will not comply with any requests from the requester until payment is received.

Public Hearing Comments

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

No person filed written comments in the docket file nor came forward to be heard during the rulemaking hearing.

See attached Memorandum.

TENNESSEE PUBLIC UTILITY COMMISSION

502 Deaderick Street, 4th Floor
Nashville, Tennessee 37243

MEMORANDUM

From: Kelly Cashman Grams, General Counsel

RE: Public Hearing Comments
Rulemaking 1220-01-04 Access to Public Records
TPUC Docket No. 17-00126

Date: December 7, 2018

The Tennessee Public Utility Commission filed its Notice of Rulemaking Hearing with the Secretary of State on August 23, 2018, and held a rulemaking hearing on the proposed new rule on October 15, 2018. No person filed written comments in the docket file nor came forward to be heard during the rulemaking hearing.

Regulatory Flexibility Addendum

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

This rule does not impact small businesses.

Impact on Local Governments

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

This rule does not impact local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

On April 10, 2017, the Commission established a written public records policy, which these rules will replace. Public Chapter 712 of the Public Acts of 2018 amended the Tennessee Public Records Act at Tenn. Code Ann. § 10-7-503(g) to require state governmental entities to promulgate rules concerning access to public records.

First, this rulemaking deletes Rule 1220-01-01-.07, *Requests for Public Information and Copying Charges,* because it is outdated and does not comply with Tenn. Code Ann. § 10-7-503(g).

Next, the new rules, 1220-01-04-.01 through .09, *Access to Public Records,* comply with the requirements of Tenn. Code Ann. § 10-7-503(g). A summary, in pertinent part, is as follows:

- The purpose of the rules is to provide timely and efficient access to public records of the Commission while at the same time preserving the confidentiality of confidential records or information as provided in state and federal law.
- Public records requests shall be made to the public records request coordinator (PRRC) and the rule provides the contact information for doing so.
- Requests for copies shall be made in writing to the PRRC, and that requests for inspection only may be made verbally or in writing.
- When responding to public records requests, the rules require that requested records be made available promptly or that the PRRC respond within seven business days that more time is needed to respond, production of records shall be segmented in installments, or that the request is being denied in whole or in part because of an applicable exemption.
- Records that contain confidential or privileged information will be redacted and the requestor will be informed of basis for the redaction.
- There is no charge for inspection of records and, so long as it does not compromise the integrity or organization of the records, a requestor will be permitted to make copies or video using a camera or cell phone during the inspection.
- Inspection of records shall take place during office hours at the Commission's offices in Nashville, and the PRRC may require an appointment for inspection.
- A requestor may use a personal camera or cell phone to take a photograph of a public record so long as the organization and integrity of the record is maintained.
- An itemized estimate of the fees for producing copies and labor charges, as applicable, will be provided to the requestor before the records will be produced. Pre-payment is required. Fees and charges are based on the "Schedule of Reasonable Charges" established by the Tennessee Office of Open Records Counsel.
- Aggregation of frequent or multiple requests when 4 or more requests are received within a calendar month. Fees associated with aggregated requests will not be waived.
- After a failure to inspect/view records within 15 days of receiving notice that the records are available, or 2 missed appointments to view the records, the Commission will not comply with any requests from the requestor for a period of 6-months.
- If after agreeing to pay an estimated cost for production of copies, a requestor fails to pay for requested copies, the Commission will not comply with any requests from the requestor until payment is received.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Public Chapter 712 of the Public Acts of 2018 amended the Tennessee Public Records Act at Tenn. Code Ann. § 10-7-503(g) to require state governmental entities to promulgate rules concerning access to public records.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Tennessee citizens

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

None

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

No change to state or local revenues or expenditures anticipated as a result of the changes to these rules.

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

Kelly Cashman-Grams, General Counsel

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

Kelly Cashman-Grams, General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Kelly Cashman-Grams, General Counsel
502 Deaderick Street, 4th Floor, Nashville, Tennessee 37243
(615) 770-6856
Kelly.Grams@tn.gov

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

None

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-01-19
Rule ID(s): 8765-8766
File Date: 3/4/19
Effective Date: 6/2/19

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Public Utility Commission
Division:	Legal
Contact Person:	Kelly Cashman-Grams, General Counsel
Address:	502 Deaderick Street, 4th Floor, Nashville, Tennessee
Zip:	37243
Phone:	615-77-6856
Email:	Kelly.grams@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
X Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row).

Chapter Number	**Chapter Title**
1220-01-01	Rules and Regulations of Practice and Procedure
Rule Number	**Rule Title**
1220-01-01-.07	Requests For Public Information And Copying Charges

Chapter Number	**Chapter Title**
1220-01-04	Access to Public Records Held by the Commission
Rule Number	**Rule Title**
1220-01-04-.01	Purpose and Scope
1220-01-04-.02	Definitions
1220-01-04-.03	Requests for Access to Public Records
1220-01-04-.04	Responses to Requests for Public Records
1220-01-04-.05	Redaction of Records

1220-01-04-.06	Inspection and Copies
1220-01-04-.07	Fees, Payment, and Waivers
1220-01-04-.08	Aggregation of Frequent and Multiple Requests
1220-01-04-.09	Failure to Inspect Records or Failure to Pay for Copies

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Rule 1220-01-01-.07 *Requests For Public Information And Copying Charges* is deleted in its entirety.

Chapter 1220-01-04 *Access to Public Records Held by the Commission* is created with the following language in its entirety:

1220-01-04-.01 PURPOSE AND SCOPE.

(1) Pursuant to Tenn. Code Ann. § 10-7-503(g), the purpose of the following public records rules are to provide timely and efficient access to public records of the Commission while at the same time preserving the confidentiality and protection of records or information as provided under state and federal law.

(2) The Tennessee Public Records Act provides that all state public records shall, at all times during regular business hours, be open for personal inspection by any citizen of this state, and those in charge of the records shall not refuse such right of inspection to any citizen, unless otherwise provided by state law.

(3) Through the Public Records Request Coordinator identified in this Rule below, the Tennessee Public Utility Commission shall timely and efficiently provide access and assistance to persons requesting to view or receive copies of public records. No provisions of this Rule shall be used to hinder access to open public records. However, the integrity and organization of public records, as well as the efficient and safe operation of the Commission, shall be protected as provided by current law. Questions about these Rules should be addressed to the Commission's Public Records Request Coordinator or to the Tennessee Office of Open Records Counsel ("OORC").

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.02 DEFINITIONS.

(1) "Commission" or "TPUC" means the Tennessee Public Utility Commission.

(2) "Public Record" means all documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental agency.

(3) "Public Records Request Coordinator" or "PRRC" means the individual(s) whose responsibility it is to ensure public record requests are routed to the appropriate records custodian and fulfilled in accordance with the Tennessee Public Records Act. The PRRC is the Commission's Docket and Records Manager within the Legal Division.

(4) "Records Custodian" means the office, official, or employee lawfully responsible for the direct custody and care of a public record. The records custodian is not necessarily the original preparer or receiver of the record.

(5) "Requestor" means a citizen of the State of Tennessee seeking access to a public record, whether for inspection or duplication.

Rule 1220-01-01-.07 *Requests For Public Information And Copying Charges* is deleted in its entirety.

~~**1220-01-01-.07 REQUESTS FOR PUBLIC INFORMATION AND COPYING CHARGES.**~~

~~(1) The Chair of the Commission, as the custodian of the public records of the Commission, shall accept requests for public information and copies of public documents and retain such requests in the files of the Commission.~~

~~(2) The Chair of the Commission shall charge the same fees that are charged by the Secretary of State for producing copies.~~

Chapter 1220-01-04 *Access to Public Records Held by the Commission* is created with the following language in its entirety:

1220-01-04-.01 PURPOSE AND SCOPE.

(1) Pursuant to Tenn. Code Ann. § 10-7-503(g), the purpose of the following public records rules are to provide timely and efficient access to public records of the Commission while at the same time preserving the confidentiality and protection of records or information as provided under state and federal law.

(2) The Tennessee Public Records Act provides that all state public records shall, at all times during regular business hours, be open for personal inspection by any citizen of this state, and those in charge of the records shall not refuse such right of inspection to any citizen, unless otherwise provided by state law.

(3) Through the Public Records Request Coordinator identified in this Rule below, the Tennessee Public Utility Commission shall timely and efficiently provide access and assistance to persons requesting to view or receive copies of public records. No provisions of this Rule shall be used to hinder access to open public records. However, the integrity and organization of public records, as well as the efficient and safe operation of the Commission, shall be protected as provided by current law. Questions about these Rules should be addressed to the Commission's Public Records Request Coordinator or to the Tennessee Office of Open Records Counsel ("OORC").

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.02 DEFINITIONS.

(1) "Commission" or "TPUC" means the Tennessee Public Utility Commission.

(2) "Public Record" means all documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental agency.

(3) "Public Records Request Coordinator" or "PRRC" means the individual(s) whose responsibility it is to ensure public record requests are routed to the appropriate records custodian and fulfilled in accordance with the Tennessee Public Records Act. The PRRC is the Commission's Docket and Records Manager within the Legal Division.

(4) "Records Custodian" means the office, official, or employee lawfully responsible for the direct custody and care of a public record. The records custodian is not necessarily the original preparer or receiver of the record.

(5) "Requestor" means a citizen of the State of Tennessee seeking access to a public record, whether for inspection or duplication.

(6) "Tennessee Public Records Act or "TPRA" means the State law codified in T.C.A § 10-7-503, *et seq.*

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.03 REQUESTS FOR ACCESS TO PUBLIC RECORDS.

(1) Public record requests, whether written or oral, shall be made to the PRRC or designee so as to ensure that such requests are routed to the appropriate records custodian and fulfilled in a timely manner.

(2) Public record requests shall include the following information clearly and concisely expressed:

(a) Name and Tennessee contact information, including telephone and email address (in order to provide any communication required under the TPRA);

(b) Detailed description of the records being requested, including type, time frame, subject matter or key words, and any other information identifying the records;

(c) Statement whether the request is for inspection or receipt of copies, or both; and

(d) Delivery preference if requesting copies.

(3) Proof of Tennessee citizenship by the presentation of a valid, unexpired state government-issued photo identification is required in order to inspect or receive copies of public records. If a person does not possess photo identification or validity of the identification is in question, the PRRC may require other forms of identification. Upon a satisfactory showing, such proof of state citizenship will not be kept or retained by the PRRC. If copies of documentation are provided by mail or electronically to the PRRC, after verification, the information will be disposed of in such a way as to maintain the confidentiality of the information.

(4) Requests for access to inspect public records maintained or received by the Commission may be made to the PRRC in-person, by mail, telephone, fax, or email.

(5) Requests for copies, or requests for inspection and copies of public records, shall be made in writing. A requestor may use the TPUC Public Records Request form available on the TPUC website. If the TPUC Public Records Request form is not used, the written request must still contain all information required under (2) of this section.

(6) Requests not made in an appropriate manner or requests that are not directed to the PRRC as provided herein, will not be accepted. Requests made via any method other than those prescribed herein will not be accepted.

(7) The contact information for the PRRC is as follows:

Tennessee Public Utility Commission
ATTN: Docket & Records Manager/Public Records Request Coordinator

Andrew Jackson State Office Building,
502 Deaderick Street, 4th Floor
Nashville, Tennessee 37243
Phone: 615-770-6850
Fax: 615-741-9934
Email: TPUCRecRequest@tn.gov

(8) Any changes to the contact information for the PRRC shall be posted on the TPUC's website.

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.04 RESPONSES TO REQUESTS FOR PUBLIC RECORDS.

(1) Public Records Request Coordinator.

(a) The PRRC shall review public records requests and make a determination of the following:

1. Whether the requester has provided evidence of Tennessee citizenship pursuant to Rule 1220-01-04-.03(3);

2. Whether the records requested are described with sufficient specificity to identify them;

3. Whether the TPUC is the custodian of the records; and

4. Whether the records requested, or any of their contents, are protected and, thus, not subject to disclosure based on applicable federal or state law or rules.

(b) The PRRC shall acknowledge receipt of the request and take any of the following appropriate actions:

1. Inform the requester of this rule chapter and the determinations made regarding:

(i) Evidence of Tennessee citizenship;

(ii) Fees (and labor threshold and waivers, if applicable);

(iii) Aggregation of multiple or frequent requests; or

(iv) Need for clarification of the request(s).

2. As appropriate, deny the request in writing and provide the appropriate ground(s) for denial,which may include:

(i) The requester is not a Tennessee citizen or has not presented evidence of Tennessee citizenship;

(ii) The request lacks specificity. The Commission may work with a requestor to clarify the request;

(iii) An exemption makes the requested record protected from disclosure;

(iv) TPUC is not the custodian of the requested records;

(v) The records requested do not exist; or,

(vi) Any other legal grounds for denial.

3. As appropriate, contact the requestor to see if the request can be narrowed or otherwise clarified.

4. Forward the records request to the appropriate records custodian within TPUC.

5. If requested records are in the custody of a different governmental entity, and the PRRC knows the correct governmental entity, advise the requestor of the correct governmental entity and PRRC for that entity, if known.

(2) Records Custodian.

(a) Upon receiving a public records request, a TPUC records custodian in collaboration with the PRRC shall gather the requested public records in accordance with Tenn. Code Ann. § 10-7-503. Before making the records available, General Counsel or his/her designee shall conduct a review to ensure the preservation of confidential or protected information as provided in state and federal law.

(b) If it is not practicable to promptly provide the requested records, the records custodian in collaboration with the PRRC shall, within seven (7) business days from the records custodian's receipt of the request, direct the PRRC to send the requestor a written response indicating the reason for the delay and an estimate of the additional time necessary to produce the records or information. Reasons for delay may include:

1. To determine whether the requested records exist;

2. To search for, retrieve, or otherwise gain access to records;

3. To determine whether all or part of the records are open or confidential;

4. To redact records; or

5. For other similar reasons.

(c) If a records custodian in collaboration with the PRRC denies a public records request, the PRRC shall deny the request in writing.

(d) If a records custodian in collaboration with the PRRC reasonably determines that production of records should be segmented because the records request is for a large volume of records, or additional time is necessary to prepare the records for access, the PRRC's response shall notify the requester that production of the records will be in segments and that a records production schedule will be provided as expeditiously as practicable. As appropriate, the records custodian or PRRC should contact the requester to see whether the request can be narrowed.

(e) If a records custodian discovers that records responsive to a request were omitted, the records custodian shall promptly contact the PRRC concerning the omission and produce the records as quickly as practicable. The PRRC will contact the requestor and supplement the records response.

Authority: *T.C.A. §§ 65-2-102, 10-7-503, and 10-7-504.*

1220-01-04-.05 REDACTION OF RECORDS.

(1) If a record contains confidential information, or information that is not open for public inspection, the PRRC or the records custodian shall prepare a redacted copy of the record and consult with General Counsel or his/her designee before providing access to the records.

(2) Whenever a redacted record is provided, the PRRC will provide the requestor with the general basis for redaction without revealing confidential or protected information.

Authority: *T.C.A. §§ 65-2-102, 10-7-503, 10-7-504, and 10-7-515.*

1220-01-06-.06 INSPECTION AND COPIES.

(1) For inspection of public records:

(a) There shall be no charge for the inspection of public records.

(b) The location for inspection of public records will be in the office location of the PRRC in Nashville and such inspection will occur during the Commission's normal business hours.

(c) Under reasonable circumstances, the PRRC may require an appointment for inspection or may require inspection of records at an alternate location.

(2) If after viewing the records, a requestor wishes to obtain copies, the Commission will make copies and assess charges in accordance with Rule 1220-01-04-.07 or copies may be made as follows:

(a) A requestor may use a personal camera or cell phone to take a photograph of a public record so long as the organization and integrity of the record is maintained. If a record contains confidential or protected information, the record may not be photographed until all appropriate redactions are completed.

(b) The requestor will not be allowed to connect any personal equipment to a TPUC computer or electronic device, including but not limited to utilizing a flash drive, in order to make copies of public records.

(3) Upon receipt of a request for copies of open public records, the Commission shall calculate the cost based on copy and labor charges for the entire request, or pro-rate the charges on a per page basis and promptly make the copies available to the requestor in the following manner:

(a) For pickup at a location specified by the PRRC;

(b) By regular mail delivery through the United States Postal Service to the requestor's home or other acceptable address within Tennessee; or

(c) Electronic records that can be sent in a single transmission will be sent by email, except when such records include personally identifiable information.

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.07 FEES, PAYMENT, AND WAIVERS.

(1) The Commission shall assess charges for copying and labor required to produce copies of the requested public records based on the most current version of the Schedule of Reasonable Charges issued by the OORC. The Schedule of Reasonable Charges is available on the Tennessee Comptroller of the Treasury's website on the OORC page.

(2) The PRRC will provide requestors with an itemized written estimate of the charges prior to producing copies of records. Requestors must pay the estimate before the records will be released.

(3) When fees for copies and labor do not exceed ten dollars ($10.00), the fees may be waived by the PRRC.

(4) Fees associated with aggregated record requests will not be waived.

(5) Payment of charges shall be payable to the Commission by cashier's check, money order, or other reliable means determined by the TPUC, and delivered as specified by the PRRC.

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.08 AGGREGATION OF FREQUENT AND MULTIPLE REQUESTS.

(1) TPUC will aggregate record requests for records of TPUC when four (4) or more requests are received within a calendar month either from a single individual or a group of individuals deemed working in concert by the PRRC.

(2) The PRRC is responsible for making the determination that a group of individuals are working in concert, and upon such determination, shall inform the individuals that they have been deemed to be working in concert and that requests will be aggregated.

(3) Routinely released and readily accessible records shall be excluded from aggregation. Such records include, but are not limited to, any public docket filings, notices, orders, agendas, meeting minutes, and other materials that are accessible on the Tennessee Public Utility Commission's website.

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

1220-01-04-.09 FAILURE TO INSPECT OR FAILURE TO PAY FOR COPIES.

(1) If a requestor makes two (2) or more requests to view a public record within a six-month period and, for each request, the requestor fails to view the public record within fifteen (15) business days of receiving notification that the record is available to view, or misses two (2) or more scheduled appointments to view, TPUC will not comply with any public records request from the requestor for a period of six (6) months from the date of the second request to view the public record unless the TPUC determines failure to view the public record was for good cause.

(2) If, after agreeing to pay an estimated cost prior to the production of copies, a requestor fails to pay the cost to produce the requested copies, TPUC will not comply with any public record requests from the requestor until payment is received.

Authority: *T.C.A. §§ 65-2-102 and 10-7-503.*

* 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)
Chair Robin L. Morrison	X				n/a
Vice Chair Kenneth C. Hill	X				n/a
Commissioner Herbert H. Hilliard	X				n/a
Commissioner David F. Jones	X				n/a
Commissioner John A. Hie	X				n/a

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Public Utility Commission (board/commission/ other authority) on DECEMBER 19, 2018, 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: 8/23/2018

Rulemaking Hearing(s) Conducted on: (add more dates). 10/15/2018

Date: 12/20/18

Signature: Kelly Cashman Grams

Name of Officer: Kelly Cashman Grams

Title of Officer: General Counsel

Subscribed and sworn to before me on: 12/20/2018

Notary Public Signature: [illegible]

My commission expires on: 3/8/2022

VICTORY RENEE LAWLESS
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY

Agency/Board/Commission: Tennessee Public Utility Commission

Rule Chapter Number(s): 1220-01-04-.01 through .09

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Attorney General and Reporter

1/17/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/4/19

Effective on: 6/2/19

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Tourist Development
DIVISION:	Administrative
SUBJECT:	Access to Public Records of the Department of Tourist Development
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 10-7-503(g)
EFFECTIVE DATES:	June 11, 2019 through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	No changes in previous regulation. This proposed rule derived as a result of Public Chapter 712 effective April 12, 2018 codified at TC.A Section 10-7-503(g)(2), requiring departments to promulgate rules to effectuate the public records request process.

Regulatory Flexibility Addendum

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

Proposed rule does not affect small business, unless said business makes a request for public records. Then said small business will be required to submit payment for the department of tourist development's efforts to produce requested records for inspection or for copies of requested records, based upon Rule 1670-07-01-.05. This review yielded that small business are no more affected than any individual Tennessee citizen.

Impact on Local Governments

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

Local governments shall have no increase in expenditures or decrease in revenues unless said local government requests the department of tourist development to produce requested records for inspection or for copies of requested records, based upon Rule 1670-07-01-.05.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

No changes in previous regulation. Rule derived as a result of Public Chapter 712 effective April 12, 2018 codified at T.C.A. Section 10-7-503(g)(2), requiring departments to promulgate rules to effectuate the public records request process.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. Section 10-7-503(g)(2): Requiring state government entities to promulgate rules regarding public records which must include the process for making requests to inspect public records or receive copies of public records, the process for responding to requests, a statement of feeds charged for copies of public records, billing procedure, and the name or title and contact information for the individual(s) within the governmental entity designated as the public records request coordinator.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

No known impact.

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

N/A

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

Fiscal impact is minimal.

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

Alicia C. B. Widrig, General Counsel

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

Alicia C. B. Widrig, General Counsel

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

312 Rosa L. Parks Ave., 13th Fl., Nashville, TN 37243; (615)741-9065; Alicia.Widrig@tn.gov

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

No.

Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-09-19
Rule ID(s): 8865
File Date: 3/13/19
Effective Date: 6/11/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission:	Tennessee Department of Tourist Development
Division:	Administrative
Contact Person:	Alicia C. B. Widrig, General Counsel
Address:	312 Rosa L. Parks Ave., 13th Fl. Tennessee Tower, Nashville, TN
Zip:	37243
Phone:	615-741-9065
Email:	Alicia.Widrig@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Table of Contents

Chapter Number	**Chapter Title**
1670-07	Access to the Public Records of the Department of Tourist Development
Rule Number	**Rule Title**
1670-07-01-.01	Purpose and Scope of Authority
1670-07-01-.02	Definitions
1670-07-01-.03	Requesting Access to Public Records
1670-07-01-.04	Responding to Public Records Requests
1670-07-01-.05	Inspection and Copies of Records
1670-07-01-.06	Fees, Payment and Waivers
1670-07-01-.07	Aggregation of Frequent and Multiple Requests
1670-07-01-.08	Failure to Inspect Copies or Failure to Pay

Rule 1670-07-01-.01 Purpose and Scope of Authority. The Tennessee Public Records Act ("TPRA"), T.C.A. §§ 10-7-501 et seq., requires each state agency to provide public access to agency records, unless exempted by the TPRA. This chapter establishes the process and procedure through which the Department of Tourist Development shall provide access to public records, pursuant to T.C.A. § 10-7-503.

(1) Department of Tourist Development public records shall, at all times during regular business hours from 8:00 AM to 4:30 PM Central Time, Monday through Friday, except for holidays and/or state issued office closures, be open for personal inspection by any citizen of this state, and those in charge of the records shall not refuse such right of inspection to any citizen, unless provided by law. Appointments for viewing are required and are to be done through the contact mechanisms of Rule 1670-07-01-.03.

(2) The Department of Tourist Development is not required to sort through files to compile information or to create or recreate a record that does not exist.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.02 Definitions.

(1) "Records Custodian" means any office, official or employee of the Department of Tourist Development lawfully responsible for the direct custody and care of a public record. The Records Custodian is not necessarily the original preparer or receiver of the record.

(2) "Public Records" means all documents, papers, letters, maps, books, photographs, mircofilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form of characteristics, made or received pursuant to law or ordinance or in connection with the transaction of official business by any governmental agency, not otherwise protected by law or exempt from disclosure under the TPRA; and does not include the device or equipment, including, but not limited to, a cell phone, computer, or other electronic or mechanical device or equipment, that may have been used to create or store a public record.

(3) "Public Records Request Coordinator" or "PRRC" means any individual within the Department of Tourist Development whose responsibility it is to ensure that public records requests are routed to the appropriate records custodian and fulfilled in accordance with the TPRA. The Public Records Request Coordinator may also be a records custodian.

(4) "Requestor" means a person seeking access to a public record, whether it is for inspection or duplication.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.03 Requesting Access to Public Records.

(1) Public record requests shall be made to the PRRC or designee in order to ensure public records requests are routed to the appropriate custodian and fulfilled in a timely manner.

(2) Proof of Tennessee citizenship is required as a condition to inspect or receive copies of public records. Proof of citizenship can be furnished by:

(a) Presentation of a valid Tennessee driver's license, or other state issued photographic identification card that includes the requestor's Tennessee address prior to the inspection of records or a requestor obtaining the records in person; or

(b) Submission of a request on business letterhead with the business address in Tennessee. Records will be sent to the Tennessee address on the letterhead and not to any other address.

(c) Requestor may affirm Tennessee citizenship through the mechanisms of submission set out in Section (5) below. Additional identification may be requested if conflicting

information about the requestor's residency is provided.

(3) The Department of Tourist Development reserves the right to request additional identification of the validity of the identification presented or of the business address is in question. The requestor will be notified in writing, when possible, of the need for additional documentation.

(4) A Requestor shall make a request for copies of Public Records in writing to the PRRC. When submitting a written request for copies, a Requestor may, but is not required to use the Public Records Request Form, located on the Department of Tourist Development website on the About the Department, Staff Directory Page, link below at Rule 1670-07-01-.03(5).

(5) A Requestor may request access to Public Records maintained and received by the Department of Tourist Development by making a request in-person, by telephone, fax, mail, email or online portal, depending on whether the Requestor is asking to inspect or receive copies of the Public Records.

Department of Tourist Development
Attn: Public Records Request Coordinator
312 Rosa L. Parks Avenue, TN Tower, 13th Floor
Nashville, TN 37243
p: (615) 741-9065 f: (615) 741-9071
Tourism.OpenRecords@tn.gov
https://stateoftennessee.formstack.com/forms/tourism_public_records_request

(6) Requests for inspection only are not required to be in writing.

(7) A request for inspection or copying of a Public Record shall be sufficiently detailed to enable the Department to identify the specific records for inspection or copying.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.04 Responding to Public Records Requests.

(1) Upon receipt of a public records request(s), the PRRC will review the request and make a determination of the following:

(a) If the Requestor provided evidence of Tennessee citizenship, pursuant to Rule 1670-07-01-.03;

(b) If the records requested are described with sufficient specificity as to be identified;

(c) If the Department of Tourist Development is the custodian of the Public Records;

(d) If the records requested, or any of their contents, are not subject to disclosure based on applicable federal or state laws or rules; and

(e) If applicable, the Department of Tourist Development will inform the Requestor, in writing, of the reasonable copying and labor charges to produce copies and any determinations made regarding aggregation of multiple or frequent requests.

(2) The PRRC shall acknowledge receipt of the request to the requestor and take any of the following appropriate action(s):

(a) Advise the requestor of this rule and the elections made regarding:

1. Proof of Tennessee citizenship;

2. Form(s) required for copies;

3. Fees (and labor threshold and waivers, if applicable); and

4. Aggregation of multiple or frequent requests.

(b) If appropriate, the request will be denied in writing and the ground(s) provided as one (1) of the following:

1. The requestor is not, or has not presented evidence of being a Tennessee citizen;

2. The request lacks specificity. The Department of Tourist Development may work with requestors to clarify the request;

3. An exemption makes the record not subject to disclosure under the TPRA, and inform the requestor of the specific exemption;

4. The Department of Tourist Development is not the custodian of the requested record; and/or

5. The records requested do not exist.

(c) If appropriate, the requestor will be contacted to determine if the request can be specified and/or narrowed.

(d) If requested records are in the custody of a different government entity and the PRRC knows the correct governmental entity, the Requestor will be advised of the correct governmental entity and PRRC for that entity, if known.

(3) Upon receiving a public records request, a Department of Tourist Development records custodian in collaboration with the PRRC shall promptly make requested public record available. If the records custodian is uncertain than an applicable TPRA exemption applies, the custodian may consult with the PRRC or the Office of General Counsel.

(a) If not practicable to promptly provide requested records, a records custodian in collaboration with the PRRC shall, within seven (7) business days from the records custodian's receipt of the request, communicate with the requestor the reason for the delay and an estimate of the time necessary to produce the records or determine the proper response to the request because additional time is necessary:

1. To determine whether the requested records exist;

2. To search for, retrieve, or otherwise gain access to records;

3. To determine whether the records are open;

4. To redact records; or

5. For other similar reasons.

(b) If a public records request is denied, the requestor shall be notified in writing.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.05 Inspection and Copies of Records.

(1) There shall be no charge to inspect Public Records. Charges may be assessed for reasonable costs incurred in producing requested materials in accordance with Tenn. Code Ann. § 10-7-503(a)(5) and Tenn. Code Ann. § 10-7-503(a)(7)(c)(i).

(2) If, after viewing the records, a requestor wishes to obtain copies, the Department of Tourist Development shall calculate cost based on the copy and labor charges for the entire request, and, if the requestor does not wish to obtain all records produced, shall pro-rate the charges on a per page basis.

(a) The Requestor will be allowed to make copies of personally inspected Public Records with his or her personal equipment, to include portable scanner, cell phone or camera;

(b) The Requestor will not be allowed to connect any personal equipment directly to a Department of Tourist Development computer or electronic device, including but not limited to, utilizing a flash drive, in order to make copies of Public Records.

(3) If the Department of Tourist Development determines to fulfill the request, the Department shall promptly respond to a public records request for copies by making the copies available to the Requestor in the following manner:

(a) For pick-up at a location specified by the PRRC;

(b) By regular mail delivery through the United States Postal Service to the Requestor's home address or other acceptable address within Tennessee; or

(c) By electronic delivery of copies to an email address as provided by the Requestor.

1. Records which include personally identifiable information cannot be sent by email.

2. Records which contain allowable personally identifiable information will only be provided by Secure File Transfer Protocol, if provided electronically.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.06 Fees, Payment and Waivers.

(1) The Department of Tourist Development shall assess charges for the copying and labor required to produce copies of the requested Public Records based on the most current version of the Schedule of Reasonable Charges, issued by the Office of Open Records Counsel ("OORC"). The Schedule of Reasonable Charges is available on the Tennessee Comptroller of the Treasury's website on the OORC page.

(2) The Department of Tourist Development shall provide a Requestor with a written, itemized estimate of the copying or labor charges prior to producing copies of records. The Requestor must agree, in writing, to pay the charges prior to the Department producing the Public Records. Payment in advance will be required before producing requested Public Records.

(3) When charges for copies and labor do not exceed $50.00, the charges may be waived by the PRRC.

(4) Payment of charges shall be payable to the Department of Tourist Development in the form of cashier's check, money order, or other reliable means as determined by the Department of Tourist Development.

(5) If an outside vendor is utilized to compile, review or redact Public Records in response to a public records request, then the Requestor will be charged the vendor's costs.

(6) The Commissioner of the Department of Tourist Development or the Commissioner's designee, may waive or reduce any part of the fees calculated under these rules upon a written determination that such waiver or reduction would be in the best interest of the public.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.07 Aggregation of Frequent and Multiple Requests.

(1) The Department of Tourist Development will aggregate record requests in accordance with the Reasonable Charges for Frequent and Multiple Requests promulgated by the Office of Open Records Counsel when more than four (4) requests are received within a calendar month either from a single individual or a group of individuals deemed to be working in concert. Records requests will be aggregated at the Department of Tourist Development level.

(2) The PRRC is responsible for making the determination that a group of individuals are working in concert. The PRRC must inform the individuals that they have been deemed to be working in concert and that they have the right to appeal the decision to the Office of Open Records Counsel.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

Rule 1670-07-01-.08 Failure to Inspect Copies or Failure to Pay.

(1) If a Requestor makes two (2) or more requests to view a Public Record within a six (6) month period and, for each request, the Requestor fails to view the Public Record within fifteen (15) business days of receiving notification that the record is available to view, the Department of Tourist Development is not required to comply with any public records request from the Requestor for a period of six (6) months from the date of the second request to view the Public Record unless it is determined the failure to view the Public Record was for good cause.

(2) If a Requestor makes a request for copies of a public record and, after copies have been produced, the person fails to pay the Department of Tourist Development the cost of producing such copies, the Department of Tourist Development is not required to comply with any public records request from the person until the person pays for such copies; provided that the person was provided with an estimated cost for producing the copies in accordance with state law and these rules prior to producing the copies and the Requestor agreed to pay the estimated cost for such copies.

Authority: T.C.A. §§ 4-4-103 and 10-7-503

* 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)

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the (*board/commission/other authority*) on 01/08/2019 (*date as mm/dd/yyyy*), and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: January 8, 2019

Signature:

Name of Officer: Kevin Triplett

Title of Officer: Commissioner, Tourist Development

SHARON REED
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 9-7-2021

Subscribed and sworn to before me on: January 8, 2019

Notary Public Signature: Sharon Reed

My commission expires on: 9-7-2021

Agency/Board/Commission:

Rule Chapter Number(s):

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

2/1/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/13/19

Effective on: 6/11/19

Tre Hargett
Tre Hargett
Secretary of State

SECRETARY OF STATE
2019 MAR 13 PM 12:35

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Economic and Community Development
DIVISION:	Administrative
SUBJECT:	Access to Public Records
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 10-7-503(g)
EFFECTIVE DATES:	June 9, 2019 through June 30, 2020
FISCAL IMPACT:	None
STAFF RULE ABSTRACT:	Public records rules required by Public Chapter 712 of Public Acts of 2018. NOTE: Rule not submitted in redline form. Entire rule contains new language.

Regulatory Flexibility Addendum

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

This rule is not projected to affect small business.

Impact on Local Governments

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

This rule is not projected to have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

Public records rules required by Public Chapter 712 of Public Acts of 2018

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Public Chapter 712 of Public Acts of 2018, codified at TCA 10-7-503(g). This law requires agencies to promulgate rules pertaining to public records. This rule will supersede ECD's current public records policy.

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Members of the public who submit requests for department records would be most affected by this rule. The General Assembly has directed all state governmental entities to promulgate rules regarding public records by January 1, 2019.

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

N/A

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

ECD estimates that there will be neither an increase nor a decrease in state government revenues and expenditures as a result of this rule. ECD's current open records policy allows the department to charge for public records requests that will exceed $100 in copying/labor charges.

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

Sharon Kolb, General Counsel; Summer Johnson, Assistant General Counsel; Garrett Guillory, Public Records Request Coordinator

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

Sharon Kolb, General Counsel; Summer Johnson, Assistant General Counsel; Garrett Guillory, Public Records Request Coordinator

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Sharon Kolb, General Counsel – 615-253-8988, Sharon.kolb@tn.gov; Summer Johnson, Assistant General Counsel – 615-253-1944, summer.carr@tn.gov; Garrett Guillory, Public Records Request Coordinator – 615-532-6346, garrett.e.guillory@tn.gov

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

n/a

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For Department of State Use Only

Sequence Number: 03-08-19
Rule ID(s): 8858
File Date: 3/11/19
Effective Date: 6/9/19

Proposed Rule(s) Filing Form

Proposed rules are submitted pursuant to Tenn. Code Ann. §§ 4-5-202, 4-5-207, and 4-5-229 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within ninety (90) days of the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by ten (10) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of ten (10) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.

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

Agency/Board/Commission:	Department of Economic and Community Development
Division:	Administrative
Contact Person:	Summer Johnson, Assistant General Counsel
Address:	312 Rosa L. Parks Ave., 27th Floor, Nashville, TN
Zip:	37243
Phone:	615-253-1944
Email:	Summer.carr@tn.gov

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

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0500-09-01	Access to Public Records
Rule Number	**Rule Title**
0500-09-01-.01	Purpose
0500-09-01-.02	Definitions
0500-09-01-.03	Requesting Access to Public Records
0500-09-01-.04	Responding to Public Records Requests
0500-09-01-.05	Inspection of Public Records
0500-09-01-.06	Copies of Public Records
0500-09-01-.07	Fees and Charges and Procedures for Billing and Payment
0500-09-01-.08	Aggregation of Frequent and Multiple Requests
0500-09-01-.09	Failure to Inspect Copies or Failure to Pay

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to http://sos-tn-gov-files.s3.amazonaws.com/forms/Rulemaking%20Guidelines_September2016.pdf.

Proposed Rules
of the
Tennessee Department of Economic and Community Development

Chapter 0500-09-01
Access to Public Records

Table of Contents

0500-09-01-.01 Purpose.
0500-09-01-.02 Definitions.
0500-09-01-.03 Requesting Access to Public Records.
0500-09-01-.04 Responding to Public Records Requests.
0500-09-01-.05 Inspection of Public Records.
0500-09-01-.06 Copies of Public Records.
0500-09-01-.07 Fees and Charges and Procedures for Billing and Payment.
0500-09-01-.08 Aggregation of Frequent and Multiple Requests.
0500-09-01-.09 Failure to Inspect Copies or Failure to Pay.

0500-09-01-.01 Purpose.

The purpose of these rules is to establish procedures regarding Public Records requests received by the Tennessee Department of Economic and Community Development and to provide economical and efficient access to Public Records as provided under the Tennessee Public Records Act.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.02 Definitions.

(1) As used in these rules, the following terms are defined as follows:

(a) "ECD" means the Tennessee Department of Economic and Community Development.

(b) "Office of Open Records Counsel" or "OORC" means the office established pursuant to Tenn. Code Ann. §§ 8-4-601 *et seq.*, or any successor office or entity.

(b) "Public Records" means all documents, papers, letters, maps, books, photographs, microfilms, electronic data processing files and output, films, sound recordings, or other material, regardless of physical form or characteristics, made or received pursuant to law or ordinance in connection with the transaction of official government business by any governmental entity, not otherwise protected by law or exempt from disclosure under the TPRA.

(c) "Public Records Request Coordinator" or "PRRC" means the individual, or individuals, designated in 0500-09-01.03(1)(c) of these rules who has, or have, the responsibility to ensure public record requests are routed to the appropriate records custodian and are fulfilled in accordance with the TPRA. The Public Records Request Coordinator may also be a records custodian.

(d) "Records Custodian" means the office, official or employee lawfully responsible for the direct custody and care of a public record. The records custodian is not necessarily the original preparer or receiver of the record.

(e) "Requestor" means a person seeking access to a public record, whether it is for inspection or duplication.

(f) "TPRA" means the Tennessee Public Records Act.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.03 Requesting Access to Public Records.

(1) Public records requests shall be made to the PRRC or his/her designee in order to ensure public records requests are routed to the appropriate records custodian and fulfilled in a timely manner.

(2) Requests for inspection only are not required to be made in writing. The PRRC will request a mailing or email address from the Requestor for providing any written communication required under the TPRA.

(3) Requests for inspection may be made orally or in writing using ECD's Public Records Request Form, available on ECD's official State of Tennessee website under the "Legal" tab, at 312 Rosa L. Parks Ave., 27th Floor, Nashville, Tennessee 37243, by telephone at 615-532-6346, by fax at 615-399-0447, or by email at ECD.PublicRecords@tn.gov.

(4) Requests for copies, or requests for inspection and copies, may be made in writing using the Public Records Request Form, available on ECD's official State of Tennessee website under the "Legal" tab, at 312 Rosa L. Parks Ave., 27th Floor, Nashville, Tennessee 37243, by fax at 615-399-0447, or by email at ECD.PublicRecords@tn.gov.

(5) A request for inspection or copies of Public Records shall be sufficiently detailed to enable ECD to identify the specific records requested for inspection or copies.

(6) Proof of Tennessee citizenship by presentation of a valid Tennessee driver's license (or alternative acceptable form of ID) is required as a condition to inspect or receive copies of Public Records. Submission of a request on business letterhead with a business address in Tennessee will also be accepted. Records will be sent to the Tennessee address on the letterhead and not to any other address.

(7) ECD reserves the right to request additional identification if the validity of the identification or business address presented is in question. The Requestor will be notified, in writing when possible, of the need for additional documentation.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.04 Responding to Public Records Requests.

(1) Public Records Request Coordinator.

(a) The PRRC shall review public record requests and make an initial determination of the following:

1. If the Requestor provided evidence of Tennessee citizenship pursuant to Rule 055-09-01-.03;

2. If the records requested are described with sufficient specificity to identify them;

3. If ECD is the custodian of the records; and

4. If the records requested or any of their contents are not subject to disclosure based on applicable federal or state laws or rules.

(b) The PRRC shall acknowledge receipt of the request and take any of the following appropriate action(s):

1. Advise the Requestor of any elections made regarding:

(i) Proof of Tennessee citizenship pursuant to Rule 0500-09-01-.03;

(ii) Form(s) required for copies;

(iii) Fees and labor threshold and waivers; and

(iv) Aggregation of multiple or frequent requests.

2. If appropriate, deny the request in writing, providing the appropriate ground such as one of the following:

(i) The Requestor is not, or has not presented evidence of being, a Tennessee citizen.

(ii) The request lacks specificity. ECD may work with the Requestor to clarify the request.

(iii) An exemption makes the record not subject to disclosure under the TPRA. ECD will notify the Requestor of the specific exemption.

(iv) ECD is not the custodian of the requested records.

(v) The records do not exist.

3. If appropriate, contact the Requestor to see if the request can be narrowed.

4. Forward the records request to the appropriate records custodian in ECD.

5. If requested records are in the custody of a different governmental entity, and the PRRC knows the correct governmental entity, advise the Requestor of the correct governmental entity and PRRC for that entity if known.

(c) The designated PRRC is the Director of Contracts of ECD; provided, however, that the responsibilities of the PRRC under this Rule may be delegated to one or more employees under the direction of the PRRC. The PRRC may be contacted at:

Tennessee Department of Economic and Community Development
ECD Legal
312 Rosa L. Parks Ave., 27th Floor,
Nashville, Tennessee 37243
Telephone: 615-532-6346
Email: ECD.PublicRecords@tn.gov

(2) Records Custodian.

(a) Upon receiving a Public Records request, a records custodian shall promptly make requested Public Records available in accordance with T.C.A. § 10-7-503. If the records custodian is uncertain that an applicable exemption applies, the custodian may consult with the PRRC, legal counsel, or the OORC.

(b) If not practicable to promptly provide requested records because additional time is necessary to determine whether the requested records exist; to search for, retrieve, or otherwise gain access to records; to determine whether the records are open; to redact records; or for other similar reasons, then a records custodian shall, within seven (7) business days from the records custodian's receipt of the request, send the Requestor a completed Public Records Request Response Form.

(c) If a records custodian denies a public record request, the Requestor shall be notified in writing.

(d) If a records custodian reasonably determines production of records should be segmented because the records request is for a large volume of records, or additional time is necessary to prepare the records for access, the records custodian shall notify the Requestor in writing that production of the records will be in segments and that a records production schedule will be provided as expeditiously as practicable. If appropriate, the records custodian should contact the Requestor to see if the request can be narrowed.

(e) If a records custodian discovers records responsive to a records request were omitted, the records custodian should contact the Requestor concerning the omission and produce the records as quickly as practicable.

(3) Redaction.

(a) If a record contains confidential information or information that is not open for public inspection, the records custodian shall prepare a redacted copy prior to providing access. If questions arise concerning redaction, the records custodian should coordinate with legal counsel or other appropriate parties regarding review and redaction of records. The records custodian and the PRRC may also consult with the OORC or with the Office of Attorney General and Reporter.

(b) Whenever a redacted record is provided, a records custodian should provide the Requestor with the basis for redaction. The basis given for redaction shall be general in nature and not disclose confidential information.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.05 Inspection of Public Records.

(1) There shall be no charge for inspection of open Public Records.

(2) The location for inspection of records within the offices of ECD will be determined by either the PRRC or the records custodian.

(3) Under reasonable circumstances, the PRRC or a records custodian may require an appointment for inspection or may require inspection of records at an alternate location.

(4) If, after viewing the records, the Requestor wishes to obtain copies, ECD will calculate cost based on the copy and labor charges for the entire request. If the Requestor does not wish to obtain copies of all records produced, ECD will pro-rate the charges on a per-page basis.

(a) The Requestor will be allowed to make copies of personally inspected Public Records with his or her personal equipment including portable scanner, cell phone, or camera.

(b) The Requestor will not be allowed to connect any personal equipment directly to an ECD computer or electronic device, including but not limited to using a flash drive to make copies of Public Records.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.06 Copies of Public Records.

(1) A records custodian shall promptly respond to a public record request for copies in the most economic and efficient manner practicable.

(2) Copies will be available for pickup at a location specified by the records custodian.

(3) Upon payment for postage, copies will be delivered to the Requestor's home address or Tennessee business address by the United States Postal Service or other courier service.

(4) Copies may be delivered electronically by email, flash drive, or other electronic medium. ECD will use a flash drive or other electronic medium if the electronic documents exceed the State's file size limitations for e-mail attachments.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.07 Fees and Charges and Procedures for Billing and Payment.

(1) ECD will assess charges for copying and labor required to produce copies of requested Public Records based on the most current version of the Schedule of Reasonable Charges issued by the OORC. The Schedule of Reasonable Charges is available on the Tennessee Comptroller of the Treasury's website on the OORC page.

(2) Records custodians shall provide Requestors with an itemized estimate of the charges prior to producing copies of records. Payment shall made in advance when charges exceed $100. If payment is not required in advance, the Requestor must agree, in writing, to pay the charges prior to ECD producing the records.

(3) When fees for copies and labor do not exceed $100, the fees may be waived. Requests for waivers for fees above $100 must be presented to the Executive Leadership Team of ECD, who is authorized to determine if such waiver is in the best interest of ECD and for the public good. Fees associated with aggregated records requests will not be waived.

(4) If an outside vendor is utilized to compile, review or redact Public Records in response to a Public Records request, the Requestor will be charged the vendor's costs.

(5) Payment will be made by personal check payable to "Tennessee Department of Economic and Community Development" presented to the PRRC.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.08 Aggregation of Frequent and Multiple Requests.

(1) ECD will aggregate record requests in accordance with the Reasonable Charges for Frequent and Multiple Request Policy promulgated by the OORC when more than four (4) requests are received within a calendar month either from a single individual or a group of individuals deemed to be working in concert. Requests will be aggregated at the ECD level.

(2) The PRRC is responsible for making the determination that a group of individuals are working in concert. The PRRC must inform the individuals that they have been deemed to be working in concert and that they have the right to appeal the decision to the OORC.

Authority: Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

0500-09-01-.09 Failure to Inspect Copies or Failure to Pay.

(1) If a Requestor makes two (2) or more requests to view Public Records within a six (6) month period and, for each request, the Requestor fails to view the public record within fifteen (15) business days of receiving notification that the record is available to view, ECD is not required to comply with any Public Records request from the Requestor for a period of six (6) months from the date of the second request to view Public Records unless it is determined than the failure to view the Public Records was for good cause.
(2) If a Requestor makes a request for copies of a public record and, after copies have been produced, fails to pay ECD the cost of producing such copies, ECD is not required to comply with any Public Records request from the person until the person pays for such copies; provided, that the person was provided with an estimated cost for producing the copies in accidence with state law prior to producing the copies and the Requestor agreed to pay the estimated cost for such copies.

Authority: T.C.A. §§ 4-3-702, 4-3-706, and 10-7-503.

* 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 O. Rolfe, Commissioner	1				n/a

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Department of Economic and Community Development on 12/18/2018 (*date as mm/dd/yyyy*) and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of ninety (90) days of the filing of the proposed rule with the Secretary of State.

Date: 12/18/2018

Signature: Robert O. Rolfe

Name of Officer: Robert O. Rolfe

Title of Officer: Commissioner

JULIA ESCHBACH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 10-7-2019

Subscribed and sworn to before me on: December 18, 2018

Notary Public Signature: Julia Eschbach

My commission expires on: October 7, 2019

Agency/Board/Commission:

Rule Chapter Number(s):

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

1/28/2019
Date

Department of State Use Only

2019 MAR 11 AM 8:20
SECRETARY OF STATE
PUBLIC CHAPTERS

Filed with the Department of State on: 3/11/19

Effective on: 6/9/19

Tre Hargett

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Mental Health and Substance Abuse Services
DIVISION:	Administrative and Regulatory Services
SUBJECT:	Licensure Administration and Procedures, Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities, and Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization – Fees – Inspection Fees
STATUTORY AUTHORITY:	Chapter 978 of the Public Acts of 2018
EFFECTIVE DATES:	June 27, 2019 through June 30, 2020
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	In light of the opioid epidemic confronting Tennessee and the need for high quality, safe, and effective treatment options, the Department, as authorized by Chapter 978 of the Public Acts of 2018 is promulgating these rules to establish: (1) Standards for determining what constitutes a high dose of the opioid employed in treatment at an OBOT; (2) Protocols for initiating or switching a patient at an OBOT to a high dose of the opioids employed in treatment; and (3) Protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment. These requirements, (1) - (3) above, are new rule requirements, and are in addition to the other Minimum Program Requirements for OBOTs found in Rule Chapter 0940-05-35. These new rule requirements establish that a dosage of greater than 16mg per day shall be considered a high dose of the treatment medication. Furthermore, these requirements establish that when initiating or

switching a patient to a high dose of the treatment medication, the prescriber must discuss the high dose treatment with the patient and document the rationale for why it is clinically appropriate. Additionally, these requirements establish that prescribers shall initiate and lead a discussion with the patient regarding readiness to taper down or off treatment medications with each patient at any time the patient requests, but no later than one year after initiating treatment and then every six months thereafter.

Secondly, the Department revised the fee schedule and inspection fee requirements found in Rule 0940-05-02 to make them consistent with the fee requirements found in PC 978, now codified at Tennessee Code Annotated, Section 33-2-406(h).

Thirdly, these rules make a number of revisions to the minimum program requirements for OBOTs found in Rule Chapter 0940-05-35, which initially became effective in January 2017. These revisions include a revision of the definition of an OBOT to make it consistent with the definition of an OBOT found in PC 978, revisions for various requirements of service according to phases of treatment, revisions to the required medical director qualifications, and several additional technical revisions.

Finally, these rules establish a new licensure category and minimum program requirements for OBOT Pluses, as required by PC 978. These rules, found in Rule Chapter 0940-05-36, include a requirement that a provider who dispenses buprenorphine products at an OBOT Plus must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR part 2. These rules only allow buprenorphine dispensing at an OBOT that has been fully licensed and in good standing for at least one year and has obtained an OBOT Plus license from TDMHSAS. An OBOT Plus facility must meet all the rule requirements of an OBOT as well as new requirements related to medication storage, recordkeeping, reporting, inventory, employing a consultant pharmacist, reporting certain patient information to the Central Registry approved by the Department, etc., before dispensing buprenorphine containing products.

The Department consulted with physicians, alcohol and substance abuse counselors, and other experts and relied on well-established practice guidance such as SAMHSA's

Treatment Intervention Protocol (TIP) 63 in the development of these rules.

Public Hearing Comments

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

See attached.

Regulatory Flexibility Addendum

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

The agency shall consider, but not be limited to, each of the following methods of reducing the impact of the proposed rule on small businesses while remaining consistent with health, safety, and well-being:

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

These rules have been written to conform to state and federal rules and to incorporate best practices for the treatment of individuals at a nonresidential office-based opiate treatment facility (OBOT) and office-based opiate treatment facilities with dispensing authorization (OBOT Plus).

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

These rules exhibit clarity, conciseness, and lack of ambiguity. As is indicated in the comments section, TDMHSAS made changes suggested by stakeholders participating in the rulemaking process to improve rule clarity, conciseness and address ambiguity.

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

These rules do not establish flexible compliance or flexible reporting requirements for small businesses because the main goal of TDMHSAS's licensure function is to safeguard the health, safety, and well-being of all individuals served by a TDMHSAS licensed provider. However, these rules were written utilizing input from small businesses, including a committee of experts that included several practicing addiction medicine physicians (T.C.A. § 4-5-205(c)), and in a way so as not to be overly burdensome to licensed providers.

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

These rules do not establish friendly schedules or deadlines for compliance and reporting requirements for small businesses because the main goal of TDMHSAS's licensure function is to safeguard the health, safety and well-being of all individuals served by a TDMHSAS licensed provider. However, these rules were written utilizing input from small businesses, including a committee of experts that included several practicing addiction medicine physicians (T.C.A. § 4-5-205(c)) and in a way so as to acknowledge the everyday business obligations of all licensed providers and provide for a common sense approach to compliance and reporting.

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

These rules are written to be clear, simple, and easy for all TDMHSAS licensed providers, including small businesses, to read and understand their obligations under the rules.

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

These rules are designed to address the operational standards necessary to safeguard the health, safety, and well-being of all individuals who receive services at an OBOT or OBOT Plus.

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

The Department worked with various stakeholders, including a committee of experts that included several practicing addiction medicine physicians (T.C.A. § 4-5-205(c)), some of which were small business owners, to ensure that these rules do not unnecessarily create entry barriers or other effects that stifle entrepreneurial activity or curb innovation.

Impact on Local Governments

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

These rules will not have an impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

(A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

In light of the opioid epidemic confronting Tennessee and the need for high quality, safe, and effective treatment options, the Department, as authorized by Public Chapter 978 of the Public Chapter Acts of 2018 (PC 978), is promulgating these rules to establish:

(1) Standards for determining what constitutes a high dose of the opioid employed in treatment at an OBOT;
(2) Protocols for initiating or switching a patient at an OBOT to a high dose of the opioids employed in treatment; and
(3) Protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment.

These requirements, (1) – (3) above, are new rule requirements, and are in addition to the other Minimum Program Requirements for OBOTs found in Rule Chapter 0940-05-35. These new rule requirements establish that a dosage of greater than 16mg per day shall be considered a high dose of the treatment medication. Furthermore, these requirements establish that when initiating or switching a patient to a high dose of the treatment medication, the prescriber must discuss the high dose treatment with the patient and document the rationale for why it is clinically appropriate. Additionally, these requirements establish that prescribers shall initiate and lead a discussion with the patient regarding readiness to taper down or off treatment medications with each patient at any time the patient requests, but no later than one year after initiating treatment and then every six months thereafter.

Secondly, the Department revised the fee schedule and inspection fee requirements found in Rule 0940-05-02 to make them consistent with the fee requirements found in PC 978, now codified at T.C.A. § 33-2-406(h).

Thirdly, these rules make a number of revisions to the minimum program requirements for OBOTs found in Rule Chapter 0940-05-35, which initially became effective in January 2017. These revisions include a revision of the definition of an OBOT to make it consistent with the definition of an OBOT found in PC 978, revisions for various requirements of service according to phases of treatment, revisions to the required medical director qualifications, and several additional technical revisions.

Finally, these rules establish a new licensure category and minimum program requirements for OBOT Pluses, as required by PC 978. These rules, found in Rule Chapter 0940-05-36, include a requirement that a provider who dispenses buprenorphine products at an OBOT Plus must report the fact that the provider dispenses buprenorphine products to the provider's licensing board, check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR part 2. These rules only allow buprenorphine dispensing at an OBOT that has been fully licensed and in good standing for at least one year and has obtained an OBOT Plus license from TDMHSAS. An OBOT Plus facility must meet all the rule requirements of an OBOT as well as new requirements related to medication storage, recordkeeping, reporting, inventory, employing a consultant pharmacist, reporting certain patient information to the Central Registry approved by the Department, etc., before dispensing buprenorphine containing products.

The Department consulted with physicians, alcohol and substance abuse counselors, and other experts and relied on well-established practice guidance such as SAMHSA's Treatment Intervention Protocol (TIP) 63 in the development of these rules.

(B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

There are no federal laws or regulations mandating promulgation of these rules. However, Public Chapter 978 of the Public Acts of 2018 requires the Commissioner of Mental Health and Substance Abuse Services to, revise existing OBOT licensure rules to establish:

(1) Standards for determining what constitutes a high dose of the opioid employed in treatment at an OBOT;
(2) Protocols for initiating or switching a patient at an OBOT to a high dose of the opioids employed in treatment; and
(3) Protocols for initiating periodic prescriber-initiated-and-led discussions with patients regarding patient readiness to taper down or taper off the opioids employed in treatment.

The Department filed emergency rules effective January 1, 2019 to meet the requirements above. Subsections (1)(a)(3), (1)(c), and (1)(d) of 0940-05-35-.13 contained within this permanent rule filing will replace those emergency rules.

Additionally, PC 978 required the Department to promulgate rules to establish requirements for approval of dispensing of buprenorphine products at an OBOT Plus

(C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The entities that will be most directly impacted by these rules are service entities that include, but are not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients. A rulemaking hearing for these rules was held on October 30, 2018. The Department received several comments at that rulemaking hearing, which the Department considered and relied upon in drafting these final rules. All in all, the Department did not receive any comments urging rejection of this rule.

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

None.

(E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

It is estimated that these rules will have a minimal fiscal impact on state and local governments.

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

Zack Blair
TDMHSAS
Director, Office of Legislation and Rules

Dr. Wesley Geminn
TDMHSAS
Chief Pharmacist and State Opioid Treatment Authority

Alex King
TDMHSAS
Director, Office of Licensure

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

Zack Blair
TDMHSAS

Director, Office of Legislation and Rules
Dr. Wesley Geminn
TDMHSAS
Chief Pharmacist and State Opioid Treatment Authority

(H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Zack Blair
TDMHSAS
Director, Office of Legislation and Rules 500 Deaderick Street, 5th Floor
Nashville, TN 37243
(615) 532-0977
Zack.Blair@tn.gov

Dr. Wesley Geminn
TDMHSAS
Chief Pharmacist and State Opioid Treatment Authority
500 Deaderick Street, 6th Floor
Nashville, TN 37243
(615) 532-6736
Wesley.Geminn@tn.gov

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

None.

TDMHSAS Responses to Comments about
Rules Chapter 0940-05-02
Licensure Administration and Procedures
Rules Chapter 0940-05-35
Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities
Rules Chapter 0940-05-36
Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization
made prior to, during, or after the Rulemaking Hearing held on October 30, 2018

**The Department has attempted to present the following comments in a form that is both easy to read and accurate to the intent of the commenter. In rare cases, the Department made technical edits to increase the readability of a comment. Please forgive any typographical errors in both the comments and responses.*

***All citations referenced by the stakeholders in this section refer to the version of the rule as it appeared in the Notice of Rulemaking Hearing document filed by TDMHSAS with the Secretary of State on August 27, 2018.*

GENERAL COMMENTS

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: Possible additions to the rules.

1. Emphasis placed that all facilities comply with relevant OSHA and HIPAA requirements.
2. If a patient leaves one OBOT for another, the discharge and/or transfer plan from the prior facility should be in the chart. The facility should be required to release within 10 days of admission to new facility.
3. Minimum amount of time in clinic for MD. Such as for every 25 patients an MD carries should require 8 hours in the clinic each week.
4. All providers should maintain a TennCare ID.
5. Employees **OR** MD from each OBOT should maintain a board or committee seat at a social service non-profit.
6. Patient cap of 25 visits per day per MD. Office visit should be defined as...with a qualified provider lasting no less than 15 minutes.
7. 24/7 call/answering service coverage.
8. 40 "open" office hours per week.

TDMHSAS Response: In response to (1) above, the Tennessee Department of Mental Health and Substance Abuse Services ("TDMHSAS" or "Department") believes that the requirements of Rule 0940-05-06-.01(1) Minimum Program Requirements for All Services and Facilities are sufficient to inform nonresidential office-based opiate treatment facilities ("OBOTs")and nonresidential office-based opiate treatment facilities with dispensing authorization ("OBOT Plus") that they must comply with all applicable federal, state and local laws, rules, and regulations.

In response to (2) above, the Department believes that this concern is appropriately addressed in Rule 0940-05-35-.08(1).

In response to (4) above, while TennCare is currently in the process of enhancing its medication assisted treatment (MAT) network, requiring OBOTs to maintain a TennCare ID might result in limiting access to MAT services.

In response to (5) above, the Department believes that such a requirement would be outside the scope of these rule requirements, and could be overly burdensome. In response, in general, to the comments above, the Department wants to stress that these are minimum program standards for OBOTs and OBOTs Pluses. Although there are several suggestions above that may be good practice (see (3), (5), (6), (7), and (8) in Mr. Manning's comment), the purpose of these rules is to establish minimum program requirements and the Department intends to give facilities the flexibility to establish their own best practices in order to provide quality care to their patients.

For these reasons, the Department does not adopt the changes suggested by this comment.

MARY LINDEN SALTER, LCSW, EXECUTIVE DIRECTOR, TENNESSEE ASSOCIATION OF ALCOHOL, DRUG & OTHER ADDICTION SERVICES ("TAADAS"): On behalf of the Tennessee Association of Alcohol, Drug and other Addiction Services (TAADAS), I am pleased to submit comments concerning the proposed amendments to TDMHSAS's current rules for Nonresidential Office-Based Opiate Treatment Facilities (OBOT) and the proposed establishment of TDMHSAS licensure rules re: Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization (OBOT Plus). TAADAS is a statewide association of alcohol and drug abuse, recovery and prevention professionals and organizations across Tennessee. We represent over 69 agencies statewide and over 39 individual member professionals. I attended the rulemaking hearing on October 30 although TAADAS did not provide any public comments at that time.

The second issue *[TDMHSAS has grouped Ms. Linden's first comment with similar comments, see p. 18 of TDMHSAS's responses to stakeholder comments.]* that we would like to bring to your attention has to do with the lack of definition and insertion of the use of telehealth and telemedicine in to these requirements. This addition could address some of the concerns noted above with the allocation of a medical director's time. TAADAS would advocate for the insertion of telehealth and telemedicine standards and usage consistent with the current DEA standards throughout both rules. The use of telemedicine and telehealth are approved and in use for TennCare as well as other insurance companies.

Thank you for your attention to our comments and concerns regarding proposed changes to TDMHSAS licensure rules. I am happy to answer any questions that you may have regarding our comments and would welcome the opportunity to discuss the impact of this proposal on those seeking or in addiction treatment or recovery programs. We appreciate your commitment to making this proposal responsive to the realities of community providers in our state. I can be reached at marylinden@taadas.org or by phone at 615-780-5901, x-118 to respond to questions on this proposal or any other issues at any time.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: Just a couple of things I got to thinking about. I don't know if it would be appropriate or not but for the department to consider rules regarding telemedicine within the facilities. I didn't see anything on that. I know telemedicine is, can be a great thing, but I've also heard of the doctors that live in Montana doing telemedicine and flying them to Tennessee were serving as medical directors and are here once every two months or something like that. That goes on so I don't know if the department could craft some rules regarding that, maybe consistent with the DEA rules or something.

TDMHSAS Response: The Department acknowledges the comments above, but contends that the current version of Rule 0940-05-35-.02(2)(e) sufficiently addresses the concerns expressed in these comments. Although the Department contends a change to this rule is unnecessary at this time, pursuant to Public Chapter 978 of 2018 ("PC 978"), now codified at T.C.A. § 33-2-403, the Department will be reviewing these rules every even-numbered year. For these reasons, the Department does not adopt the changes suggested by these comments.

Y.T. "JANIE" MCGINLEY, CHIEF EXECUTIVE OFFICER, LIFESPAN HEALTH, HARDIN COUNTY REGIONAL HEALTH CENTER: Hardin County Regional Health Center dba Lifespan Health appreciates the opportunity to comment on Chapter 0940-05-02 Licensure Administration and Procedures and

Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities. These proposed rules will result in a reduction of treatment options for many persons in our area. Persons without insurance or sufficient resources to pay for this care will be impacted. In addition, in my service area none of the 'cash' clinics accept TennCare, effectively making this care unavailable to this population as well.

Lifespan Health is a Federally Qualified Health Center with 6 locations in Hardin, Wayne, and McNairy counties in Tennessee. We provide comprehensive medical, mental health and substance use services for almost 13,000 underserved and uninsured Tennesseans. Over 44% of our patient population has TennCare coverage. We are the only OB provider within our service area. Our program began as a small scale taper program in order to assist patients to taper through a 16 week or longer period of time followed by monthly naltrexone injections. We have had some success with the program. Additionally, approximately 1/3 of participants in our program at any given point in time are pregnant women, so we are effectively doubling our impact with this program.

Brian Haile, the CEO of Neighborhood Health gave me permission to reference his letter, and I'm writing to let you know that we also share many of his same concerns. We currently have two other providers (cash clinics) within our community. These are not valid options for our patients. In 2016, my Medical Director (Anjeanette Hall, MD) who had started our MAT program suffered a stroke on the Friday before Labor Day. This left me scrambling all weekend attempting to find a physician who could take care of her weekly buprenorphine Tuesday clinic (which included 10 pregnant women). What I discovered during that period of time was that there was an abundance of access to the services, but none of the providers within driving distance of 80 miles accepted TennCare and would not provide the services without cash payment (varying from $300-$400) up front for the visit. Lifespan Health has been committed to making the service available since that time, and we are currently attempting to expand it. I fear that these proposed rules will significantly limit our ability to do so.

Like Brian, I genuinely believe that the Department is sincere in its efforts and attempting to balance the multi-faceted issues related to this treatment (motivation, diversion, availability, etc.). It is our fervent hope to be able to expand our program to its full potential, and it makes us sad to think that these proposed rules could result in our being unable to meet this within our community. We stand ready to work with the Department in addressing this issue and hope that we will be able to do so.

Please move carefully as you propagate rules that actually impede our ability to serve the underserved people in our area.

BRIAN HAILE, JD, MPP, MA, CHIEF EXECUTIVE OFFICER, NEIGHBORHOOD HEALTH:
Neighborhood Health appreciates the opportunity to comment on the proposed Chapter 0940-05-02 Licensure Administration and Procedures and Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities. These proposed rules will effectively reduce treatment options for persons struggling with opioid addiction and will force Tennessee to further ration care. Those Tennesseans who lack insurance or resources will largely suffer this cruel impact. We write to explain the basis for our conclusions and to recommend options to avoid these preventable outcomes.

By way of background, Neighborhood Health is a Federally Qualified Health Center with 13 locations in Nashville and rural Middle Tennessee. We provide comprehensive medical, dental, mental health and substance use services for over 30,000 underserved and uninsured Tennesseans. The need we serve is great: Over 5,000 of our patients are experiencing homelessness, and more than 56% have no health insurance.

Through our work we see each day the human cost to individuals and families of the opioid use disorder epidemic. We initiated a medication assisted treatment (MAT) program for patients with opioid use disorder at one health center in 2016. Perhaps because of our direct experience we were among the first community health centers in Tennessee to launch a MAT program. Since that time we have been able to expand services to three additional health center locations, including two in public housing communities and one in rural Wilson County. Four of our family practice physicians have been able to provide MAT services as part of their practice.

Despite our best efforts to expand treatment capacity (While we have expanded our clinics and prescribing physicians, we have been limited as many physicians were in their first year of providing treatment. As we approach the second year, though, we look forward to expanding the number we serve. This will help to meet the growing demand for MAT services.), we still have over 70 individuals on our waiting list – and more call each week. These are generally patients who cannot get services elsewhere due to their lack of insurance and limited financial resources. The only alternative for these patients is to pay prohibitively large amounts at other providers (typically cash clinics) for ongoing outpatient services. While we have worked closely with your Department to identify other options for those on our waiting list, we have had no success in reducing the waiting list by any meaningful amount. Our experience reflects the reality that outpatient treatment slots in Middle Tennessee are already perilously small.

Were it not for these proposed rules, community health centers would be the providers best able to expand outpatient opioid use disorder treatment in Tennessee. Recognizing the needs and our potential (and the dearth of good alternatives), federal and state officials have awarded millions of dollars in new grants to community health centers in Tennessee to provide this care. This makes eminent sense: community health centers care for the uninsured and otherwise underserved patients with opioid use disorder – and we provide these patients with a robust, comprehensive health care home. Yet, these proposed rules will now effectively limit the capacity of providers like us to expand our offerings (and treat more patients) at the very time such treatment options are most needed in our state.

The underlying cause for concern is straightforward: The proposed rules were written primarily for entities (largely for-profit) whose principal business or practice relates to addiction medicine and opioid treatment. The proposed rules do not reflect the clinical or operational realities of those (non-profit) providers who are most likely to care for the uninsured and underserved. Because the proposed rules lack such nuance, the application of these rules to community health centers effectively forecloses our ability to expand treatment above very restrictive thresholds.

Implementation of these provisions would effectively limit each community health center to treat no more than 149 MAT patients at any one time, thereby reducing treatment slots compared with what would otherwise be available.

What, then, happens to patient #150? If the patient is uninsured or has only limited coverage, where can they go for outpatient addiction treatment? Our experience recounted above makes clear that this patient (and every one after him or her) has few if any options. These individuals are effectively sentenced to a life of continued addiction. They will get what they can on the street and will suffer almost certain death, if not by an opioid overdose then by heroin or fentanyl. In this sense, the application of the proposed rules to community health centers is not only counterproductive, it is deadly.

There are at least several alternatives that would prevent these outcomes:

- **Exempt entirely** [Emphasis added by Neighborhood Health] community health centers from the staffing requirements, inspections, and licensure fees in the proposed rules; or
- **Provide expansive waivers** [Emphasis added by Neighborhood Health] for community health centers from the staffing requirements, inspections, and licensure fees in the proposed rules.

The exemption or waivers could be time-limited – and linked to a concrete public health standard. For example, community health centers could be exempt or receive waivers unless and until the number of opioid-related deaths decline to below numbers for 2014. If overdose deaths fall (either because of an additional expansion in the supply of outpatient treatment from other providers or a reduction in the demand for treatment because of a reduction in underlying opioid use), the Department could end the exemption or waiver. The key, though, is to adopt a standard that is tied to the underlying policy goal: the reduction in the prevalence of opioid addiction and resulting overdose deaths.

The exemption or waivers could also be targeted. For example, the exemption or waivers could expressly apply only to Federally Qualified Health Centers as defined at 42 USC § 254b (i.e., § 330 of the Public Health Service Act). The exemption or waivers could apply only to the subset of community health centers that had established MAT programs prior to July 1, 2018 and/or that receive dedicated funding for

opioid treatment from the U.S. Department of Health and Human Services (including but not limited to funding from SAMHSA or HRSA) or from your Department. In addition, the exemption or waivers could be limited to community health centers whose Boarded family practice or internal medicine providers treat no more than a specified number (perhaps 100 patients), though the aggregate number for a community health center location may exceed 150.

While this is not the appropriate forum to outline legal arguments, we do believe the Department has the legal authority to issue the exemption or waivers described above. If the Department is uncertain about its authority, we will be able to provide additional comments or interpretive guidance to support our contention in this regard. Should the Department ultimately conclude it does not have adequate legal authority, then we believe it is incumbent on the Department to seek appropriate statutory clarification so as to ensure these rules do not adversely affect the number of outpatient treatment slots available to those without insurance or ability to pay. We stand ready to partner with and advocate for the Department at every stage of this analysis and process.

We genuinely believe that the Department is sincere in its desire to create more access to outpatient opioid addiction treatment and to save lives. **We also believe equally strongly that only exemptions or waivers from the proposed rules for community health centers will accomplish this goal.** [Emphasis added by Neighborhood Health] This is one of few occasions in which substitutions, alternatives, or compromises will not just fall short, they will cost lives.

You have a partner in Neighborhood Health and many, many other community health centers who are ready to do more even than we do today. No one else but us is now in a position or has the demonstrated willingness to serve these patients in a comprehensive fashion and sustain their recovery. We as community health centers can do it, but we can only do so with your help – and your decision to exempt community health centers from the proposed rules or provide broad waivers. I promise Neighborhood Health will provide high-quality treatment and expand treatment slots in a way to make you proud you made this decision. I promise, too, we will help you save lives and sustain recoveries.

Please create the conditions that allow us to help meet the demand in our communities for outpatient opioid addiction treatment. This is a matter of life and death.

LIBBY THURMAN, HEALTH POLICY DIRECTOR, TENNESSEE PRIMARY CARE ASSOCIATION ("TPCA"): We are the member group for federally qualified health centers in the state of Tennessee. So we have 30 organizations with approximately 200 sites all across the state that are in rural and urban areas. I'm going to comment very generally here and we're going to submit some very specific comments to you in writing.

So, we're pleased to offer comments on this rule. We do have concerns that if the rules are implemented as written they will significantly impede access to care for some Tennesseans who really need treatment. So we acknowledge that you cannot change the patient thresholds that were set in law but we do feel there's some changes to the proposed rules that would make these rules more workable for health centers who could then continue to offer essential treatment to those in their communities.

So, OBOTs are one setting for medication assisted treatment but applying the requirements designed for OBOTs to all settings does seem challenging and restrictive. Comprehensive care is offered at community health centers. We serve underserved areas and populations and offer medical, dental, behavioral and increasingly, substance abuse treatment, often under one roof so it is an integrated setting.

Additionally, most community health centers are patient-centered medical homes so they focus on team based care, evidence based care, patient centered access and continuity, care management and quality improvement. Community health centers can offer responsible and affordable treatment for patients who often have no other place to obtain that treatment. Of all of our patients across the state, not just those receiving MAT, but in general, 77% of our patients are under 100% of the federal poverty level. Additionally, 33% of them are uninsured. So you can see they have few options for access to care and we are their source of care for all the services I mentioned and again, increasingly, the MAT services.

Currently, there are seven Tennessee community health centers that offer MAT but we do expect that number to increase. Recently through some federal investments, $6.1 million was awarded to 23 health centers across the state all for the purposes of substance abuse and mental health treatment. So, not all of those will be offering MAT but we believe a good many will. So again these rules could come into play for more health centers.

So of the programs that are currently, or the health centers that are currently offering MAT, all of them offer behavioral health care as a part of their care and they also all serve uninsured, underinsured and TennCare patients which I think is a unique population that our health centers have a lot of experience serving. So we do understand the need for structure and oversight on MAT services and we hope that we can work with you and suggest some ways that these rules would not impede access to care for the really vulnerable populations that we serve.

TERRI SABELLA, CEO, TPCA [These are a portion of TPCA's written comments referenced in Libby Thurman's comments above]: The Tennessee Primary Care Association is pleased to offer comments on the proposed rules on Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities (OBOTs). If the proposed rules are finalized as written, they will limit access to care for many Tennesseans who desperately need treatment for opioid use disorder. We acknowledge that TDMHSAS cannot alter the OBOT patient thresholds outlined in Public Chapter 978 but we believe that changes to some sections of the proposed OBOT rules will enable Federally Qualified Health Centers (also known as FQHCs or community health centers) to offer essential access to treatment for opioid use disorder in their communities. As creating access to treatment for opioid use disorder is a priority for not only your agency, but many state and federal agencies, facilitating the provision of services through our state's community health centers is essential.

OBOTs are one setting for medication assisted treatment (MAT); applying requirements that are designed for the OBOT setting to other care settings is challenging and unnecessarily restrictive. Community health centers offer comprehensive primary care services to underserved areas and populations and have been leaders integrating medical care, behavioral health, dental care, pharmacy, and other services under one roof. Most community health centers are Patient Centered Medical Homes, meaning they focus on team-based care, delivering evidence-based care, patient-centered access and continuity, care management and support, care coordination and care transitions, and performance measurement and quality improvement. Community health centers offer responsible and affordable access to treatment for uninsured patients who cannot afford to pay the cash prices of other treatment facilities in their areas. The majority of existing OBOTs that responded to a recent TDMHSAS survey indicated that their facilities were private pay or cash only facilities. Based on 2017 data, 77% of Tennessee's 437,533 FQHC patients had incomes under 100% of the Federal Poverty Level and 33% of patients were uninsured. It is clear that our patients have limited access to private insurance and lack the funds to pay cash for MAT services. Without access to treatment through community health centers, the opioid crisis will not adequately be addressed in Tennessee.

Currently, seven Tennessee community health centers provide MAT services but we expect that additional centers will begin providing MAT, given recent federal investments, unless regulatory barriers prevent development of this access. The U.S. Health Resources and Services Administration recently awarded $6.1 million to 23 Tennessee community health centers to support expanding access to quality substance use disorder and behavioral health services. The funding was provided in recognition of community health centers' ability to provide quality substance abuse and behavioral health care in their communities and positions them to significantly increase their role in fighting the opioid crisis. Each health center that currently offers MAT provides treatment to uninsured, underinsured and TennCare patients. Each program also includes behavioral health services as an integral part of treatment. Many of Tennessee community health center MAT programs have waiting lists and are unable to locate a credible provider that can treat their patients. Our community health centers understand the need for structure and oversight around the development and operation of MAT programs and that the Department intends to closely monitor such programs. However, our Tennessee community health centers request that the Department recognize that the care settings in which MAT is provided are not all structured, funded, and

staffed like traditional OBOTs and that safe, comprehensive care may be made available in other settings.

Exemption of Federally Qualified Health Centers (FQHCs)
Federally Qualified Health Centers operate in a highly regulated environment with support services, appropriate supervision, quality improvement, and transparency required by statute. We recommend the real difference in treatment environment be acknowledged and respected by excluding FQHCs from the proposed rules entirely. While we provide recommendations below designed to mitigate the barriers presented by the proposed rules, only an exemption will truly serve to ensure access to quality care for vulnerable Tennesseans regardless of ability to pay. Therefore, **we recommend an exemption of FQHCs from the proposed rules.** [Emphasis added by TPCA]

In the absence of an exemption of FQHCs from the proposed rules, a structured waiver process is recommended for FQHCs who are able to demonstrate need by provision of data demonstrating poverty, lack of access, incidence of addiction and NAS. Any such waiver process should, at a minimum, permit a single fee multi-site license with a program based medical director who is excluded from experience requirements designed around the traditional OBOT model and is permitted oversight of multiple sites.

Finally, the access to opioid use disorder treatment provided by waivered FQHC providers in the context of prenatal care must be preserved and protected to prevent Neonatal Abstinence Syndrome (NAS). **An explicit exemption of those providers treating opioid use disorder in the context of prenatal care is recommended.** [Emphasis added by TPCA]

Thank you for the opportunity to provide these comments, TPCA would be happy to have discussions with you or your staff about any of our suggested changes. Please contact me at terri.sabella@tnpca.org or 615-425-5841 at any time.

DR. MARY BUFWACK, PhD, CEO EMERITUS, NEIGHBORHOOD HEALTH: My name is Mary Bufwack and I'm with Neighborhood Health, a community health center that has multiple sites in Middle Tennessee. I want to express my appreciation for the opportunity to comment on these rules and also to provide just very brief comments about things that we see that may limit access, echoing what Libby Thurman had to say, that our focus is on the underserved and the uninsured. That these are primarily community health centers, are primarily primary care centers. They are not developed to do specific and very targeted MAT services. They more or less incorporate that in response to community need and so it's one of the services that we do offer. Because we're responding to community need and these are people who cannot get services elsewhere. So, in many cases, without a community health center that are providing these services, many of these individuals would go without. So if we're talking about saving lives, particularly the lives of the most vulnerable populations that we have in Tennessee, we have to be sensitive to the things that might limit community health centers from being able to provide MAT services.

On the whole, most of the things in the rules would not be prohibitive. The two that would be prohibitive are essentially by establishing the limit at 150 for the facility and then requiring medical director to have certification in addiction psychiatry or an addiction medicine specialist certified by one of the other boards that has been discussed. This will absolutely limit the numbers a community health center can see. So you are artificially setting the limit that any community health center can see to 149 patients and beyond 149 simultaneous patients a health center cannot do this. That in fact may be provided by one provider. It might be provided by two physicians or three physicians cause community health centers often have to consolidate their services in one location. So you are saying no matter how many prescribers are there, no matter how many physicians are at the site, you are limited to 149 patients because you can neither afford to be able to hire these individuals, you can't find them and recruit them and many of them have no interest in serving the underserved or being in remote areas that address the needs of the underserved and uninsured. I would request that either the circumstances and the certification for the medical director be removed which would enable us to meet these standards or that the cap at 150 be changed to something more reasonable to recognize that multiple clinicians at a site may be prescribing and this artificially limits and certainly does, we're talking about life and death, condemn underserved and uninsured individuals to almost certain death on the street.

Thank you for the opportunity.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: We also understand that the FQHCs have concern with some of the rules, but they should not be held to a different standard than the OBOTs. We would submit that there are no difference in [these] facilities and FQHCs, who may be doing treatment. Especially on a large scale (150 or more patients). The standard needs to be universal.

TDMHSAS Response: The Department acknowledges the comments above.

It is TDMHSAS's hope that TennCare's considerable efforts to enhance its MAT network will lead to greater access to MAT in Tennessee for TennCare enrollees and that this effort will address some of the comments made in the preceding comments by stakeholders.

While it is outside the scope of the Department's authority to exempt specific facilities or categories of facilities from the statutory definition of an OBOT found in T.C.A. § 33-2-402 or the licensure fees for OBOTs or OBOT Pluses, which are set in statute pursuant to T.C.A. § 33-2-406, the Department does have the authority to waive Departmental rules requirements. The Department's licensure rule waiver authority is detailed in Rule 0940-05-02-.19, should a facility desire to seek a waiver. The Department will consider all waiver applications. The Department will strive to fairly administer these rules and will work with licensees to ensure optimal regulatory relationships whether that be via the use of technical assistance, the waiver process, or by other means.

For these reasons, the Department does not adopt the changes suggested by these comments.

SPECIFIC COMMENTS

Chapter 0940-05-02 Licensure Administration and Procedures

0940-05-02-.05 Fees

KEVIN CATNEY, MD, DABAM, DABFM, & PENDING EXAMINATION RESULTS FROM ABPM IN ADDICTION: I am writing to comment on the proposed change to the fee schedule charged to licensed office based providers of Medication Assisted Treatment. I hope that I am reading this proposal incorrectly; *Is the department now wanting to charge $1,500 a year for a license?* Is there a lesser renewal fee that I am missing?

I am a solo practitioner in private practice. I currently pay a $400 annual Professional Privilege Tax, for the privilege of practicing medicine in Tennessee. In addition, I pay $235 every 2 years for my medical license, and I pay $731 every 3 years for my DEA license.

The proposed TNDMHSAS rules require that I be Board Certified by the A.B.P.M. in Addiction. (I am already Board Certified in Addiction Medicine by A.B.A.M.) The application fee to A.B.P.M. to confirm that I was Board Eligible was $495. The fee to take the A.B.P.M. examination was $1995. In addition, the A.B.P.M. requires maintenance of Board Certification in another A.B.P.S. primary medical specialty, in order to be Board Certified in Addiction. (In my case this is A.B.F.M.) Therefore I am now mandated to pay annual maintenance of certification fees in two specialties, as well as annual academy memberships in two specialties, and periodic re-certification examination fees in two specialties.

Why is the proposed annual license fee for a solo physician in the practice of addiction the same cost as for a large group practice with multiple physicians and mid-level providers? Why is the solo practice of medicine by a single physician not covered by the professional privilege tax? If not, what is the justification of the professional privilege tax?

I estimate my cost to maintain all of the current proposed mandated certifications and licenses will be just over $10,000 annually. This is for a solo physician practice, not a multi physician group. At this point I believe the fees have become overly burdensome, and I would ask for some sort of a fee relief accommodation for solo practitioners.

Thank you for your consideration.

TERRI SABELLA, CEO, TPCA: The proposed rules include a site-based fee structure for outpatient facilities that would be potentially cost prohibitive for community health centers that are non-profit providers operating on very slim margins. Community health centers frequently operate small satellite facilities to provide critical access to care in rural communities where transportation to larger sites would present a barrier for patients in need. A waiver of the fee structure for organizations providing care without regard to the patients ability to pay would serve to facilitate access for individuals who do not have other options. **We recommend FQHCs either have fees waived or be charged a flat organizational fee that does not financially penalize the community health centers for providing multiple more convenient points of access in small communities....**[Emphasis added by TPCA]

FQHCs are subject to operational site visits from HRSA, which ensure that they are compliant with federal FQHC program requirements. These include areas such as clinical staffing, accessibility, continuity of care, quality improvement/assurance, and financial management and accounting systems. The inspections mandated for OBOTs may be duplicative and therefore we request that FQHCs be excluded from the inspections outlined on page 3.

TDMHSAS Response: A Nonresidential Office-Based Opiate Treatment facility is defined in T.C.A. § 33-2-402(10)(A) as a "service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to twenty five percent (25%) or more of its patients or to one hundred fifty (150) or more patients."

This rule is being updated to reflect the recent statutory fee change found in T.C.A. § 33-2-406(h). The statutorily-set fee for this licensure category does not differentiate between solo practitioners; larger, multi-physician groups; or by the number of qualifying locations. Each site, meeting the licensure threshold, as established in the definition above, is required to be licensed, and is subject to the fee. The threshold for qualification as an OBOT for licensure is the same regardless of total number of physicians in that practice. Pursuant to PC 978, the annual licensure fee is $1,500.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-02-.23(1) Inspection Fees

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: If facilities have the option to arrange an off schedule inspection outside of the initial and annual inspections. The fee should be much higher (suggested $1,500). For instance, regional OSHA agencies perform consultative visits for free. However, the typical wait time after request is around 18 months. If a facility is seeking department involvement, $50 may bottleneck the system.

TDMHSAS Response: While TDMHSAS appreciates this comment, our mid-licensing period inspections are intended to address change requests related to the operation of a licensed facility. If requested by a licensee, the Department will provide technical assistance as resources allow. Examples of a change request related to the operation of a licensed facility may include providing authorization for an agency to provide services to non-ambulatory patients to ensure

compliance with life and safety requirements for that patient profile or to adjust licensure designations accordingly as needed.

For these reasons, the Department does not adopt the change suggested by this comment.

Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Programs

0940-05-35-.02(2)(e) Definitions

TIMOTHY SMYTH, MD, TENNESSEE SOCIETY OF ADDICTION MEDICINE ("TNSAM"): TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "ASAM's National Practice Guideline does not support mandating a specified type or frequency of psychosocial treatment for patients, stating "psychosocial treatment is provided using a variety of approaches in various milieus, including social skills training; individual, group, and couple counseling; cognitive behavioral therapy; motivational interviewing; and family therapy. Determining the level of need and best approach to psychosocial treatment is individualized to each patient."

I agree with the ASAM's national practice guideline mandating specified type and frequency of psychosocial treatment for patients is not the best way to do it. That we should use the nationally approved practice guidelines and perhaps we can refer to that. Again, I understand the reality of the situation and that's not going to happen. We're still going to have to follow the rules that you guys put forward but allowing as much flexibility as possible would be appreciated on that. But I think a minimum as you guys have put forward is important.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: The department should allow Certified Peer Recovery Support Specialists to lead group educational sessions, but not individual therapeutic counseling sessions.

This has been an issue that has been brought up to the department a few times. Consider allowing CPRS to only be allowed to host group educational sessions, not individual therapy or individual counseling but if they would consider allowing them to do group settings. We know that the new TennCare program will not be paying or reimbursing for that but would like the option to be on the table.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: [Made in response to Paul Trivette comment above] I believe this should only be allowed if the clinic has a licensed counselor on site. Otherwise how does an immediate need get addressed that falls outside of the CPRS' training/knowledge?

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule.

The current rules establish minimum standards regarding counseling and encourage all facilities to individualize counseling for each patient. Additionally, the Department contends that although certified peer recovery specialists (CPRSs) are a valuable resource for individuals in recovery, they are not adequately qualified or trained to provide counseling services as required by these rules.

Although the Department contends a change to this rule is unnecessary at this time, pursuant to PC 978, now codified at T.C.A. § 33-2-403, the Department will be reviewing these rules every even-numbered year.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.02(2)(z) Definitions

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: The department should clarify that a failed drug screen does not necessarily include a relapse, but that every patient should be evaluated for the indicators of such. I don't think this has changed at all.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition].

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule. Additionally, the Department finds that this clarification is unnecessary at this time. Although the Department contends a change to this rule is unnecessary at this time, pursuant to PC 978, now codified at T.C.A. § 33-2-403, the Department will be reviewing these rules every even-numbered year.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.02(2)(aa) Definitions

TERRI SABELLA, CEO, TPCA: The definition states that "Taper", "Tapering", and "Medically Supervised Withdrawal" are interchangeable but these terms do not mean the same thing. **We recommend defining each term** [Emphasis added by TPCA]. Taper should be defined as "the prescribed reduction in dose of buprenorphine for the purpose of establishing a new maintenance dose or achieving cessation of buprenorphine therapy." Tapering is the act of the taper. Medically supervised withdrawal, or "withdrawal management," per ASAM is "the provision of care to alleviate the physiological and psychological effects of substance withdrawal."

TDMHSAS Response: This change to 0940-05-35-.02(2)(aa) was made to the rules following the passage of PC 978 and the requirements therein. Based on the Department's consultation with the Buprenorphine Treatment Guidelines Committee, the Department has decided to define these terms as interchangeable for the purposes of these rules, and no further distinction is necessary.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.04(2) AND 0940-05-35-.04(4) Licensing Procedures

MICHAEL TINO, MD, FASAM, DABAM, DOCTORS ASSISTED WELLNESS & RECOVERY CTR, LLC: [An] issue that should be addressed is regarding the ownership structure of these facilities. I am familiar that there is a law that restricts the corporate practice of medicine. This law, all too often, is not enforced. I submit that all facilities should be 100% physician owned and operated.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: The department really needs to highlight the corporate practice of medicine statute and may should even include language as the following: "Non-physicians or non-medical staff shall not direct the medical care, medications, or any other part of a patient's treatment that requires a medical diagnosis or the use of a prescription for treatment."

The department should also consider language clarifying that non-physicians cannot contract with physicians to provide medical services to ensure the physician remains autonomous.

"Every facility shall ensure that it remains compliant with the TN statute regarding the corporate practice of medicine."

There is a lot of concern about the corporate practice of medicine in a number of these facilities. Lastly, a number of facilities are giving physicians contracts to work for them and in certain scenarios, if the physician leaves, then the non-physician assumes the direction of the patients and chooses to assign him/her to another physician.

Can a corporate entity do this legally? Can a corporate entity engage in the practice of medicine?

Language specifically related to the corporate practice of medicine. Gray area. Consider some language that would say an OBOT shall ensure that it is compliant with the corporate practice of medicine statute or something along those lines as well.

Also important that non-physicians/owners/corporations acting as an OBOT understand they do not have authority over the practicing medicine physicians, what meds someone would be receiving, anything related medically.

TIMOTHY SMYTH, MD, TNSAM: TNSAM and I ask the TDMHSAS to be more rigorous in its requirement germane to physician ownership. Specifically, consistent with Tennessee law germane to the corporate practice of medicine, we suggest that this exclusion be clarified in these Rules. That is, these Rules should reiterate the fact that non-physicians cannot contract with physicians to provide medical services. An arrangement such as this may cause the physician provider to be unduly influenced by non-clinical factors when providing care to this vulnerable population.

I'm just going to reflect that I agree with the Tennessee Recovery Coalition on that. I grow concern about the corporate practice of medicine and some of the less desirable clinics at least that I've seen in my experience have not really been owned by the doctor. They've been owned by another entity so I appreciate you guys putting more attention on that and I agree with the Tennessee Recovery Coalition.

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule. Additionally, the Department finds that this clarification is unnecessary at this time.

Although the Department contends a change to this rule is unnecessary at this time, pursuant to PC 978, now codified at T.C.A. § 33-2-403, the Department will be reviewing these rules every even-numbered year.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.09(6) Individualized Treatment Plan and Best Practices Utilized

TIMOTHY SMYTH, MD, TNSAM: TNSAM and I realize that a discussion about medically supervised withdrawal and tapering to abstinence is required by law, however, we would submit that a less onerous method for documenting the fact that this discussion has taken place should be instituted.

In addition, TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "Patients should not be encouraged to be abstinent from medication to treat addiction. There is substantial evidence that medication-assisted treatment is the gold standard of addiction medicine, so continuing treatment with medication can be in the patient's best interest for their overall health. It should also be the patient's own decision if they wish to discontinue their use of medication, as being encouraged by a medical professional to discontinue treatment is unethical and goes against evidence. The following sentence should be eliminated from the rules: "Alternatives such as medically-supervised withdrawal shall be presented to the patient at the time of the discussion and documented in the patient's record."

We recognize that this is also germane to 0940-05-35-.13 both regarding the tapering discussion. And that is that we understand that the law requires us to have a discussion with the people who want to taper and move into abstinence. Again this is 0940-05-35-.13(1)(c)1 and 0940-05-35-.09(6). Number 6 is where you review the individual treatment plan every six months and the patient has to sign that they want to stay in treatment. My opinion on that and that of ASAM is that I'd like to have a perhaps less onerous way of doing that. You know that we can document that we had the discussion on my electronic sheet. I have a box that I check and the truth is I talk about getting down to a minimal effective dose and consider zero if that's the desire at pretty much every single visit so I don't have a problem with that discussion but having a patient sign off that you had that discussion seems a bit onerous to me. So I'd rather not have it so onerous. And ASAM agrees with that.

TDMHSAS Response: The Department acknowledges these comments and notes that PC 978 requires that this topic be included in TDMHSAS licensure rules regarding OBOTs. Moreover, the Buprenorphine Treatment Guidelines Committee has endorsed the language found in this provision. The Department contends that the rule provides flexibility to prescribers while also complying with the requirements of PC 978.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.10 Phases of Treatment

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: Department requires individualized treatment plans specific to that individual and what they need. I think this is one of the greatest things in these rules so that people are not treated universally, however, I think on the phases of treatment portion some notation that there may come a point that a person has either progressed or reached recovery goals and may not need that case management every month, especially if they are getting office visits once every two months. That should unequivocally be documented in the individualized treatment plan and should be shown that the patient has obtained those goals. We would like to see something in regards to the individualized treatment plan that a patient may attain such to where they don't need that.

WILLIAM CONWAY, MD, FACP, FASAM: Counseling and Case Management are crucial and critical components of any chronic illness. The department has strict rules and requirements regarding monthly counseling and case management services, even in the maintenance phase.

These rules should be interpreted in the context of medical necessity. In any chronic illness with long term attendance, patients will require guidance, emotional support, and counseling about the entire range of human experience. The real question is the demonstrated capacity of a program to provide self-management and guidance when necessary.

There are some patients that may no longer need those services after a period of time or even at the beginning, but that should be determined by the individual treatment plan and that person's needs. I have patients that have jobs, education, good family structure, primary care physician, and transportation. Those patients do not need monthly case management services. The same is true for counseling. I evaluate each individual and determine the counseling and services needed. At the very least, the department should not mandate case management and counseling monthly and let the facility follow the individual treatment plan.

I would appreciate for the department to consider changing the observed drug screening rule and policy. While this policy appears to be reasonable, it is associated with a host of unanticipated side effects.

a. For patients who have been sexually or physically abused, every office visit becomes potentially traumatic.
b. For patients who are doing well, this is both insulting and abusive.
c. Cost of operation will increase significantly requiring both a male and female to supervise urine drug screens, and these costs will be passed on as increased prices.

d. Maintenance of public safety is an evolving and complicated matter which can be addressed in other more effective manner than watching patients urinate on every visit. Observed urination is a simple distraction from the real issue of constant vigilance of risk of diversion.
e. Does the Tennessee Department of Mental Health and Substance Abuse Services really want to promote and enforce "We are watching Tennesseans Urinate."
f. If this policy becomes statute, it will be challenged in court as arbitrary and discriminatory.

TDMHSAS Response: The Department agrees with some of the concerns from stakeholders regarding case management services and has addressed the comments concerning case management by revising Rule 0940-05-35-.10(1)(d)(4).

In regards to the comments regarding observed drug screens. The Department acknowledges these comments and contends that observed drug screens are a reasonable requirement to ensure quality care, treatment effectiveness, and address diversion concerns.

For these reasons, the Department does not adopt the suggested changes regarding observed drug screens.

0940-05-35-.10(1)(b) 2. and 4. Phases of Treatment

TIMOTHY SMYTH, MD, TNSAM: TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "The practice of requiring patients to do the specific amount of counseling these rules would require could take away the flexibility of both the provider and the patient in determining an individualized treatment plan. In addition, ASAM's Public Policy Statement on the Regulation of Office-Based Opioid Treatment states "it is important to note that many services are not available in all communities, and that this should not preclude patients from accessing the treatment components that are available. Generally, unstable patients in early treatment require both more structured treatment and greater intensity of integrated services. However, in areas where such services are not available, pharmacological treatment alone with the support of the treating clinician results in improved outcomes for some patients." These types of requirements put a burden on the provider and the patient, forcing them to engage in certain aspects of treatment that may not be necessary based on the patient's individual needs, and thus potentially causing some providers to no longer provide MAT."

Again, this is ASAM's comments that I agree with the practice of requiring patients to do a specific amount of counseling. Again, we would push for as much flexibility as possible and I'm going to have that in my written comments.

TDMHSAS Response: The Department acknowledges the comments above, however, these rules represent minimum program requirements that are intended to ensure a certain level of quality care while also giving providers the flexibility to individualize treatment and a patient's treatment plan.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.10(1)(b) 3. Phases of Treatment

TIMOTHY SMYTH, MD, TNSAM: TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "Instead of putting in statute prescriptive measures on the frequency of drug testing, we recommend providers follow evidence-based guidelines on the effective use of drug testing in the identification, diagnosis, treatment, and promotion of recovery for patients with, or at risk for, addiction."

UDS frequency. Using the evidence based guidelines that are put forward by ASAM is recommended there as well.

TDMHSAS Response: These rules represent minimum program requirements that are intended to ensure a certain level of quality care and are consistent with federal Substance Abuse and Mental Health Services Administration ("SAMHSA") guidance referenced in Treatment Improvement Protocol ("TIP") 63 regarding the frequency of drug testing.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.10(1)(c) 3. Phases of Treatment

TERRI SABELLA, CEO, TENNESSEE PRIMARY CARE ASSOCIATION: Clarification is needed on the phrase "be subject to" with regard to frequency of drug screens. It is not clear if this is a suggestion or a directive for OBOTs. If the intent is to make urine drug screening a requirement, the wording should specify this. Additionally, mandating observed drug screens could present financial or logistical hardships for some health centers. **We suggest eliminating the "observed" portion of the statement, given that collection cups used by many providers have built-in technology to identify falsified urines (e.g. temperature indicators and creatinine/specific gravity measurements). We suggest changing the wording to mandate that "at least 25% of specimens will be observed based upon the provider's professional judgement."** [Emphasis added by TPCA].

TDMHSAS Response: While it was always the intent of the Department that OBOTs require drug screens, the Department agrees with this comment in part and has revised the Rule 0940-05-35-.10(1)(c)3. The Department believes observed drug screens are a reasonable requirement to ensure quality care and discourage diversion. Additionally, observed drug screens are consistent with SAMHSA guidance.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.10(1)(c) and (d). Phases of Treatment

TERRI SABELLA, CEO, TPCA: We recommend changing mandated monthly case management for those in the maintenance phase to "as needed, based upon provider's professional judgement."

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: There needs to be a clause at the beginning or end that clarifies that not all patients need case management or counseling or some have progressed and accomplished recovery goals. In this case, the office visits and the individualized treatment plan should demonstrate and reflect that such may not be or is not needed.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition]. Case management services may not always be needed. However, if an individual is maintaining treatment, counseling should remain a constant. If a medication is all that stands between a patient and relapse, failure is inevitable.

TDMHSAS Response: The Department agrees with these comments in part, and has addressed these comments by revising Rule 0940-05-35-.10(1)(d)(4).

0940-05-35-.13(1)(a)4. Medication Management

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: While it is understood that anything greater than 16mg is considered a 'high dose,' it is not beyond impossible for a person to possibly need to be prescribed 32mg. The department should at least state that 'proper justification should be provided in the extremely rare cases where a person may need greater than 24mg per day.' The department should also consider that any dose greater than 24mg should have permission from the SOTA.

Regarding prescribing, I think TIP 63 was pretty clear that anything greater than 16 mg is a high dose. Anything greater than 24mg not clinically significant however on 0940-05-35-.13(4) we would ask the

department to remove a maximum dose of 24mg and consider language in the extremely rare circumstance that a patient would need to go over 24mg it should be clearly documented or if the department would also consider permission from the state opioid treatment authority to go over 24mg. If that may be kind of a compromise on that instead of just saying a maximum. I think it is extremely rare, some of them very few have argued that there are studies out there that would show there is some benefit, we just don't think that should be in a rule that that's a maximum dose.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition, on just first paragraph above].

DR. EVANN HERRELL, MEDICAL DIRECTOR, EHC MEDICAL: I wholeheartedly, categorically agree with all of the comments that all of the speakers have made thus far. Paul stole all my thunder so I had really nothing to say other than say that I really agree with him. The one point that I would like to emphasize myself is on page 11 [of the Notice of Rulemaking Hearing Draft], there where we're talking about the maximum dosage being 24mg. I agree with the comments before and I also agree with the terminology of "rare". Okay, I'm not trying to, you know, open the floodgates here but there are a few patients who, there's evidence, there's studies, there's papers that I can show you, the documentation that patients in some cases would benefit from a dose greater than 24mg. And you know, an example of that would be the patient who has a very significant history utilizing high morphine equivalent medication. This is somebody who has no desire at all to go to a methadone clinic or any such facility. It conflicts with their life. Maybe they have a full-time job and it's just not practical but there's evidence that shows that if you put somebody like that on, say for example, 32mg, that you can achieve stabilization with them. I've actually spoken to a number of physicians across the country and in various meetings who have told me that they have actually performed COWS scores on folks like this. They put them on 24mg and guess what? They're still having objective, physical withdrawal. And they say that you hit them with 32 and it goes away. So I think that this is a very, very, very controversial issue when we talk about dosing. There's people on this side of the fence and people over here and they're very adamant about their position. But I think at the end of the day what really, really matters is saving lives and doing the right thing for the patient. And I know that sometimes when we talk about dosing this medication, that it can be kind of twisted and construed that you know, if you write a certain amount or you put patients on a certain dose then you know, you're just a pill mill and you're just throwing out medicine to try to get these people to come back and all this sort of thing. And I know that that's a concern and I know that there are people that are operating that way out there and that's the whole reason why we're here and the whole reason why we exist. But I will tell you that there are patients who would benefit from being able to utilize a higher dose and it truly would be a lifesaving medication for them which is what buprenorphine is. So again, it would be a rare thing, you know I mean, if you guys want to just set some kind of limit, you know like we did with the mono product and say it shouldn't be more than. I mean if you want to say 1% of the practice or 2%, I mean I would be totally fine with something like that. But I can tell you that there's a handful of people that this medicine would make the difference in whether they live or die and I'm not just saying that. I've actually seen this. And these are people who do not want to do inpatient therapy. They do not want to go to a methadone clinic. They're okay with going to a buprenorphine facility but they fall off of treatment because they weren't adequately treated and everything else kind of failed for them. So, that's all I have to say. Thank you.

TDMHSAS Response: The Department agrees with these comments in part, and has revised the rule to allow a narrow pathway whereby a patient can receive a dose higher than the maximum daily dose of twenty-four milligrams (24mg) in rare circumstances. Rule 0940-05-35-.13(1)(a)(4), which contains requirements for prescribing above the maximum dose.

0940-05-35-.13(1)(c) 1. Medication Management

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: The rule should also include some language that prescribers may or may not encourage patients to taper down or off of medications.

We ask that the department add in language also so that based on IEP the physician may or may not recommend to the patient to taper down or taper off. Either they're having the discussion that it is an

option based on that the physician should be allowed to make their recommendation to the patient as well.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition].

TIMOTHY SMYTH, MD, TSAM: TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "Addiction is a chronic disease and, in some instances, will require a patient to be on medication for the rest of their life. By encouraging abstinence and requiring medication discontinuation, these proposed rules would maintain the stigma of this disease and its treatment, as well as go against established medical evidence and put patients' lives at risk of relapse, overdose, and death. This section should be eliminated."

TDMHSAS Response: The Department acknowledges these comments and notes that provisions regarding tapering discussions are required to be included in TDMHSAS licensure rules regarding OBOTs by PC 978. Moreover, the Buprenorphine Treatment Guidelines Committee has endorsed this language. The Department contends that the rule provides flexibility to prescribers while also complying with the requirements of PC 978. For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.13(2) Medication Management

TERRI SABELLA, CEO, TPCA: Checking the CSMD at every visit is onerous and unnecessary, especially for patients in the induction/stabilization phase. These patients are often seen every two to three days. **We recommend specifying that the CSMD check be performed at the initial visit, at least monthly during induction/first year of maintenance, and then quarterly thereafter or when clinically indicated** [Emphasis added by TPCA].

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule.

The Department believes this is a reasonable requirement to ensure patient safety and quality care and, is consistent with the Buprenorphine Treatment Guidelines. The Department believes the benefit of checking the Controlled Substances Monitoring Database ("CSMD") outweighs the added responsibility for practitioners.

For these reasons, the Department does not adopt the change suggested by this comment.

0940-05-35-.13(4)(a) Medication Management

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: How does the CSMD not already answer this issue? [referring to rule requirements that an OBOT develop procedures to ensure that a patient's prescriptions from outside physicians be reported to the medical staff and reviewed by the program physician at admission and annually thereafter]

We just wonder if this is even necessary or if the CSMD requirement checking it every visit takes care of that.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE (CATALYST HEALTH SOLUTIONS): Is the office referring to controlled medications OR medications in general? For instance, a comprehensive list of daily medications, BP Meds, etc. If so, I agree a comprehensive list should be maintained.

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule. For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.20(2)(b) Personnel and Staffing Requirements

MARY LINDEN SALTER, LCSW, EXECUTIVE DIRECTOR, TAADAS: On page 12 of the draft rules, Section 0940-05-35-.20(2)(b) specifies that a program medical director must be physically present 25% of the time the (OBOT) facility is open to the public. This requirement is mimicked in the OBOT Plus rules as well. This standard would be hard to meet for a program that is multi-faceted (multiple levels of care) if the medical director is limited to only being at one program (OBOT) for such an amount of time when other levels of care and other sites would also need supervision. As time goes on, more and more of the state contracted, non-profit providers of Medication Assisted Treatment may eventually come closer or meet the threshold to require licensure as an OBOT. Most would also need a waiver of this requirement given the issues I have just outlined, as many of them have multiple levels of care and some also have multiple program sites. Some agencies could potentially purposefully maintain a lower number of clients to avoid this threshold and this would limit the capacity to provide MAT services across the state. Many non-profits struggle to recruit and retain medical staff at all for MAT programs and a 25% rule for a medical director's role could be cost prohibitive or unrealistic given the limited pool of physicians that are available. Given that this may become a pervasive issue for such agencies, and that most of them may require such a waiver, it should be worth considering that this requirement is not uniformly appropriate. One of TAADAS members is currently pursuing a waiver of this requirement for these very reasons.

BRIAN HAILE, JD, MPP, MA, CHIEF EXECUTIVE OFFICER, NEIGHBORHOOD HEALTH: We find the staffing requirements (0940-05-35-.20) to be unduly burdensome and unnecessary. Few if any community health centers could meet the qualifications for the Medical Director (2)(b) with the years of experience required (3)(b). These staffing requirements far exceed any in our federal or state grants to provide these services, and they appear to be the most stringent requirements anywhere in the country that apply to MAT programs successfully operated by community health centers.

We also find the requirements for the Medical Director (a) to spend at least 25% of his or her time onsite at each specific location and (b) to supervise a maximum of three locations to be unduly burdensome. Both of these requirements assume the primary business of the entity is addiction medicine, in which case such rigorous supervision and experience may arguably be more appropriate or necessary. In the context of community health centers, though, this only serves to reduce treatment slots.

Implementation of these provisions would effectively limit each community health center to treat no more than 149 MAT patients at any one time, thereby reducing treatment slots compared with what would otherwise be available.

TERRI SABELLA, CEO, TPCA: The proposed rules read that the governing body of each facility "shall designate in writing a medical director to be responsible for the supervision of all medical staff at the "Facility" and the administration of all medical services at the Facility...". It is not feasible for FQHCs to hire and retain individual medical directors for each site. **We request that FQHCs be permitted to designate an organizational level medical director that will have oversight of the organization's treatment sites** [Emphasis added by TPCA].

The proposed rules specify that the medical director "shall be physically present at the Facility the equivalent of twenty-five (25) percent of the time the Facility is open to the public each week." FQHCs are comprehensive primary care facilities; MAT may comprise a small portion of the center's operational hours. **We request that for FQHCs, the medical director of the organization's MAT program specify a primary practice site, at which he or she will be on-site at least 25% of time that the site provides MAT. For sites that the medical director supervises, we request that the on-site time provision be waived, if the organization outlines policies and procedures that will be utilized to ensure proper oversight and clinical quality. The policies and procedures should be consistent with prevailing best practices** [Emphasis added by TPCA].

The proposed rules specify that "no physician may serve as the medical director of more than three (3) Facilities without the prior written approval of the TDMHSAS Office of Licensure." We appreciate the flexibility that may be available through approval by the Office of Licensure but **recommend that the Department provide FQHCs with the option to utilize number of patients served, rather than number of facilities, to determine appropriate Medical Director oversight** [Emphasis added by TPCA]. As mentioned previously, some FQHC sites are small while others are large. Specifying oversight based on patients treated would likely improve the quality of the oversight medical directors can provide and reduce variability in the number of patients various medical directors are overseeing while permitting oversight to essential access in small rural sites.

With regard to the requirement that the "medical director review 10% of the medical charts for patients currently admitted at the facility..." **We suggest changing "admitted" to "treated"** [Emphasis added by TPCA] for clarity.

SHAWN CARRIGAN, RUTH CLINIC: I just wanted to express a little bit of our experience in regards to medical director. I think it's a great difficulty to recruit medical directors at this point for a small clinic. We do have a medical director but the resistance that I have often get is the 25% onsite rule. I think that if a medical director was allowed to use telemedicine to monitor the patient file review. I think they should be onsite some, maybe 10% of the time would be worthwhile but the requirements that stands now means that a medical director could, at the most, supervise 4 clinics and many of these clinics are small. It's just not economically feasible. They don't want to drive that far. They don't want to take that much time out of their lives. So if there was some way to have flexibility on that onsite percentage I think we could achieve better supervision. We'd have more people acting as medical directors.

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged from the current effective version of the rule. The process for a facility to seek a waiver of rule requirements is provided in Rule 0940-05-02-.19, should a facility desire to seek a waiver. The Department will consider all waiver applications. The Department will strive to fairly administer these rules and work with licensees to ensure optimal regulatory relationships whether that be via the use of technical assistance, the waiver process, or by other means.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.20(2)(d) Personnel and Staffing Requirements

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: I'm not going to go into too much detail outside of the taskforce for the nurse practitioners and PAs but we will probably be submitting some written comments regarding physicians assistants and nurse practitioners and the utilization of them within an OBOT and if the department would consider some rules on that as well.

[These are the written comments received in reference to the rulemaking hearing comment referenced above.]The department should prepare language regarding nurse practitioners and physician assistants that could read as follows: "A nurse practitioner or physician assistant shall be supervised by a physician, who has a certification in addiction psychiatry by the American Board of Psychiatry and Neurology; certification as an addiction medicine specialist by the American Board of Addiction Medicine or American Board of Preventative Medicine; or is fellowship trained in addiction medicine or addiction psychiatry. The facility and/or its' providers shall be credentialed and contracted with the state Medicaid agency and its' Managed Care Organizations to provide addiction treatment services in order to utilize nurse practitioners and physician assistants, who have been given prescriptive authority to issue prescription medications for Buprenorphine that are indicated for Opioid Use Disorder."

This will take care of issues with opening the authority to NPs and Pas to prescribe. Specifically, board certification will be required AND to take care of the fee for service issue, the facility will have to be contracted/credentialed with the state Medicaid agency and its' MCOs.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition].

TDMHSAS Response: Should the Tennessee General Assembly decide to allow advance practice nurses and/or physician assistants to prescribe buprenorphine containing products for the treatment of opioid use disorder ("OUD"), the Department contends that Rule 0940-05-35-.19(2)(d) appropriately addresses the concerns expressed in this comment.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.20(3)(b) Personnel and Staffing Requirements

MICHAEL TINO, MD, FASAM, DABAM, DOCTORS ASSISTED WELLNESS & RECOVERY CTR, LLC: Lastly, the Medical Director should be either board certified by the American Board of Addiction Medicine, American Board of Preventative Medicine, board eligible to take the aforementioned exam, or fellowship trained in such. The department needs to remove the 5 years of experience allowance. Board eligibility is absolutely sufficient.

WILLIAM CONWAY, MD, FACP, FASAM: I was disheartened to read about the proposed change in rule concerning the Medical Director requirement. The department should not have removed the 'American Board of Addiction Medicine' certification as to who qualifies to serve in that role. The department should not change the original rule and just simply add the new certification by the American Board of Preventive Medicine with a subspecialty in addiction medicine. The "five years of documented experience" does not make any sense as that does not account for total hours worked nor the specific capacity in which that physician operated. Board Exam."

BRIAN HAILE, JD, MPP, MA, CHIEF EXECUTIVE OFFICER, NEIGHBORHOOD HEALTH: Few if any community health centers could meet the qualifications for the Medical Director (2)(b) with the years of experience required (3)(b). These staffing requirements far exceed any in our federal or state grants to provide these services, and they appear to be the most stringent requirements anywhere in the country that apply to MAT programs successfully operated by community health centers.

TERRI SABELLA, CEO, TPCA: The standards for medical director qualification in the proposed rules are unattainable for FQHCs, meaning that their treatment capacities will be capped at levels under 150 per site. There are simply not enough physicians with the outlined certifications that are willing to practice in non-profit settings, many of which are located in rural areas. We request that the Department recognize that access to vulnerable populations may best be preserved through modification of supervision requirements in the FQHC environment.

Options:

1. **Exempt FQHCs from the Medical Director qualifications outlined on page 13(3)(b).** This is our preferred option; it is the most clear cut and would ensure that community health centers could provide treatment to those in their communities. This exemption would acknowledge that FQHCs operate with extensive oversight from the federal Bureau of Primary Health Care, including requirements on appropriate staffing, supervision, and quality. Specifically, in addition to providing required and additional services, ensuring that services are available and accessible to ensure continuity of services, the health center must "utilize staff that are qualified by training and experience to carry out the activities of the center." TDMHSAS would of course have the opportunity to evaluate the qualifications of the medical director, but offering this exemption to the medical director certification and/or experience requirements would ensure that treatment capacity for vulnerable populations is not limited by an unattainable standard.
2. **Exempt organizations that are active Patient Centered Medical Homes under the TennCare payment reform initiative from the Medical Director qualifications outlined on page 13(3)(b).** As outlined on the TennCare Patient Centered Medical Home (PCMH) webpage, "With the primary care provider at the center of patient care, the PCMH model of care coordination

should provide all members access to the full spectrum of medical care. Relationships are developed and a team of providers is accountable for a patients' physical and behavioral health care needs. There is a focus on wellness and appropriate acute and chronic care. Comprehensive care is organized across the healthcare system with clinicians and staff seeking to enhance the quality of care provided while also instructing patients and families in how to actively engage in self-management." Exempting organizations that have met and continue to meet this standard of care would leverage the work and oversight of other state departments and provide flexibility in terms of treatment settings. Community health centers are appropriate settings for opioid use disorder treatment and patients will benefit from comprehensive care management and treatment in a medical home setting. Additionally, obtaining opioid use disorder treatment in a Patient Centered Medical Home can reduce the stigma individuals may experience by visiting a standalone treatment facility and may increase the likelihood of patients to access needed care.

3. **Reduce the five year experience threshold outlined in (3)(b)(3) to no more than 2 years.** We appreciate that the Department has provided an experience-based option for medical director certifications, but it will be difficult for FQHCs to employ physicians with five or more years of experience in addiction. Reducing the years of required experience would be more consistent with DEA requirements and board certification eligibility – under federal law, physicians who have prescribed buprenorphine for at least one year to 100 patients to increase their patient load to 275, which we understand to be a threshold for presumptive board certification eligibility. We understand the 275 patient load demonstrates competence that correlates with board eligibility standards.
4. **Provide an option in which medical directors can demonstrate experience through number of patients treated.** This would avoid the confusion of layered, inconsistent standards between the state and DEA and increase the likelihood that FQHCs could employ medical directors that meet the Department's requirements. Additionally, this would be a more accurate measure of experience since physicians can treat varying numbers of patients over an annual period.

DR. MARY BUFWACK, PhD, CEO EMERITUS, NEIGHBORHOOD HEALTH: I know there was a great deal of concern about the five years of experience. I understand the concern cause often times it's usually talked about in terms of hours of treatment experience as opposed to years. And five, often times a physician doesn't even stay with us for five years and the opportunity to be in settings where there's been MAT services provided before are, in fact, very limited for many of the physicians that are serving in underserved areas. So I would say establishing some number of hours for something that can be accomplished perhaps reasonably with 25 percent of a practice maybe in a year. So if it's usually a 40-hour week if an individual is spending 10 hours a week in treatment for a year, it seems to me that might be sufficient. And I think we could certainly give that some thought and send additional comments on that. We understand the desire for experience in the individual who is medically directing the program but the experience can be for the 149 patients but setting it at 5 years you might as well require board certification at that level.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: The original rule does not need to be changed with the exception of adding "The American Board of Preventative Medicine." There are a number of physicians who are board certified by the American Board of Addiction Medicine and that certification is valid until its' expiration date.

One thing we have some heartburn and concern about is under staffing qualifications for the medical director. We believe that the department really needs to remove the 5 years of documented experience and the "treatment of persons who are addicted to alcohol or other drugs" so we would submit that number 3 needs to be striked entirely. Number 2 I feel like it was kind of condensed from the original rule. It only allows for board certification of the American Board of Preventative Medicine, however, we still have a Board, an American Board of Addiction Medicine and there are still physicians that are actively certified in that and it doesn't expire for a number of years so we would ask that the department not change the original rule that is currently in place but rather add certification by the American Board of Preventative Medicine in that definition.

We also believe that the fact that somebody is board eligible to take an exam that should be completely sufficient to serve as the medical director.

Just one more comment about the five years of documented experience, that five years could mean a multitude of things. It's not clear at all actually. We have physicians in this space that work four hours one month and they've been doing it for years. We've got physicians that work forty hours a week and have been doing it for five years so having the year's piece is not necessary. We would submit that board eligibility is sufficient.

The five (5) years of documented experience needs to be absolutely removed. There is no way to accurately track 'five years.' Moreover, there is no clear definition of 'years.' Some physicians work 4 hours per week and have done such for five years. Does that put that physician in the same category as one who has worked 20 hours per week for five years? We would argue that it does not. The rule should require Board Certification, fellowship training, or board eligible to take the exam; no other options.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition]. This is why board certification should be required to eliminate the question of qualification. I'd remove board eligible if it was my call to avoid significant delays on part of the MD.

MICHAEL BARON, MD, MPH, MEDICAL DIRECTOR, TMF-PHP, TENNESSEE MEDICAL FOUNDATION: The American Board of Addiction Medicine (ABAM) is still an active and recognized Board for Addiction Medicine. ABAM is not recognized by the American Board Medical Specialties (ABMS) which is why ABAM worked to have the American Board of Preventative Medicine (ABPM) accept a sub specialty tract for Addiction Medicine. ABPM is an ABMS recognized specialty. The qualifications for the ABPM-subspecialty in Addiction Medicine and ABAM are virtually identical. So certification as an addiction specialist should include certification or maintenance of certification by the American Board of Addiction Medicine (ABAM) as well as the ABPM – Addiction Medicine.

My first comment is related to what was already addressed by Mr. Trivette about ABAM certification. The American Board of Preventative Medicine does not exempt or override ABAM certification. ABAM certification still exists. So to remove that is just kind of wrong. Most addiction medicine specialists still in the state are, a higher amount, are under ABAM certification than the American Board of Preventative Medicine. That will change over the years but not yet.

Also, five years of experience is pretty nebulously defined as was already described. One of the problems that I have is that a lot of primary care physicians are not experienced at all and they're not going to be running one of these types of clinics but like in pain management there's no experience that way. They have to be board certified or in the certification process.

The time requirement for experience needs to match the time requirements for American Board of Addiction Medicine (ABAM) and American Board of Preventative Medicine (ABPM) listed below.

The following is directly from the ABPM-Addiction Medicine website:

"Time in practice: Applicants must submit documentation of a minimum of 1,920 hours in which they were engaged in the practice of Addiction Medicine at the subspecialty level; this minimum of 1920 hours must occur over at least 24 of the previous 60 months prior to application. The minimum of 24 months of practice time need not be continuous; however, all practice time must have occurred in the five-year period preceding June 30 of the application year. Practice must consist of broad-based professional activity with significant Addiction Medicine responsibility. Applicants must also demonstrate a minimum of 25% (or 480 hours) as Direct Patient Care. Addiction Medicine practice outside of direct patient care, such as research, administration, and teaching activities, may count for a combined maximum of 75% (or 1440 hours.

Only 25% (480 hours) of general practice can count towards the required hours for the Practice Pathway, and the remaining 75% must be specific Addiction Medicine practice."

TIMOTHY SMYTH, MD, TSAM: TNSAM endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "This should also include certification from the American Board of Addiction Medicine."

I agree with Dr. Baron and Dr. Trivette on the 0940-05-35-.20(3)(b)2. We should include ABAM certification.

This "credential" is ambiguous and rife with the potential for abuse/falsification. If the purpose of defining who may be a Medical Director is to ensure that the individual has the requisite knowledge and experience to deliver high quality care and oversight, then 0940-05-35-.20(3)(b)3. should be removed.

Regarding five years of experience just seems incredibly nebulous. If you want to be more specific, for example, to sit for the board, for ABAM board originally I had to demonstrate I think it was five years of full-time experience and I'd been practicing pain management for twenty-five years and they allowed me 20% of that time to be dealing with addiction so I was able to fit the qualifications that way. So to me, you know, just saying we have to be board certified by ABAM or board of preventative medicine or board eligible will give you the best criteria. I think that's in agreement with Dr. Baron and Mr. Trivette from the Tennessee Recovery Coalition but just simply saying five years is too nebulous.

TDMHSAS Response: Pursuant to several comments, the Department has revised the Rule 0940-05-35-.20(3)(b) to make clear that those certified under the American Board of Addiction Medicine (ABAM) are eligible to serve as a facility medical director. Additionally, in response to several comments, the Department has revised the rule to add an additional eligibility criteria for serving as a medical director at an OBOT (addiction specialist as defined by TDH), removed the proposed five years of documented experience qualification, and created an exemption for facilities meeting certain criteria related to accreditation.

Furthermore, the process for applying for a waiver of certain departmental rules requirements is detailed in Rule 0940-05-02-.19, should a facility desire to seek a waiver. The Department believes the revisions made to the Medical Director Qualifications lend themselves to expanding the eligible pool of individuals qualified to serve in this capacity while still holding facilities and/or their medical directors to a high standard.

0940-05-35-.20(3)(e) Personnel and Staffing Requirements

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: Does this supersede the rule regarding counseling and who can perform it? We should not require the counselors to be licensed or certified as that may not be attainable in every circumstance. I know this is also in the original rule.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree licensure should not be required if a supervisor is on-site, i.e., LPC, LCSW, Psych. We need to raise the standard on the 'who' is a counselor. More emphasis on educational credentials; Bachelor or Masters in social work, counseling, etc.

TDMHSAS Response: The Department acknowledges the comments above, however, the provision to which these comments are directed is unchanged in the rule from the current effective version of the rule. For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-35-.20(4) Personnel and Staffing Requirements

TERRI SABELLA, CEO, TPCA: We recommend providing organizations with the ability to random drug screen non-clinical employees at the organization's discretion [Emphasis added by TPCA]. Drug screens on an annual basis for all employees may prove cost prohibitive for community health centers.

TDMHSAS Response: The Department agrees with these comments, in part, and has revised Rule 0940-05-35-.20(4) so that these drug screen requirements only apply to employees whose job descriptions include direct patient interaction for OBOT services. The Department contends these individuals will be working with vulnerable individuals and this requirement is a reasonable requirement to ensure patient safety and quality care and prevent diversion.

Chapter 0940-05-36 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization

MICHAEL TINO, MD, FASAM, DABAM, DOCTORS ASSISTED WELLNESS & RECOVERY CTR, LLC: I would like to submit some information that I have gathered and instituted prior to the new rule proposals. I had previously done significant research on physician office medication dispensing including safety and security measures, compliance with DEA regulations, and reporting measures to the state CSMD. I previously submitted some of this information to Mr. Alex King for review and at one point I mentioned to Mr. King all interested parties were welcome to come by the office to review and discuss a dispensing set-up.

Regarding the upcoming Rulemaking Hearing, I wanted to submit to you a very simple and compliant means of physician in-office dispensing. I discovered a system with "Pharmalink" which includes patient medications that are shipped to a proper DEA registered location in the registered physicians name. The system includes software that maintains inventory of all medications received at the office and dispensed from the office up to the moment. Medications are ordered by the physician and received in pre-sealed child proof containers based on prospected need for the upcoming 30 days. Dispensed medications are then automatically reported to the state CSMD within 48 hours. The running inventory is kept up to date in real time and includes reports of all individuals as well as total dispenses completed.

Patients are given an option to fill their prescription at any pharmacy of their choice, with one option being to fill at their prescribing physician's office. They are also notified they have privacy protection under 42 CFR Part 2, and give permission and waiver the right for reporting purposes to the State CSMD, in order for the dispensing physician to meet the states reporting guidelines for all opioid prescriptions.

As an example of how the above system works:

- The physician has seen a client whom is stable on Suboxone 8 mg tablets (2 sublingual tablets daily). The client is seen regularly every 2 weeks, and compliant with all phases of treatment.
- The physician has previously ordered a pre-filled, pre-sealed bottle of Suboxone 8 mg tablets, #28 tablets.
- Client wishes to fill prescription on site. CSMD was checked at patient check in and last filled Rx was from 2 weeks ago at local pharmacy and due to be filled.
- Prescribing-Dispensing physician enters patient data into Pharmalink software system, along with instructions for taking medication and number of days supply. Pre-sealed bottle of #28 Suboxone tablets is retrieved from medication safe, and scanned by barcode into system.
- Medication label is generated including all required information, (Prescription number, date of Rx, patient name, Name, address and phone number of clinic and prescribing-dispensing physician, name of drug, instruction for use, expiration date, controlled substance precautionary statement regarding illegal transfer to anyone else). Drug safety information sheet is included with prescription.
- The patient is instructed to return to pick up prescription at prearranged time for enhanced security of clinic and patient. Patient signs for prescription including initials for above mentioned waivers.

The Pharmalink system is excellent and includes all necessary accountability measures included. There is no need for a consultant pharmacist due to ease of use with this system along with built in Inventory Control and printable Reports. They also offer any assistance needed in case of data entry errors, etc.

In reference to the aforementioned, I believe that OBOT facilities that utilize such programs should be the only facilities given authority to dispense Buprenorphine medications.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: Going back to the dispensing piece of it. I'd mentioned that program and I know there's been some concern about the pharmacist and things like that and I don't want to disparage any pharmacists cause you know I love you guys and you guys have done a fantastic job in all of our roundtables and all that. But I would think that the department should say that hey, before we can approve it [Pharmalink], there has to be evidence, you guys have seen the software, the knowledge, that it will report to the CSMD before approval to try to eliminate a lot of that concern.

TIMOTHY SMYTH, MD, TSAM: The most important comments I wanted to make today is regarding OBOT Plus. As you guys know, I had a great interest in dispensing at my clinic, you know, from the get-go. Whether I wanted to go through the red tape was the only hurdle and now there's more red tape so it's even more of a hurdle.

TDMHSAS Response: The Department acknowledges these comments. Facilities are required to comply with all state, federal, local laws, rules, and regulations. The Department contends that these Rule requirements represent reasonable standards to allow OBOT Pluses to dispense buprenorphine containing products while also ensuring patient safety and quality care.

0940-05-36-.02(2)(j) Definitions

BRAD LAMPLEY, ADAMS AND REESE LLP: Thank you for your consideration of the following comments to the above-referenced rules, which are being offered on behalf of our client, Indivior. My client is concerned that the rules as drafted may serve to limit access to the care set forth in Public Chapter 674, which passed during the 2018 legislative session. That law serves to expand the types of patients who may be prescribed buprenorphine mono or buprenorphine without use of naloxone for the treatment of substance abuse disorder, to those circumstances where the substance is directly administered by the health care provider at the premises. This Public Chapter is specifically intended to address advancements made in medically assisted treatments, where FDA-approved long acting injectables administered onsite by health care providers -- under an FDA-mandated restricted distribution system -- can be effective treatments for opioid addiction, and which should substantially reduce the potential for diversion that exist with other treatments.

Specifically, Indivior requests that the proposed regulations be modified to account for the specific method of delivery/administration set forth in Public Chapter 674, where the controlled substance is lawfully injected or implanted into the patient, and that such practice not be considered as "dispensing" as set forth at proposed section 0940-05-36-.02(2)(j) to render a facility an OBOT Plus. Such a modification would make the regulation consistent with the new Federal law signed by President Trump last week (these comments were submitted to TDMHSAS in late October 31, 2018). That law does not change the Federal CSA definition of "dispense," but instead clarifies that a pharmacy may deliver an injectable or implantable buprenorphine maintenance or detoxification treatment medication to a provider that administers -- but does not dispense -- the substance by injection or implantation, thus carving this specific method of delivery from the definition of "dispensing."

The new Federal statute provides in pertinent part as follows:

> SEC. 3204. DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO BE ADMINISTERED BY INJECTION OR IMPLANTATION.

(a) IN GENERAL.—The Controlled Substances Act is amended by inserting after section 309 (21 U.S.C. 829) the following: "DELIVERY OF A CONTROLLED SUBSTANCE BY A PHARMACY TO AN

ADMINISTERING PRACTITIONER "SEC. 309A. (a) IN GENERAL. Notwithstanding section 102(10), a pharmacy may deliver a controlled substance to a practitioner in accordance with a prescription that meets the requirements of this title and the regulations issued by the Attorney General under this title, for the purpose of administering the controlled substance by the practitioner if—

"(1) the controlled substance is delivered by the pharmacy to the prescribing practitioner or the practitioner administering the controlled substance, as applicable, at the location listed on the practitioner's certificate of registration issued under this title;

"(2) the controlled substance is to be administered for the purpose of maintenance or detoxification treatment under section 303(g)(2) and—

"(A) the practitioner who issued the prescription is a qualifying practitioner authorized under, and acting within the scope of that section; and

"(B) the controlled substance is to be administered by injection or implantation;

"(3) the pharmacy and the practitioner are authorized to conduct the activities specified in this section under the law of the State in which such activities take place;

"(4) the prescription is not issued to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients;

"(5) except as provided in subsection (b), the controlled substance is to be administered only to the patient named on the prescription not later than 14 days after the date of receipt of the controlled substance by the practitioner; and

"(6) notwithstanding any exceptions under section 307, the prescribing practitioner, and the practitioner administering the controlled substance, as applicable, maintain complete and accurate records of all controlled substances delivered, received, administered, or otherwise disposed of under this section, including the persons to whom controlled substances were delivered and such other information as may be required by regulations of the Attorney General.

"(b) MODIFICATION OF NUMBER OF DAYS BEFORE WHICH CONTROLLED SUBSTANCE SHALL BE ADMINISTERED.—

"(1) INITIAL 2-YEAR PERIOD.—During the 2-year period beginning on the date of enactment of this section, the Attorney General, in coordination with the Secretary, may reduce the

number of days described in subsection (a)(5) if the Attorney General determines that such reduction will—

"(A) reduce the risk of diversion; or

"(B) protect the public health.

"(2) MODIFICATIONS AFTER SUBMISSION OF REPORT.—After the date on which the report described in section 3204(b) of the SUPPORT for Patients and Communities Act is submitted, the Attorney General, in coordination with the Secretary, may modify the number of days described in subsection (a)(5).

"(3) MINIMUM NUMBER OF DAYS.—Any modification under this subsection shall be for a period of not less than 7 days.".

(b) STUDY AND REPORT.—Not later than 2 years after the date of enactment of this section, the Comptroller General of the United States shall conduct a study and submit to Congress a report on access to and potential

diversion of controlled substances administered by injection or implantation.

(c) TECHNICAL AND CONFORMING AMENDMENT.— The table of

contents for the Comprehensive Drug Abuse Prevention and Control Act of 1970 is amended by inserting after the item relating to section 309 the following:
"Sec. 309A. Delivery of a controlled substance by a pharmacy to an administering practitioner."

Again, Indivior is not requesting that Tennessee alter the definition of "dispense," but rather permit physicians to receive and administer lawfully prescribed, injectable/implantable buprenorphine dependence treatment products without characterizing and regulating that activity as "dispensing." Indivior respectfully requests that it be made clear that administration by injection of an FDA-approved buprenorphine product in a long acting injectable form (LAI) does not render a facility an OBOT-Plus, and recommends the following revision to subsection 0940-05-36-.02(2)(a), as indicated by the bold and underlined language below.

(2)(a) "Nonresidential office-based opiate treatment facility with dispensing authorization" or "Facility" or "OBOT Plus" is a service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing and dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients. An association by contract, fee for service, business arrangement, or two or more unaffiliated authorized providers with a DATA 2000 waiver operating at the same physical location and who dispense product containing buprenorphine shall be considered an OBOT Plus. **Notwithstanding 0940-05-36-.02(2)(j), practices that administer buprenorphine products as otherwise permitted by law, but do not dispense such products, do not fall within the definition of OBOT Plus.** [Emphasis added by Adams and Reese LLP]. An OBOT Plus does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction.

Please do not hesitate to contact me if you have any questions. Thank you for your consideration.

TREY MOORE, VICE PRESIDENT OF GOVERNMENT RELATIONS, ACADIA HEALTHCARE, INC.: Acadia Healthcare, Inc. appreciates TDMHSAS staff's diligence in drafting the above referenced rule and respectfully submits this comment for the Department's consideration.

At the issue is the definition of "dispense" at 0940-05-36-.02(2)(j). Specifically, Acadia draws TDMHSAS staff's attention to the inclusion of "administering" within the definition and is concerned that such inclusion within the definition of "dispense" creates confusion with respect to P.C. 978(https://publications.tnsosfiles.com/acts/110/pub/pc0978.pdf), which appears to distinguish the two terms:

Notwithstanding any other law, the dispensing of buprenorphine products is prohibited by any person or entity unless [Emphasis added by Acadia] the dispensing is done by a nonresidential office-based opiate treatment facility, as defined in § 33-2-402, with approval from the department of mental health and substance abuse services, a nonresidential substitution-based treatment center for opiate addiction as defined in § 33-2-402, a pharmacy licensed under title 63, chapter 10, or a hospital licensed under title 33, or title 68, chapter 11. ***This subsection (g) does not apply to the administering of buprenorphine products or otherwise permitted by law.*** Tenn. Code Ann. 53-11-311(g)(1)(A) [emphasis added by Acadia]

Reading the statute with the 36.02(2)(j) definition renders the provision nebulous with respect to administering (i.e. on-site supervised consumption) of buprenorphine. The "notwithstanding any other law" clause arguably would be negated by the "does not apply...as otherwise permitted by law" clause within the same subsection.

Acadia respectfully suggests TDMHSAS staff consider rewriting the definition to distinguish and/or exclude administration (i.e. supervised on-site consumption) of buprenorphine from the rule's definition. For guidance, the Department may consider the definition in the Prescription Safety Act of 2016 (i.e. "to physically deliver a controlled substance...with the intent that it be consumed away from the premises...")(Tenn. Code Ann. §53-10-302(8)), as well as TDMHSAS rules governing Non-residential Opioid Treatment Program Facilities ("to prepare and give out more than one single dose...")(Rules and Regulations of the State of Tennessee, 0940-05-42.01(2)(h).).

Acadia again thanks the Department for its considerable effort in drafting the proposed rules and the opportunity to comment.

TDMHSAS Response: The Department agrees with the comments above and has revised the definition of "dispense" in Rule 0940-05-36-.02 so as to not include references to "administering" and to be consistent with T.C.A. § 63-10-204(14) relative to pharmacies.

0940-05-36-.02(2)(v) Definitions

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: This needs to be completely removed in form and concept. A facility should not be required to employ or contract with a pharmacist. This is physician dispensing within an OBOT setting. The liability and accountability ultimately rests with the physician, not a pharmacist.

MICHAEL MANNING, VP OF OPERATIONS AND COMPLIANCE, CATALYST HEALTH SOLUTIONS: I agree [with the TN Recovery Coalition]. Also, I would emphasize the difference between a dispensary and pharmacy. My understanding is a "dispensary" is not under the jurisdiction of the pharmacy board. Some ASC accrediting bodies require a quarterly pharmacist inspection to ensure proper storage and documentation of controlled substances. This is typically met through a pharmacy consultant.

TDMHSAS Response: The Department agrees with the comments above regarding the role of this pharmacist and the pharmacist's involvement in OBOT Plus facilities. Accordingly, the Department has replaced the term "pharmacist-in-charge" with "consultant pharmacist" but has otherwise left the definition unchanged. The Department contends that the role of the consultant pharmacist strikes a balance between ensuring accountability for the labeling, dispensing, and storage requirements for buprenorphine, and access to the medication through physician dispensing. The Department contends that the ultimate responsibility for dispensing still lies with the physician.

0940-05-36-.04(2) Licensing Criteria AND 0940-05-36-.09(6) Inventory

MICHAEL BARON, MD, MPH, MEDICAL DIRECTOR, TMF-PHP (TENNESSEE MEDICAL FOUNDATION): What I worry about and what has been echoed is that some of these rules limit access. And I think one that limits access especially in metropolitan areas is the restriction of no more than two OBOT Plus facilities in the same county. So that treats basically Shelby County like Union County or like Robertson County or Montgomery County. So there's no relation to population density which doesn't make sense to me. Again, it does restrict access to the metropolitan areas where more people live. Knox, Davidson, Williamson, Shelby are all pretty dense areas and not even healthcare shortage areas so you're limiting them to two OBOT Plus treatment facilities within those metropolitan areas. I worry that that limits access.

This rule would be somewhat logical if all 95 counties had equal population densities, but they don't. Shelby county has a population of @950K whereas Pickett county has a population of about 5,000. So, Shelby County is limited to 2 OBOT Plus clinics for a population of 950,000. Healthcare is generally based on patient populations not county lines. Limiting metropolitan counties to 2 OBOT Plus clinics is arbitrary, restrictive and will grossly limit healthcare resources. Imagine if certificates of need for hospital beds were given out on a per county limit. If so, then Davidson county would be limited to an equal number of hospitals as Perry county.

The 10 mile restriction is also illogical as it bases access on geographic distance not on population density.

TIMOTHY SMYTH, MD, TSAM: I want to echo what Dr. Baron just said. Treating every county the same. Addiction, particularly opioid deaths is happening more frequently for urban counties that have more widespread pharmacists and pharmacies not available. And with apologies I'd also like to mention something pointed out by the National Chapter, ASAM, in that they talk about the fact that the doctors, you know, there are new formulations coming on board and it has been my experience in getting pharmacies to order and carry these has not been the easiest thing because they may sit on the shelf for a while and they may not move. Sometimes they have minimal ordering amounts and that kind of thing whereas hopefully an OBOT Plus could order what they need for that patient and get it in and administer it. So again, that allows easier access to care and the patient doesn't have to go to the pharmacy and get that. So that's the other thing I wanted to mention when it comes to limiting the availability of OBOT Plus's to exist improving the inadequacy of current pharmacies. Thank you.

These two sections independently, and especially together, work synergistically to accomplish the goal of limiting the opportunity for a practitioner to open an OBOT Plus. All governmental health agencies (e.g. NIDA, NIH, CDC), national standard guidelines (e.g. ASAM, American Academy of Addiction Psychiatry) and the peer reviewed published professional literature inform us that access to care and maintaining patients in treatment, especially Medically Assisted Treatment (MAT), combined with individualized counseling and wrap around services, is the key to limiting overdoses and overdose deaths. As described below, an OBOT Plus allows expanded access to MAT and can decrease the stigma associated with addiction treatment. By reducing stigma, and the concomitant anxiety associated with seeking care for addiction, an OBOT Plus can bring more patients into care and maintain them in care. Placing arbitrary barriers for opening and OBOT Plus will defeat this purpose.

The points I want to make is that the two sections I'm referring to is 0940-05-36-.09 and 0940-05-36-.04. Under .04 it's section 2 a, b and c. And under 0940-05-36.09 pharmacist-in-charge. You know, these can be done but it's going to make the costs prohibitive. I'm not sure how I go about proving the adequacy of pharmacy services and having an arbitrary limit on how many OBOT Plus it can be in any county. Seems to me to be a barrier to limiting care. When I talk to my colleagues that want to open up an OBOT Plus, they have three main reasons for doing so. One is to help reduce the stigma and personal embarrassment experienced by patients. We've had this discussion many times. When you go to a pharmacy, many, many times the pharmacy employees treat these patients with addiction differently. I'm not trying to say that all of them do but enough of them do that it becomes a barrier to treatment for them. The most common co-occurring psychiatric diagnosis with addiction is social anxiety disorder. These people hate going to the grocery store. They hate going to Walmart. They hate going to the pharmacy. And when they go to a pharmacy they're treated poorly. And some drop out of treatment. Again, it's anecdotal but myself and my colleagues hear it enough that it's worth considering.

Also, as we've discussed many times, pharmacies report having limited capacity. You know, whether this is arbitrary, true or not, you know, we've heard some from the TBI and DEA that indeed the suppliers do put a limit on how many controlled substances they can have. Again, I've had some pharmacies say, "Well, if you want me to give them the buprenorphine, then you have to write something that is not controlled for them, too." In an OBOT Plus we wouldn't have that problem.

Also, just as far as the supply goes, one would hope that the supplier could supply the doctor with enough medicine to treat at least their patients. You know, we have this many patients on this many doses and we have enough.

Also, my main motivation for doing it is I believe I can offer the lowest price. It seems like, at least in Northeast Tennessee, the pharmacy that has the greatest availability has the highest cost of its medicine. You know, up to $10, $12 a pill each. You know, you can get co-pay cards and that kind of thing but it would be my hope that if the overhead was low enough I could offer the least expensive medicine. It would also give me the flexibility of patients who were testing positive for crystal meth I have them come back very soon. I give them a three day supply and they have to come back and they complain pretty frequently now I got to go to the pharmacy twice. Which again, they're treated poorly. They have the

anxiety. So I could have them come back in three days, make sure the methamphetamine, cocaine is gone and see whether they're still appropriate to stay in treatment.

So OBOT Plus I see as limiting the barrier of care, making access easier for patients, and hopefully lowering the costs for the patients. And by especially having the pharmacist-in-charge, which as Mr. Trivette mentioned, OTPS, we have one at Overmountain on a part-time basis for consultation but we're not required to have one. It's just, pharmacists are expensive. They really are because we did investigate that early on cause, to jump through the hoops we thought we'd hire a pharmacist to jump through the hoops for us but it was too expensive at that time.

So I think that's a summary of my comments. I appreciate all you guys do.

Tennessee Society for Addiction Medicine (TNSAM) members who are considering establishing an OBOT Plus do so for one or more of the following reasons:

1. To help reduce stigma and personal embarrassment experienced by their patients. Many employees of pharmacies stigmatize patients with Opioid Use Disorder (OUD) and treat them much differently (i.e. poorly) than they treat other patients. Furthermore, Social anxiety disorder is the most common co-occurring psychiatric disorder experienced by people with addiction. Simply entering a pharmacy causes anxiety for these patients. The added stigma brought on by pharmacy employee prejudice compels them to leave treatment. Members of TNSAM have heard this story hundreds of times. Although anecdotal, the number of stories cannot be ignored.
2. Pharmacies report limited capacity to treat patients with OUD. An OBOT Plus should be able to obtain enough medication for their patients. It is the perception of the providers that the limit placed by pharmacies is arbitrary; although limitations placed by suppliers has recently come to light.
3. An OBOT Plus would be able to offer medication to their patients at the lowest price. All individuals I have interviewed verbalize this cost savings they can pass on to their patients as a motivational factor for opening an OBOT Plus. The cost of the medication varies greatly from one pharmacy to another. It often appears that the only pharmacy with availability if the most expensive pharmacy. Placing these requirements for obtaining an OBOT Plus is unnecessarily burdensome, and will discourage doctors from helping their patients as outlined above because of "too much red tape".

TNSAM further endorses the following comments made by our national chapter (ASAM) germane to this Rule. I request these comments be addressed on TNSAM and my behalf: "The licensing of an OBOT facility that can dispense shouldn't be based on how many pharmacies are in the area and whether those pharmacies carry certain buprenorphine products and dispense. The licensing of these types of facilities has to do with ensuring physicians in OBOTs are adequately regulated to effectively dispense buprenorphine directly to the patient, particularly for new formulations such as injectable and implantable buprenorphine. There is nothing being enacted that ensures pharmacies that dispense will require the pharmacists to be updated and trained on dispensing buprenorphine, particularly the new formulations. As a result, the proximity of a pharmacy in the area, even one that stocks buprenorphine, doesn't necessarily mean the pharmacists there will be trained and willing to dispense buprenorphine directly to the patient, particularly the new formulations, which is one reason why OBOT Plus's are needed in the state. In addition, large, rural counties may not have any pharmacies that dispense any formulations of buprenorphine, so the limit on two OBOT Plus's per county is not based on any evidence."

MICHAEL TINO, MD, FASAM, DABAM, DOCTORS ASSISTED WELLNESS & RECOVERY CTR, LLC: The department should also remove the rules regarding a facility having to identify pharmacies or other OBOT+ licensees within a certain radius. The fact of the matter is that if a physician wishes to dispense from within an OBOT+ setting then he/she should have the opportunity. There are a number of factors that go into the decision wishing to dispense. My patients have encountered stigma from a number of pharmacists and pharmacies in addition to higher costs of medications. I can understand if the department wishes to limit an OBOT+ license to no more than two or three licensees per county, but the fact that a pharmacy may be nearby should not exclude the issuance of an OBOT + license. Lastly, we have encountered supply issues within pharmacies that have caused patients to have to seek other

pharmacies, who may or may not have adequate supply. Nonetheless, the department should only approve facilities that utilize programs such as 'Pharmalink.'

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: This should not have any impact whatsoever as to allowing a physician to dispense from an OBOT setting. The department is failing to factor in costs, ease of access, relationships with surrounding pharmacists (stigma), supply/accessibility, and what the physician feels is best for the patient within the rules and guidelines. This section needs to be completely reconsidered or removed. The department has the authority to choose who or who does not receive authority to become an OBOT+. The two per county rule is also an issue in that it does not account for the size of each county.

We believe this is pretty limited. There are other circumstances besides this regarding pharmacies within ten miles or a lack of pharmacies and things like that. As many of you know at this table we have encountered stigma issues. We have encountered supply issues where pharmacies have not been able to carry things and also costs. This is physician dispensing within an OBOT setting and so we would argue that 0940-05-36-.04(2)(c) should stay regarding OOT Plus within 10 miles and no more than two per county. That that should stay but that it should not be limited in argument to the first two regarding pharmacies because there could be a multitude of factors that go into that.

TDMHSAS Response: Upon consideration of the comments above and the totality of the Rule's requirements, the Department agrees and has removed the requirements previously found in Rule 0940-05-36-.04(2), which required potential licensees to provide documentation of proof of insufficient pharmacy services in order to receive an OBOT Plus license.

Additionally, Rule 0940-05-36-.04 has been reorganized and revised in part to provide clarity to the OBOT Plus application process and criteria.

0940-05-36-.06(3) Recordkeeping

MICHAEL BARON, MD, MPH, MEDICAL DIRECTOR, TMF-PHP, TENNESSEE MEDICAL FOUNDATION: OBOT Plus facilities must report all medications dispensed to the CSMD, as defined in Rule 0940-05-35-.02(2)(d), to the extent permitted by 42 C.F.R. Part 2. Yikes...If this is enforced we will have 2 patient populations, those that go to a non OBOT Plus facility and those that do. Mental Health and addiction patients have been having their medications reported to the CSMD since its inception. A patient with alcohol use disorder that gets put on an outpatient diazepam taper gets reported to the CSMD. A patient with Opioid use disorder that gets treated at a psychiatrist office gets reported to the CSMD.

Not having controlled substances documented in the database is a GIANT STEP BACKWARDS. When that OBOT Plus patient goes to the doctor, ED or walk-in-clinic it is exceedingly important to know that they are on MAT. This helps to prevent relapse, drug to drug interaction and promotes interaction between patient and provider.

As permitted by 42 C.F.R. Part 2 should not be a part of this decision. It is bad enough that OTP clinics do not report to the CSMD. Let's not create 2 patient populations. Doing so probably creates more constitutional problems for DMHSAS, than does 42 C.F.R.

The other one which I really feel strongly about is on page 19 on the redline version about the OBOT Plus number 3. The controlled substances monitoring database is probably the most powerful screening tool we have to look for aberrant behavior, substance use disorders, and to exempt OBOT Plus as permitted by 42 CFR Part 2 is wrong. I know that federal law trumps state law but what federal laws, we sometimes choose what federal laws we want to listen to such as medical marijuana. And clearly that is against federal law but many states are, and we're probably going there here as well, hopefully not under my watch but we probably will. So I would not want to create two patient populations, ones that get registered in the CSMD because they go to a local physician for their buprenorphine and then have an exempt group that are getting treated in OBOT Plus type of clinic. I think that creates two populations. That's one

and two, when a patient is treated in the emergency room or other avenues it's really important to know if they're on buprenorphine or methadone or naltrexone or receiving MAT somewhere. Not to discriminate but to treat them appropriately so they absolutely need to be registered in the CSMD. I think leaving that outlet as is exempt by 42 CFR well substance abuse treatment is very confidential, it absolutely is. But our CSMD, we don't want to go in reverse with that. It's a very powerful clinical tool that we just need to utilize across the board. If we could utilize that for OTPs that would be great, too but I know that's not what we're talking about today. And that's all I have. Thanks.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: There needs to be a rule that only allows physician dispensing in these settings where a program or service is utilized that reports to the CSMD; such as 'Pharmalink.' OR The facility should not have to employ a pharmacist (which they should not be required to anyways) if the physician utilizes programs such as the aforementioned.

Regarding reporting to the CSMD. I think everyone's biggest concern is that very thing – reporting to the CSMD. We would submit that in order for an OBOT physician to dispense out of the OBOT Plus setting they would have to utilize a program such as Pharmalink, that that would be a mandatory, mandate if you will. There are other programs out there that operate similarly to that but we know for a fact that that program does report to our CSMD and it solely operates off of physician dispensing. So we would submit that a program would have to be utilized that did that. I would also ask the department to look specifically into that. I know that you guys probably don't want to list company names. I know that regarding benzos we've listed the clonepan by name but if it could be such as a program like that.

TDMHSAS Response: Pursuant to PC 978, Section 7 (2), OBOT Pluses shall "check the controlled substance database prior to dispensing, and enter the amounts dispensed into the controlled substance database, to the extent permitted by 42 CFR Part 2." The Department contends that these rules cannot conflict with applicable federal statute and/or regulations, including 42 C.F.R. Part 2, and therefore the Department can only require an OBOT Plus to report medications dispensed to the extent permissible by law. OBOT Plus facilities will be participating in the Central Registry even if they are not submitting to the CSMD, and this requirement will allow for additional patient safety measures by preventing dual enrollment.

For these reasons, the Department does not adopt the changes suggested by these comments.

0940-05-36-.08(2) Labeling and Packaging of Buprenorphine Products

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: Are pharmacists required to do such as well?

TDMHSAS Response: Yes, this requirement mirrors Board of Pharmacy rules.

0940-05-36-.09(6) Inventory

MICHAEL TINO, MD, FASAM, DABAM, DOCTORS ASSISTED WELLNESS & RECOVERY CTR, LLC: I would also like to submit comment regarding the 'Pharmacist in Charge' proposed rule as well. This requirement needs to absolutely and unequivocally be removed from the rules. The physician is solely responsible for the dispensing of the medications and ultimately, the physician is held responsible and accountable for the dispensing. It adds an unnecessary and arbitrary burden to require a facility to have to contract with or employ a pharmacist to review information. I have become aware that not even methadone clinics are required to have such staff. Moreover, weight loss clinics and such are not required to have a "Pharmacist in Charge" either. Other providers are also allowed to dispense opioids so long as their dispensing of such does not exceed 50% of their total. In short, the department needs to remove that requirement, without question.

TIMOTHY SMYTH, MD, TNSAM: I ask the TDMHSAS to provide precedent for the concept of a "pharmacist-in-charge" in this type of clinical setting. There are Rules and Regulations for Physician run

clinics to follow when dispensing controlled substances, e.g. weight loss clinics, and family practice clinics. This added burden will make obtaining an OBOT Plus license prohibitively expensive. A Tennessee Licensed OTP (methadone clinic) is not required to have a "pharmacist-in-charge". What is the reasoning for forcing an OBOT to require a "pharmacist-in-charge"? This requirement seems all the more arbitrarily burdensome given the fact that the responsibility of proper record keeping ultimately rests on the dispensing physician, not the pharmacist.

The points I want to make is that the two sections I'm referring to is 0940-05-36-.09 and 0940-05-36-.04. Under .04 it's section 2 a, b and c. And under 0940-05-36.09 pharmacist-in-charge. You know, these can be done but it's going to make the costs prohibitive. I'm not sure how I go about proving the adequacy of pharmacy services and having an arbitrary limit on how many OBOT Plus it can be in any county. Seems to me to be a barrier to limiting care. When I talk to my colleagues that want to open up an OBOT Plus, they have three main reasons for doing so. One is to help reduce the stigma and personal embarrassment experienced by patients. We've had this discussion many times. When you go to a pharmacy, many, many times the pharmacy employees treat these patients with addiction differently. I'm not trying to say that all of them do but enough of them do that it becomes a barrier to treatment for them. The most common co-occurring psychiatric diagnosis with addiction is social anxiety disorder. These people hate going to the grocery store. They hate going to Walmart. They hate going to the pharmacy. And when they go to a pharmacy they're treated poorly. And some drop out of treatment. Again, it's anecdotal but myself and my colleagues hear it enough that it's worth considering.

Also, as we've discussed many times, pharmacies report having limited capacity. You know, whether this is arbitrary, true or not, you know, we've heard some from the TBI and DEA that indeed the suppliers do put a limit on how many controlled substances they can have. Again, I've had some pharmacies say, "Well, if you want me to give them the buprenorphine, then you have to write something that is not controlled for them, too." In an OBOT Plus we wouldn't have that problem.

Also, just as far as the supply goes, one would hope that the supplier could supply the doctor with enough medicine to treat at least their patients. You know, we have this many patients on this many doses and we have enough.

Also, my main motivation for doing it is I believe I can offer the lowest price. It seems like, at least in Northeast Tennessee, the pharmacy that has the greatest availability has the highest cost of its medicine. You know, up to $10, $12 a pill each. You know, you can get co-pay cards and that kind of thing but it would be my hope that if the overhead was low enough I could offer the least expensive medicine. It would also give me the flexibility of patients who were testing positive for crystal meth I have them come back very soon. I give them a three day supply and they have to come back and they complain pretty frequently now I got to go to the pharmacy twice. Which again, they're treated poorly. They have the anxiety. So I could have them come back in three days, make sure the methamphetamine, cocaine is gone and see whether they're still appropriate to stay in treatment.

So OBOT Plus I see as limiting the barrier of care, making access easier for patients, and hopefully lowering the costs for the patients. And by especially having the pharmacist-in-charge, which as Mr. Trivette mentioned, OTPS, we have one at Over Mountain on a part-time basis for consultation but we're not required to have one. It's just, pharmacists are expensive. They really are because we did investigate that early on cause, to jump through the hoops we thought we'd hire a pharmacist to jump through the hoops for us but it was too expensive at that time.

So I think that's a summary of my comments. I appreciate all you guys do.

PAUL TRIVETTE, EXECUTIVE DIRECTOR, TENNESSEE RECOVERY COALITION, INC.: This section needs to be deleted in its' entirety. The dispensing authority is with the physician, not the pharmacist. The department is also creating an extra cost and burden to a physician/facility that would like to dispense. Not even Opioid Treatment Programs are required to have a 'Pharmacist in Charge.' This just simply needs to be removed.

Opioid Treatment Programs (OTPs) are not required to have a 'Pharmacist in Charge' nor are clinics that dispense Phentermine medications. A physician is also allowed to dispense opioid medications so long as that does not exceed 50% of the total medications dispensed.

The pharmacist has absolutely no authority over the physician and moreover, this is not a pharmacy; this is physician dispensing within an OBOT setting.

Please remove this requirement in its' entirety.

This is probably going to be the biggest topic of controversy for a number but page 20, number 6 regarding the pharmacist-in-charge. We would submit that that section needs to be removed in its entirety. This is physician dispensing. The liability and things like that solely fall back onto the physician. It does not fall back onto a pharmacist. Moreover, this adds an extra burden to a physician or an OBOT Plus that wants to dispense. Number one, to find a pharmacist that will do it or to contract with that's willing to do it, have the hours that may be required and the cost that's associated with that. Opioid treatment programs, which the department licenses as well are not even required to have this. Weight loss clinics are also not required to have this for the dispensing of phentramine (sic). Physicians can also dispense opioids in TN as long as it does not exceed 50% of what they're doing. So I know that there's some concern about this but this is adding a pharmacist oversight to a physician who is going to ultimately carry the liability and as previously stated in these rules it requires the physician to notify his or her board that they're going to be doing dispensing as well. We would submit that that section needs to be completely striked in its entirety. And that concludes my comments.

TDMHSAS Response: The Department contends that the role of the consultant pharmacist strikes a balance between ensuring accountability for the labeling, dispensing, and storage requirements for buprenorphine, and access to the medication through physician dispensing. The Department contends that the ultimate responsibility for dispensing still lies with the physician. For these reasons, the Department does not adopt the changes suggested by these comments.

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Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Tennessee Department of Mental Health and Substance Abuse Services
Division:	Administrative and Regulatory Services
Contact Person:	Zack Blair, Director, Office of Legislation and Rules
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Revision Type (check all that apply):
X Amendment
X New
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Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0940-05-02	Licensure Administration and Procedures
Rule Number	**Rule Title**
0940-05-02-.05	Fees
0940-05-02-.23	Inspection Fees

Chapter Number	**Chapter Title**
0940-05-35	Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities
Rule Number	**Rule Title**
0940-05-35-.02	Definitions
0940-05-35-.04	Licensing Procedures
0940-05-35-.05	Policy and Procedures
0940-05-35-.07	Patient Record Requirements
0940-05-35-.09	Individualized Treatment Plan
0940-05-35-.10	Phases of Treatment
0940-05-35-.13	Medication Management
0940-05-35-.20	Personnel and Staffing Requirements

Revision Type (check all that apply):

___ Amendment
_X_ New
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0940-05-36	Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization
Rule Number	**Rule Title**
0940-05-36-.01	Purpose
0940-05-36-.02	Definitions
0940-05-36-.03	Application of the Rules
0940-05-36-.04	Licensing Criteria
0940-05-36-.05	Medication Storage
0940-05-36-.06	Recordkeeping
0940-05-36-.07	Reporting
0940-05-36-.08	Labeling and Packaging of Buprenorphine Products
0940-05-36-.09	Inventory
0940-05-36-.10	Prerequisites to Issuing Prescriptions or Dispensing Medications
0940-05-36-.11	Central Registry

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0940-05-35-.10	Phases of Treatment
0940-05-35-.13 ~~.12~~	Medication Management

0940-05-35-.20~~.19~~	Personnel and Staffing Requirements

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0940-05-36-.09	Inventory
0940-05-36-.10	Prerequisites to Issuing Prescriptions or Dispensing Medications
0940-05-36-.11	Central Registry

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

Chapter 0940-05-02
Licensure Administration and Procedures

Amendments

0940-05-02-.05 Fees.

(1) The applicant must submit fees for the processing of the application prior to the Department's making a determination to grant or to deny licensure. Each initial and renewal application for licensure must be submitted with the appropriate fees. All fees submitted are non-refundable. The fee rate is based on the number of distinct categories of service or facility, as applicable, to be operated at each site. For a residential site, the fee rate is based on the number of beds to be licensed. A fee must be submitted for each facility and/or service for which licensure is being sought under the following schedule:

Non-residential Facility Fees Per Site:

One Distinct Category of Service or Facility	$ 810.00
Two Distinct Categories of Services or Facility	$ 1,010.00
Three Distinct Categories of Service or Facility	$ 1,220.00
Four Distinct Categories of Service or Facility	$ 1,420.00
More than Four Distinct Categories of Services or Facilities	$ 1,620.00
Nonresidential Office-based Opiate Treatment Facility	$ 1,500.00
Nonresidential Office-based Opiate Treatment Facility With Dispensing Authorization	$ 1,500.00

Residential Facilities Fees Per Site:

Mental Health Hospital Facilities (per bed)	$ 175.00
~~Mental Retardation Institutional Habilitation Facilities (per bed)~~	~~$ 175.00~~

All Other Residential Facilities:

Number of Beds	
2 – 3	$ 200.00
4 – 10	$ 280.00
11 – 15	$ 410.00
16 – 50	$ 810.00
More than 50 beds	$ 1,220.00

Authority: T.C.A. §§ 4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-404, 3-2-405, 33-2-406, 33-2-407, 33-2-409, 33-2-413, and Chapter 978 of the Public Acts of 2018.

0940-05-02-.23 Inspection Fees.

(1) Pursuant to T.C.A. § 33-2-413(c), the Department is granted the authority to charge a fee in an amount not to exceed fifty dollars ($50) for an onsite inspection of any facility or service, not including an onsite initial or annual inspection which shall be charged at the rate applicable under Rule 0940-05-02-.05 for all categories of service.

(2) The Department shall invoice the applicant or licensee for each applicable inspection. The applicant or licensee shall pay the inspection fee within thirty (30) days after receipt of the invoice, unless the current license expires before the end of the 30-day period. If the current license expires before the end of the 30-day period, the licensee shall pay the inspection fee before the expiration of the current license.

(3) The Department may withhold the issuance of a license or suspend or expire an existing license pending the payment of ~~the inspection fee~~ fees required under Rule 0940-05-02-.05 or Rule 0940-05-02-.23.

(4) Pursuant to T.C.A. § 33-2-406(h)(2)(b), the Department shall apply a reinspection fee of five hundred dollars ($500) to a nonresidential office-based opiate treatment facility or to a nonresidential office-based opiate treatment facility with dispensing authorization that the Department found to be non-compliant in a prior inspection.

Authority: T.C.A. §§ 4-4-103, 33-1-302, 33-1-303, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-403, 33-2-404, 33-2-413, and Chapter 978 of the Public Acts of 2018.

Chapter 0940-05-35
Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities

Amendments

0940-05-35-.02 Definitions.

(1) Definitions of general terms used in these rules can be found in Rules Chapter 0940-05-01.

(2) Definitions specific to this chapter are as follows:

(a) "Nonresidential office-based opiate treatment facility" or "Facility" or "OBOT" is a service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to ~~fifty~~ twenty-five percent (25~~50~~%) or more of its patients or ~~and~~ to one hundred fifty (150) or more patients.

1. "Nonresidential office-based opiate treatment facility" does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction, otherwise referred to as a nonresidential opioid treatment program as licensed under Rule 0940-05-42.

(b) "Buprenorphine" means a semi-synthetic opioid partial agonist that activates the opioid receptors but not to the same degree as full agonists such as morphine and heroin, as well as any FDA-approved pharmaceutical product that contains buprenorphine.

(c) "Case Management/Care Coordination" means a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality, cost-effective outcomes.

(d) "Controlled Substance Monitoring Database" or "CSMD" means a program administered by the Tennessee Department of Health to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances as set forth by T.C.A. Title 53, Chapter 10, Part 3.

(e) "Counseling" or "Counseling Session" means a face-to-face individual therapeutic counseling session lasting not less than twenty (20) minutes with a qualified provider, or a group educational session of no more than twenty (20) patients and lasting not less

than fifty (50) minutes facilitated by a qualified provider. Counseling shall be focused on issues related to the patient's opioid use disorder and shall not include discussions related to administrative procedures. Telehealth, pursuant to the Tennessee Code Annotated, may be utilized to facilitate counseling. Attendance of a 12-step program, such as Narcotics Anonymous, shall not be considered counseling. The Facility shall document each counseling session in the patient's medical chart.

(f) "DATA 2000 Waiver" means the registered authority given to a qualified health care professional by the U.S. Drug Enforcement Administration to prescribe FDA-approved narcotic medication for opioid detoxification or maintenance treatment pursuant to 21 U.S.C. §823(g).

(g) "DEA" means the United States Drug Enforcement Administration.

(h) "Detoxification" or "Detoxification Treatment" means the use ~~dispensing~~ of an opioid agonist treatment medication in decreasing doses to the patient to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or substantial use of an opioid drug and as a method of bringing the patient to a drug-free state within that period.

(i) "Diversion Control Plan" means specific measures, including assigning responsibilities to medical and administrative staff, to reduce the possibility of diversion of controlled substances from legitimate treatment to illicit use.

(j) "Facility Director" means the person designated by the Facility's governing body who is responsible for the operation of the Facility, for the Facility's overall compliance with federal, state, and local laws and regulations regarding the operation of a non-residential office-based opiate treatment facility, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility. Non-physician facility directors shall not supervise medical staff.

(k) "FDA" means the United States Food and Drug Administration.

(l) "Governing Body" means the person or persons with primary legal authority and responsibility for the overall operation of the OBOT and to whom a director/chief executive officer is responsible. Depending upon the organizational structure, this body may be an owner or owners; a board of directors or other governing members of the licensee; or state, city, or county officials appointed by the licensee.

(m) "Inspection" means any examination by the Department or its representatives of an OBOT including, but not limited to, the premises, staff, persons in care, and documents pertinent to initial and continued licensing, so that the Department may determine whether an OBOT is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements.

(n) "Medical Director" means a physician who meets the qualifications set out in 0940-05-35-~~.19~~.20(3)(b) and who has been designated by the governing body of the Facility to be responsible for the supervision of all medical staff at the Facility and the administration of all medical services offered by the Facility, including compliance with all federal, state and local laws and rules regarding medical treatment of opioid use disorder.

(o) "Medical Record" or "Medical Chart" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations and other written electronics, or graphic data prepared, kept, made or maintained in a facility that pertains to services rendered to patients.

(p) "Medication Assisted Treatment" means use of a medication approved by FDA, in combination with counseling and behavioral therapies, for the treatment of an opioid use disorder.

(q) "Multidisciplinary Treatment Team" or "Treatment Team" means professionals, which may include a licensed physician, licensed physician assistant, licensed nurse, qualified alcohol and drug treatment personnel, and/or mental health professionals, who assess, evaluate, or treat a patient.

(r) "Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Office of Licensure.

(s) "Opiate/Opioid" means a drug that contains opium, derivatives of opium, or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor.

(t) "Observed Drug Screen" or "Observed Urine Drug Screening" means a test used to determine the presence of illicit drugs in an individual's body conducted by and in the presence of a Facility medical or lab staff or contracted medical or lab staff so as to ensure against the tampering with or falsification of the results.

(u) "Patient" or "Service Recipient" shall refer to an individual receiving treatment for opioid use disorder at an OBOT.

(v) "Physical Location" means real property on which is located a physical structure, whether or not that structure is attached to real property, containing one (1) or more units and includes an individual apartment, office, condominium, cooperative unit, mobile or manufactured home, or trailer, if used as a site for prescribing or dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal.

(w) "Phases of Treatment" means the induction, stabilization, and maintenance phases associated with office-based opioid treatment as described in the Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Intervention Protocol published by the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT).

(x) "Program Physician" means any physician, including the medical director, who provides medical services to patients at the Facility.

(y) "Qualified Provider" means a qualified mental health professional as defined in T.C.A. § 33-1-101(20), or a qualified alcohol and drug abuse treatment personnel as defined in 0940-05-01-.16(7).~~, or treatment staff operating under the direct supervision of either a qualified mental health professional or qualified alcohol and drug abuse treatment personnel.~~

(z) "Relapse" means a process in which an individual who has established abstinence or sobriety experiences a recurrence of signs and symptoms of active addiction, often including resumption of the pathological pursuit of reward and/or relief through the use of substances and other behaviors.

(aa) "Taper", "Tapering", and "Medically Supervised Withdrawal" are interchangeable terms for the purposes of these rules.

(bb~~aa~~) "TDMHSAS" or "Department" means the Tennessee Department of Mental Health and Substance Abuse Services.

(cc~~bb~~) "Treatment" or "Substance Abuse Treatment" means a broad range of services intended to assess status, reduce symptoms, or mitigate the effects of substance misuse, substance use disorders, or co-occurring disorders; reduce risk of relapse and associated

harm; or restore or establish well-being for individuals and families; provided, that said practice may include, but not be limited to, care coordination, case management, medical, pharmacological, psychological, psycho-educational, rehabilitative or social services and therapies. The overall goals are to eliminate the substance abuse as a contributing factor to physical, psychological, and social dysfunction and to arrest or reverse the progress of any associated problems.

(dd~~ee~~) "Treatment program" or "Substance Abuse Treatment Program" means an organized system of services containing a mission, philosophy, and model of substance use disorder treatment designed to address the needs of clients.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-35-.04 Licensing Procedures.

(1) An OBOT, as defined in 0940-05-35-.02(2)(a) and T.C.A. § 33-2-402, shall be licensed by the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or Department).

(2) An OBOT shall include, as part of its ownership structure, a physician who holds an unrestricted license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination and holds an active DATA 2000 waiver. "Ownership Structure" means any entity, group, or individual(s) having legal ownership of the OBOT, directing its functions and operations. This includes, but is not limited to, a sole proprietor, general partner, board member of a non-profit or for-profit corporation, or managing member of a limited liability company. Final determination as to whether ownership structure requirements for an OBOT are being met is in the sole discretion of the Department.

(3) A public benefit non-profit/charitable corporation, registered with the Tennessee Secretary of State, shall have ~~the Facility's medical director~~ a physician who holds an unrestricted license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination and holds an active DATA 2000 waiver on its Board of Trustees.

(4) A corporate entity doing business as an OBOT in the State of Tennessee shall not provide, hold itself out as providing, or advertise that it provides substance use disorder treatment for opioid use disorder in the form of opioid agonist therapy, or office-based opiate treatment, unless it complies with the following requirements:

(a) Is appropriately registered with the Tennessee Secretary of State to operate in the State of Tennessee and/or is and remains current with corporate or non-profit/charitable registration requirements of the Tennessee Secretary of State; and,

(b) In the case of a for-profit corporate entity, ~~I~~includes, as a member of its Board of Trustees, the Facility's medical director.

(5) The OBOT shall make application with the Department's Office of Licensure by providing the following information, at a minimum:

(a) Application on the Office of Licensure's designated forms to include the:

1. Initial Application;

2. Fact Sheet; and,

3. Financial Statement;

(b) Applicable fees as defined in Tennessee Administrative Procedures Rule 0940-05-02-.05;

(c) Evidence of a contracted and/or currently employed physician with a DATA 2000 waiver;

(d) Evidence of all physicians contracted and/or currently employed at the Facility holding a license from the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination;

(e) Comprehensive listing of all members of the organization's ownership structure; and

(f) Any other item the Department believes is necessary and proper for application purposes.

(6) Prior to renewal of the license, the OBOT shall be required to ~~formulate~~ develop written policies and procedures that substantially comply with the provisions of this Rule, as well as with Administrative Chapter 0940-05-06.

(7) The Department may release to and/or gather information from the Tennessee Department of Health Board of Medical Examiners (BME) as is necessary for licensing and/or investigation of complaints against an OBOT.

(8) With or without notice, the Department, or its representatives, shall have the right to enter upon or into the premises of an OBOT in order to make inspections and/or investigations deemed necessary to determine compliance with applicable law. The OBOT shall comply with all reasonable requests of the Department and allow it to obtain information from third parties as is necessary.

(9) The Department shall be given the authority to enter upon the premises of an unlicensed facility prescribing buprenorphine-type products to better determine that unlicensed facility's need for TDMHSAS oversight. The Department shall attempt to conduct inspections and investigations in the least intrusive manner needed in order to obtain necessary information. The facility shall be required to provide reasonable amounts of information to the Department for this determination.

(a) "Reasonable amounts of information," in this context, may be considered aggregate, non-patient identifying information to include, but not be limited to:

1. Patient de-identified identifiers;

2. Lists of medications prescribed to that de-identified patient; and

3. The total number of patients seen at the physical location in question.

(10) The governing body of an OBOT shall designate a facility director (as defined in 0940-05-35-.02(2)(j)), who is responsible for the operation of the Facility. Non-physician facility directors shall not supervise medical staff.

(a) Should a Facility operate in such a fashion that the physicians working at the same physical location are unassociated and/or unaffiliated to one another in some type of business arrangement, then the unassociated and/or unrelated physicians shall designate a facility director.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.05 Policy and Procedures.

(1) The governing body of the Facility shall ensure the OBOT is administered and operated in accordance with written policies and procedures in the below listed subject areas and in accordance with these rules. Each Facility shall clearly identify the governing body, as defined in

Rule 0940-05-01-.01(18) and Rule 0940-05-35-.02(2)(l), in its policies and procedures manual including the name and contact information of the governing body.

(a) Admissions and Discharges and Best Practices Utilized (0940-05-35-.06);

(b) Patient Record Requirements (0940-05-35-.07);

(c) Patient Transfers (0940-05-35-.08);

(d) Individualized Treatment Plan ~~and Best Practices Utilized~~ (0940-05-35-.09);

(e) Phases of Treatment (0940-05-35-.10);

(~~e~~f) Special Populations (0940-05-35-.11~~10~~);

(~~f~~g) Counseling (0940-05-35-.12~~11~~);

(~~g~~h) Medication Management (0940-05-35-.13~~12~~);

(~~h~~i) Drug Screens (0940-05-35-.14~~13~~);

(~~i~~j) Detoxification and Medically Supervised Withdrawal (0940-05-35-.15~~14~~);

(~~j~~k) Diversion Control Plan (0940-05-35-.16~~15~~);

(~~k~~l) Reporting Requirements (0940-05-35-.17~~16~~);

(~~l~~m) Patient Rights (0940-05-35-.18~~17~~);

(~~m~~n) Community Relations (0940-05-35-.19~~18~~); and

(~~n~~o) Personnel and Staffing Requirements (0940-05-35-.20~~19~~).

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.07 Patient Record Requirements.

(e) Acknowledgement that the patient has been informed of his or her rights as found in 0940-05-35-.18~~17~~;

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

0940-05-35-.09 Individualized Treatment Plan. ~~and Best Practices Utilized~~

(1) The admission requirements of 0940-05-35-.06 shall first be completed prior to the development of an Individualized Treatment Plan (ITP).

(2) A Facility shall develop an ITP for each patient within thirty (30) days of admission. The ITP shall be developed in accordance with peer reviewed medication assisted treatment guidelines, developed by nationally recognized organizations, such as SAMHSA and the American Society of Addiction Medicine.

(3) Medical care, including referral for necessary medical service, and evaluation and follow-up of patient complaints, shall be compatible with current and accepted standards of medical practice. All patients shall receive a medical evaluation at least annually and other medical examination or testing shall be considered as appropriate. ~~All other medical procedures performed at the time of admission shall be reviewed by the medical staff on an annual basis, and all clinically indicated~~

~~tests and procedures shall be repeated.~~ The medical director or program physician shall record the results of this annual medical evaluation and review of patient medical records in each service recipient's record.

~~(4) Requirements for services according to phases of treatment:~~

~~(a) A patient in the induction or stabilization phases of treatment shall:~~

~~1. Have weekly office visits scheduled;~~

~~2. Receive appropriate counseling sessions at least twice a month;~~

~~3. Be subject to one (1) observed drug screen at least weekly; and~~

~~4. Receive case management services weekly.~~

~~(b) A patient in the maintenance phase of treatment for less than one (1) year shall:~~

~~1. Have a scheduled office visit at least every two (2) to four (4) weeks;~~

~~2. Receive counseling sessions at least monthly;~~

~~3. Be subject to a random observed drug screen at least eight (8) times annually; and~~

~~4. Receive case management services at least monthly.~~

~~(c) A patient in the maintenance phase of treatment for one (1) year or more shall:~~

~~1. Have a scheduled office visit at least every two (2) months;~~

~~2. Receive counseling sessions at least monthly;~~

~~3. Be subject to a random observed drug screen at least four (4) times annually; and~~

~~4. Receive case management services at least monthly.~~

(4~~5~~) Each Facility shall take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, alcoholism, and social services, are made available to the patients who demonstrate a need for such services. The Facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support services that are recommended and/or utilized shall be documented in the patient's record. Each Facility shall have policies for matching a patient's needs to treatment.

(5~~6~~) If the patient experiences a relapse, his or her ITP shall document evidence of intensified services provided. Such evidence may include, but is not limited to, an increase in individual or group counseling session(s) or more frequent drug screens.

(6~~7~~) A patient's ITP shall be reviewed at least every six (6) months and a discussion shall be held with the patient regarding his or her continued desire to remain in the program for maintenance treatment. Alternatives such as medically-supervised withdrawal shall be presented to the patient at the time of the discussion and documented in the patient's record. The patient shall sign and date a statement indicating that she or he wishes to remain within the program in a maintenance phase. If the patient wishes to enter medically-supervised withdrawal, the plan of care shall reflect that choice.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

New

0940-05-35-.10 Phases of Treatment.

(1) Requirements for services according to phases of treatment:

(a) The patient's most current phase of treatment shall be clearly documented in the patient's medical record.

(b) A patient in the induction or stabilization phases of treatment shall:

1. Have weekly office visits scheduled;

2. Receive appropriate counseling sessions at least twice a month;

3. Be administered one (1) observed drug screen at least weekly, for a minimum of three (3) weeks; and

4. Receive case management services weekly.

(c) A patient in the maintenance phase of treatment for less than one (1) year shall:

1. Have a scheduled office visit at least every two (2) to four (4) weeks;

2. Receive counseling sessions at least monthly;

3. Be administered a random observed drug screen at least eight (8) times annually; and

4. Receive case management services at least monthly.

(d) A patient in the maintenance phase of treatment for one (1) year or more shall:

1. Have a scheduled office visit at least every two (2) months;

2. Receive counseling sessions at least monthly;

3. Be administered a random observed drug screen at least four (4) times annually; and

4. Be offered case management services at least every two months.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

Amendments

0940-05-35-.13 ~~.12~~ Medication Management.

(1) Opioid Drugs. Facilities shall develop and implement written policies and procedures for the prescription of opioid drugs. Any changes to these policies and procedures shall be done in consultation with the Facility's medical director. These policies and procedures shall include the following:

(a) Prescribing.

1. The proper initial dose, medication type, and dosage form shall be based on the clinical judgement of the program physician who has examined the patient and who has considered all available relevant patient-specific information including, but not

limited to, drug screens, initial screenings, medication availability and cost, and in consultation with the patient.

2. No standardized routines or schedules of increases or decreases of medication doses may be established or used.

3. A patient dose greater than sixteen milligrams (16mg), or its equivalent, per day shall be considered a high dose.

4. A patient dose of twenty-four milligrams (24mg), or its equivalent, per day shall be considered a maximum dose. Doses greater than the maximum dose may only be used with prior written approval from the State Opioid Treatment Authority. Documentation of this approval shall be kept in the patient's medical chart or otherwise be readily retrievable upon request or facility inspection.

5.~~3.~~ A copy of all prescriptions written for a patient at the Facility shall be documented in the patient's medical chart.

6. The prescriber shall demonstrate to the patient appropriate techniques for administering the particular prescribed treatment medication.

(b) Dispensing. An office based opiate treatment facility without dispensing authorization is prohibited from dispensing buprenorphine-containing products.

(c) Protocols for initiating or switching a patient to a high dose of the treatment medication used at the facility.

1. The patient's medical chart shall include documentation of rationale that it is clinically appropriate for the patient to receive a high dose of the treatment medication.

2. The prescriber shall have a discussion with the patient and the patient shall provide written consent acknowledging that the patient will receive a high dose of the treatment medication and associated risks.

(i) The provider shall document that this discussion included an assessment of the patient's administration technique and that the patient is using the appropriate technique for the prescribed medication.

3. The prescriber shall not establish or use standardized routines or schedules of increases or decreases of treatment medication doses for the patient. Decisions about dosing should be individualized with documentation of reasons for choice of dosing.

(d) Prescriber-Initiated-and-Led Tapering Discussions

1. Prescribers shall initiate and lead a discussion with the patient regarding patient readiness to taper down or taper off treatment medications employed in the patient's treatment with each patient at any time upon the patient's request but no later than one (1) year after initiating treatment and then every six (6) months thereafter.

(i) Documentation of this discussion shall be placed in the patient's medical chart.

(2) CSMD Check. The Facility shall check the CSMD upon every visit of the patient with a program physician. The patient's medical record shall include documentation of the check of the CSMD and the date upon which it occurred.

(3) Benzodiazepine Use. Benzodiazepines should only be prescribed to a patient after careful evaluation while utilizing caution and good judgement. Benzodiazepines may be prescribed to a patient on buprenorphine or a buprenorphine and naloxone combination under the following conditions:

(a) Benzodiazepines shall ~~may~~ not be initiated with a patient with opioid use disorder or the disease of addiction who has never been prescribed these products or has a history of misusing or abusing these products. ~~except in extreme circumstances for severe anxiety of panic disorder, and only after evaluation by a board certified psychiatrist.~~ Notwithstanding, in rare circumstances:

~~(b)~~ 1. Patients who present with a longstanding prescription for benzodiazepines for a legitimate medical condition from another prescriber may be prescribed buprenorphine products by a physician with a DATA 2000 waiver. Contact should be initiated with the prescriber of the benzodiazepine to coordinate care and clear documentation should be recorded in the patient's medical record ~~chart~~.

~~(c)~~ 2. A program physician at an OBOT may assume management of a patient's benzodiazepine prescribing from another physician if the patient is willing to initiate a program of tapering.

~~(d)~~ 3. If a patient presents at an OBOT with a dual diagnosis of opioid use disorder and a clear history of benzodiazepine use disorder, the duration and extent of the abuse should be clearly documented in the medical record. A program physician at an OBOT may prescribe a long acting benzodiazepine, such as clonazepam or its equivalent, under the following conditions:

(i)~~1.~~ A patient may continue on benzodiazepine therapy as medically indicated as long as there is an ongoing effort to taper the patient to the lowest effective dose in order to prevent benzodiazepine withdrawal syndrome and clear documentation of this effort is made in the patient's medical record.

~~(ii)~~ (I) Prescribing more than two (2) milligrams of clonazepam or its equivalent ~~twice~~ daily is considered "high dose therapy".

~~(i)~~ (II) Patients receiving high dose therapy should have justification for the dosing clearly documented in the patient's record.

~~(iii)~~ (III) Patients receiving high dose therapy should be tapered as rapidly as possible to two (2) milligrams or less of clonazepam or its equivalent twice daily, and if the taper is unsuccessful, the reason(s) shall be clearly documented in the patient's medical record.

~~(iv)~~ (IV) Patients receiving high dose therapy for a period of longer than six (6) weeks shall be managed by a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry, or by a physician with a DATA 2000 waiver who has obtained a formal consult from a physician who is board certified in addiction medicine or who is board certified or fellowship trained in addiction psychiatry. The formal consult shall be clearly documented in the patient's medical record.

(4) The Facility shall develop guidelines for review of prescriptions from other providers. These shall include:

(a) Procedures to ensure that a patient's prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician at admission and annually thereafter;

(b) Procedures describing the Facility's response when information about prescriptions from outside physicians is not reported to ensure compliance with this rule; and,

(c) Documentation of the Facility's efforts to obtain information about prescriptions from outside physicians in the patient's record, if a Facility is unable to acquire information about a patient's prescriptions.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-35-.20~~.19~~ Personnel and Staffing Requirements.

(1) A personnel record for each staff member of a Facility shall include an application for employment and/or resume and a record of any disciplinary action taken. A licensee shall maintain written records for each employee.

(2) Staffing.

(a) Facility Director. The governing body of each Facility shall designate in writing a facility director who is responsible for the operation of the Facility and overall compliance with federal, state and local laws and regulations regarding the operation of non-residential office-based opiate treatment programs, and for all employees at the Facility. However, non-physician facility directors shall not supervise medical staff. Facilities shall notify the TDMHSAS Office of Licensure in writing within ten (10) calendar days whenever there is a change in facility director.

(b) Medical Director. The governing body of each Facility shall designate in writing a medical director to be responsible for the supervision of all medical staff at the Facility and the administration of all medical services at the Facility, including compliance with all federal, state, and local laws and regulations regarding the medical treatment of opioid use disorder. The medical director shall be physically present at the Facility the equivalent of twenty-five (25) percent of the time the Facility is open to the public each week. On a monthly basis, the medical director shall review ten (10) percent of the medical charts for patients currently admitted at the Facility and document each chart review. No physician may serve as medical director of more than three (3) Facilities without the prior written approval of the TDMHSAS Office of Licensure.

(c) Program Physician. Facilities are required to provide sufficient physician services to provide the medical treatment and oversight necessary to serve patient need. A Program Physician may be the same individual as the Medical Director, should the Facility so choose and all qualification requirements for a medical director are still met.

(d) Physician Assistants and Advanced Practice Nurses. Licensed physician assistants and advanced practice nurses with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs may perform any functions under Federal and Tennessee law or regulations.

(e) Case management/care coordination. Each Facility shall provide case management/care coordination services by a qualified provider.

(3) Staff Qualifications.

(a) Staff Training. Prior to working with patients, all staff providing treatment or services shall be oriented in accordance with all applicable administrative rules, reporting requirements, and their individual position responsibilities. All staff shall receive ongoing training and development activities. Record of all staff training activities shall be noted in their personnel record.

(b) Medical Director. A medical director shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain an unrestricted license to practice medicine or osteopathy, hold an active DATA 2000 waiver from the DEA, be designated by the OBOT's governing body, and shall have the following experience and/or credentials:

1. Certification in addiction psychiatry by the American Board of Psychiatry and Neurology or exam eligible in addiction psychiatry; and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or

2. Certification as an addiction medicine specialist by the American Board of Addiction Medicine (ABAM) or the American Board of Preventive Medicine (ABPM) or exam eligible for certification as an addiction medicine specialist and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or

3. Meet the Tennessee Department of Health definition of addiction specialist as outlined in Rule 0880-02-.14; or

4. For an OBOT that is accredited by a national accrediting healthcare organization listed in Rule 0940-05-02-.12(1)(a) or (b) in a behavioral health or opioid treatment service category, or equivalent, the medical director shall be exempted from the requirements of (1) – (3) above.

(c) Program Physician. A program physician shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain an unrestricted license to practice medicine or osteopathy, and hold an active DATA 2000 waiver from the DEA.

(d) Facility Directors. All Facility directors shall have at least one (1) year of supervisory or administrative experience in the field of opioid use disorder treatment.

(e) Qualified Provider. A qualified provider shall be duly licensed, certified or registered as required by the State of Tennessee for the profession and shall only perform those duties that are within the scope of their applicable professional practice acts and Tennessee license.

(4) Employee Drug Screening. Facilities shall implement pre-employment and ongoing random drug screening, at least once per calendar year, of all Facility employees whose job descriptions include direct patient interaction for OBOT services.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 912 of the Public Acts of 2016.

Chapter 0940-05-36
Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization

New Rule

Table of Contents

0940-05-36-.01 Purpose
0940-05-36-.02 Definitions
0940-05-36-.03 Application of the Rules
0940-05-36-.04 Licensing Criteria
0940-05-36-.05 Medication Storage
0940-05-36-.06 Recordkeeping
0940-05-36-.07 Reporting

0940-05-36-.08 Labeling and Packaging of Buprenorphine Products
0940-05-36-.09 Inventory
0940-05-36-.10 Prerequisites to Issuing Prescriptions or Dispensing Medications
0940-05-36-.11 Central Registry

0940-05-36-.01 Purpose.

The rules in this chapter implement the law relative to licensure and regulation of "Nonresidential office-based opiate treatment facility with dispensing authorization" or "OBOT Plus" pursuant to Chapter 978 of the Public Acts of 2018.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, 53-11-311, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.02 Definitions.

(1) Definitions of general terms used in these rules can be found in Rule 0940-05-01.

(2) Definitions specific to this chapter are as follows:

(a) "Nonresidential office-based opiate treatment facility with dispensing authorization" or "Facility" or "OBOT Plus" is a service entity that includes, but is not limited to, stand-alone clinics, treatment resources, individual physical locations occupied as the professional practice of a prescriber or prescribers licensed pursuant to Title 63, or other entities prescribing and dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opioid use disorder by preventing symptoms of withdrawal to twenty-five percent (25%) or more of its patients or to one hundred fifty (150) or more patients. An association by contract, fee for service, business arrangement, or two or more unaffiliated authorized providers with a DATA 2000 waiver operating at the same physical location and who dispense products containing buprenorphine shall be considered an OBOT Plus. An OBOT Plus does not include any facility that meets the definition of a nonresidential substitution-based treatment center for opiate addiction.

(b) "Authorized provider" means a healthcare provider authorized by the state or federal government who has authority to issue and dispense prescriptions for buprenorphine.

(c) "Authorized caregiver" means any person who is given written authorization by the patient to act on the patient's behalf.

(d) "Buprenorphine" means a semi-synthetic opioid partial agonist that activates the opioid receptors but not to the same degree as full agonists such as morphine and heroin, as well as any FDA-approved pharmaceutical product that contains buprenorphine.

(e) "Care Team" means the group of healthcare professionals, social workers, and counselors who help manage the patient's detoxification and maintenance of abstinence from the patient's drug of choice.

(f) "Central Registry" means an electronic system approved by the Department to register patients currently receiving treatment at an Opiate Treatment Program ("OTP") or OBOT Plus.

(g) "Controlled substance(s)" means a drug, substance, or immediate precursor in Schedules I through VI as defined or listed in the Tennessee Drug Control Act, compiled in T.C.A., Title 39, Chapter 17, part 4.

(h) "DATA 2000 waiver" means the registered authority given to a qualified health care professional by the U.S. Drug Enforcement Administration to prescribe FDA-approved

narcotic medication for opioid detoxification or maintenance treatment pursuant to 21 U.S.C. §823(g).

(i) "DEA" means the United States Drug Enforcement Agency.

(j) "Dispense" means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent, to include a licensed health care practitioner or a health care facility providing services or treatment to the patient or patients, by or pursuant to the lawful order of a prescriber. This definition does not include administration, or supervised self-administration, as otherwise permitted by law.

(k) "Dispenser" means an authorized provider who dispenses buprenorphine to an ultimate user.

(l) "Dispensing area" refers to the actual physical location where dispensing occurs. It does not include any waiting or common areas.

(m) "Drug" means a substance recognized by the official United States pharmacopeia or formulary intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or, a substance intended to alter the structure or function of the human body.

(n) "Facility director" means the person designated by the Facility's governing body who is responsible for the operation of the Facility, for the Facility's overall compliance with federal, state and local laws and regulations regarding the operation of a non-residential office-based opiate treatment facility with dispensing authorization, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility. Non-physician facility directors shall not supervise medical staff.

(o) "FDA" means the United States Food and Drug Administration.

(p) "Licensee" means a proprietorship, partnership, association, governmental agency, or corporation, that operates a facility or a service and has obtained a license under this part.

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

(r) "Office of Licensure" means the Tennessee Department of Mental Health and Substance Abuse Services Office of Licensure.

(s) "Opiate" or "opioid" means a drug that contains opium, derivatives of opium, or any of several semi-synthetic or synthetic drugs with agonist activity at the opioid receptor(s).

(t) "Patient" or "service recipient" means an individual receiving treatment for opiate use disorder at an OBOT Plus.

(u) "Patient counseling" means communication, by an authorized provider, of information to the patient or authorized caregiver in order to improve therapeutic outcomes and ensure optimal care.

(v) "Consultant Pharmacist" means a pharmacist with an active license in good standing from the Tennessee Board of Pharmacy that is employed or contracted by the OBOT Plus.

(w) "Physical location" means real property on which is located a physical structure, whether or not that structure is attached to real property, containing one (1) or more units and includes an individual apartment, office, condominium, cooperative unit, mobile or

manufactured home, or trailer, if used as a site for prescribing and/or dispensing products containing buprenorphine, or products containing any other controlled substance designed to treat opiate use disorder by preventing symptoms of withdrawal.

(x) "Professional samples" means small quantities (less than a typical 30, 60, or 90-day supply) of medication provided to prescribers or authorized healthcare personnel to be administered to patients.

(y) "State Opioid Treatment Authority" or "SOTA" means any individual person designated by the commissioner to exercise the responsibility and authority for governing the treatment of opioid addiction in accordance with all applicable state and federal regulations, and serves as a liaison with the appropriate federal agencies.

(z) "TDMHSAS" or "Department" means the Tennessee Department of Mental Health and Substance Abuse Services.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.03 Application of the Rules.

(1) The licensee of an OBOT Plus shall comply with the following rules:

(a) Chapter 0940-05-02 Licensure Administration and Procedures;

(b) Applicable Minimum Program Requirements for All Services and Facilities found in Chapter 0940-05-06;

(c) Chapter 0940-05-35 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities; and

(d) Chapter 0940-05-36 Minimum Program Requirements for Nonresidential Office-Based Opiate Treatment Facilities with Dispensing Authorization ("OBOT Plus").

(2) If any provision of these rules, or the application thereof, to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these rules which can be given effect without the invalid provision or application, and to that end the provisions of these rules are declared severable.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.04 Licensing Criteria.

(1) Eligibility

(a) In order to be authorized to dispense buprenorphine containing products, the interested entity must be a current Full licensed Nonresidential Office-Based Opiate Treatment Facility in good standing with the Department that has been in licensed operation for at least one (1) calendar year.

(b) The Facility seeking dispensing authorization shall comply with Rule 0940-05-35-.04.

(2) Procedures

(a) The current Full licensed Office-Based Opiate Treatment Facility shall make request for dispensing authorization in written form and shall pay a $50 fee - as established in Rule 0940-05-02-.23 - via invoice provided by the Office of Licensure.

(b) The Facility seeking dispensing authorization shall be subject to an on-site inspection to ensure compliance with Rule 0940-05-36-.05 Medication Storage.

(c) Each Facility seeking a license must submit to the Office of Licensure proof that every authorized provider at the facility has submitted to their respective professional licensing board notice of his or her intent to dispense buprenorphine products.

(d) Each Facility seeking a license must submit to the Office of Licensure proof that the Facility is participating in the Central Registry.

(3) Prior to renewal of the license, the OBOT Plus shall be required to develop written policies and procedures that are specific to the dispensing of buprenorphine products, and substantially comply with the provisions of this Rule, as well as with Administrative Chapters 0940-05-06 and 0940-05-35.

(4) With or without notice, the Department, or its representatives, shall have the right to enter upon or into the premises of an OBOT Plus in order to make inspections and/or investigations deemed necessary to determine compliance with applicable law. The OBOT Plus shall comply with all reasonable requests of the Department and allow it to obtain information from third parties if necessary.

(5) The Department shall be given the authority to enter upon the premises of an unlicensed facility dispensing buprenorphine products to better determine that unlicensed facility's need for TDMHSAS oversight. The Department shall attempt to conduct inspections and investigations in the least intrusive manner needed in order to obtain necessary information. The facility shall be required to provide reasonable amounts of information to the Department for this determination.

(a) "Reasonable amounts of information," in this context, may be considered aggregate, non-patient identifying information to include, but not be limited to:

1. Patient de-identified identifiers;

2. Lists of medications prescribed to that de-identified patient;

3. Lists of medications dispensed to that de-identified patient;

4. The total number of medications dispensed at the physical location in question; and

5. The total number of patients seen at the physical location in question.

(6) No provider shall dispense buprenorphine to a patient until an OBOT Plus license has been issued by the Office of Licensure.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.05 Medication Storage.

(1) Buprenorphine products shall be stored in a secure storage area in compliance with 21 CFR Part 1301.72.

(2) All prescription drugs and controlled substances, and related materials, shall be stored in an area not accessible to the public.

(3) The patient waiting area shall be physically separated from the buprenorphine storage and dispensing area.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.06 Recordkeeping.

(1) Each OBOT Plus shall maintain records with the following information for each buprenorphine product dispensed:

(a) Name of product;

(b) Medication strength;

(c) Dosage form;

(d) Date dispensed;

(e) Adequate identification of patient;

(f) Amount dispensed; and

(g) Dispenser's initials or other identifier.

(2) OBOT Plus facilities must maintain documentation of participation in the Central Registry, pursuant to Rule 0940-05-36-.11, in order to prevent dual enrollment, diversion and to ensure patient safety.

(3) OBOT Plus facilities must report all medications dispensed to the controlled substances monitoring database, as defined in Rule 0940-05-35-.02(2)(d), to the extent permitted by 42 C.F.R. Part 2.

(4) A patient record system shall be maintained by all OBOT Plus facilities for patients for whom prescription or medical orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary to identify previously dispensed prescription or medical orders at the time a prescription or medical order is presented.

(a) In the event of a patient record system shut down, dispensing records must be maintained manually and entered into the patient records system as soon as the issue causing the shutdown is resolved.

(5) A record of compliance with Rule 0940-05-36-.09 shall be signed by the Facility Director and maintained at the OBOT Plus facility with other controlled substance records for at least two (2) years.

(6) Authorized providers shall notify their appropriate licensing board of their intent to dispense buprenorphine at an OBOT Plus facility. OBOT Plus facilities shall be required to maintain records indicating this notification for each authorized provider it employs for as long as he/she is employed and at least one (1) year thereafter.

(7) The required recordkeeping of this section will be maintained in a dispensing log at the physical location of the OBOT Plus facility.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.07 Reporting.

(1) OBOT Plus facilities must adhere to all reporting requirements of Rule 0940-05-02-.20.

(2) The Facility Director shall immediately report to the Department and appropriate licensing board(s) any robbery, embezzlement, theft, burglary, fire, or disaster resulting in a loss of prescription drugs, controlled substances, medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs, controlled substances, medical devices, or related materials lost or damaged and, shall include all other requirements under Rule 1140-03-09;

(3) Controlled substance bulk inventory lost through breakage, damage, or spillage, other than an individual patient dose, should be considered an accountable loss. Disposal of such controlled substances must be performed in accordance with DEA requirements and must be reported on DEA Form 106 Registrants Inventory of Drugs Surrendered in accordance with 21 C.F.R. 1301.76.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.08 Labeling and Packaging of Buprenorphine Products.

(1) The authorized provider shall affix to the buprenorphine package a label showing at least the following information:

(a) Name, address and telephone number of the OBOT Plus;

(b) Prescription or medication order serial number;

(c) Date of initial dispensing and/or refill date;

(d) Name of the patient;

(e) Name of the prescriber;

(f) Name of the practitioner dispensing the medication;

(g) Directions for use and cautionary statements, if any;

(h) Name and expiration date of the product, if applicable;

(i) The following controlled substance warning: "CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for who it was prescribed."; and

(j) Any other appropriate advisory labels.

(2) OBOT Plus facilities must ensure that buprenorphine products are packaged in a manner that is designed to reduce the risk of accidental ingestion, including the use of child-proof containers.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.09 Inventory.

(1) Each OBOT Plus shall be required to procure all buprenorphine containing products from a wholesaler/distributor licensed by the Board of Pharmacy pursuant to Rule 1140-09.

(2) Each OBOT Plus shall maintain an inventory of buprenorphine products. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the physical location.

(a) Each licensee shall be required to take an initial inventory of all buprenorphine products, in accordance with Rule 0940-05-36-.09(3), prior to dispensing any of these products to patients.

(b) After the initial inventory is taken, the OBOT Plus facility shall be required to maintain a perpetual inventory of buprenorphine products.

(3) Each person authorized to dispense buprenorphine products shall include the following information in the inventory documentation pursuant to 21 CFR Part 1304.11(1)(e)(iii) and (iv):

(a) The name and address of the OBOT Plus facility;

(b) The following information for each buprenorphine product in finished form:

1. The name of the substance;

2. Each finished form of the substance (e.g., 8/2 mg films);

3. The number of commercial containers of each finished form (e.g. four 30-film boxes); and

4. The exact quantity of the finished form on hand.

(c) The date of inventory; and

(d) The time the inventory was taken.

(4) The Facility Director or a designated clinical staff member shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be witnessed by a second healthcare professional and documented.

(5) For each damaged or defective controlled substance awaiting disposal, the inventories shall include:

(a) The name of the substance;

(b) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(c) The reason for the substance being maintained by the OBOT Plus facility.

(6) If an OBOT Plus destroys buprenorphine products they must be destroyed onsite or via a reverse distributor.

(a) For each buprenorphine product destroyed onsite, the facility shall keep a record of the following:

1. The name of the substance;

2. The strength of the substance;

3. The dosage form of the substance;

4. The total quantity destroyed;

5. Method of destruction;

6. Date and time of the destruction;

7. The signature of the person destroying the substance; and

8. The signature of at least one person, other than the person destroying the substance, who witnessed the destruction of the substance.

(7) Each OBOT Plus shall maintain documentation of a current employment or contractual relationship with a consultant pharmacist.

(a) If an OBOT Plus dispenses buprenorphine to less than 100 unique patients a month, the pharmacist-in-charge shall perform a quarterly inventory review of the OBOT Plus's invoices, perpetual inventory, and documentation of dispensed medications.

(b) If an OBOT Plus dispenses buprenorphine to 100 or more unique patients a month, the pharmacist-in-charge shall perform a monthly review of the OBOT Plus's invoices, perpetual inventory, and documentation of dispensed medications and review the inventory for discrepancies.

1. If a discrepancy is found, an OBOT Plus shall report the discrepancy to the Department immediately upon discovery. The OBOT Plus shall also report to the DEA any discrepancies as appropriate.

2. Within 14 calendar days of discovery of a discrepancy, the OBOT Plus shall submit to the Department a root cause analysis examining the cause of the discrepancy and a plan to prevent such discrepancies in the future.

3. Part of the plan may include an increase in inventory review by the pharmacist-in-charge.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.10 Prerequisites to Issuing Prescriptions or Dispensing Medications.

(1) Prior to writing a prescription or medication order, an OBOT Plus provider shall comply with Rule 0940-05-35 and Rule 0880-02-.14(2).

(2) Buprenorphine dispensed by an OBOT Plus may only be filled and labeled by:

(a) An authorized provider; or

(b) By a designated agent of the authorized provider, if:

1. The filling and labeling is done in the physical presence of the authorized provider at the OBOT plus;

2. The authorized provider acts as the final check in the dispensing process, and is responsible for the dispensing process in its entirety; and

3. The authorized provider documents that he or she has completed a final verification of the dispensing.

(3) Authorized providers may dispense an initial prescription only after checking the CSMD and central registry.

(4) Authorized providers must check the CSMD for every prescription dispensed.

(5) When a patient is first seen at a Facility and the patient has previously been dispensed buprenorphine, the authorized provider shall make a reasonable effort to contact the patient's previous dispenser and obtain dosing information.

(6) Authorized providers dispensing buprenorphine pursuant to Rule 0940-05-36-.10(2) above, must comply with medication counseling requirements pursuant to Rule 1140-03-.01 and Rule 0940-05-35.

(a) Upon the initial receipt of a prescription or medication order and following a review of the patient's record, the authorized provider shall personally counsel the patient or authorized caregiver "face-to-face" if the patient or authorized caregiver is present. If the patient or authorized caregiver is not present, an authorized provider shall make a reasonable effort to counsel through alternative means.

(b) The authorized provider must document the counseling or document the reasonable efforts taken to provide counseling. If the patient or authorized caregiver refuses counseling, the authorized provider must document this refusal.

(c) Patient counseling shall cover matters as defined in Rule 1140-03-.01, which in the exercise of the authorized provider's professional judgement, the authorized provider deems significant. This shall include, but is not limited to, the following:

1. The name and description of the medication;

2. The dosage form, dose, route of administration, and duration of drug therapy;

3. Special directions and precautions for preparation, administration, and use by the patient;

4. Common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

5. Techniques for self-monitoring drug therapy;

6. Proper storage; and

7. Action to be taken in the event of a missed dose.

(d) Upon a subsequent dispensing of a buprenorphine product, the authorized provider, or a person designated by the authorized provider, shall offer for the authorized provider to personally counsel the patient or caregiver about the medication.

(6) An OBOT Plus shall not require that a patient's buprenorphine be dispensed from that OBOT Plus. An OBOT Plus shall provide patients with a list of alternative locations where buprenorphine is dispensed should the patient choose to fill his or her prescription at another location.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

0940-05-36-.11 Central Registry.

(1) All OBOT Plus facilities shall participate in the Central Registry.

(2) Patients shall be informed of the Facility's participation in the Central Registry. Prior to initiating a central registry inquiry, the Facility shall obtain the service recipient's written consent.

(3) To prevent simultaneous enrollment of a service recipient in more than one OBOT Plus, the Facility shall initiate a clearance inquiry by submitting to the Central Registry the name, date of

birth, or any other relevant information required for the clearance procedure or as required by the SOTA prior to dispensing buprenorphine products. No person who is reported by the Central Registry to be enrolled at another such Facility shall be admitted to an OBOT Plus, or in the event a multiple enrollment is found, the patient shall not continue to be dispensed buprenorphine until the patient enrollment status is active solely at a single OBOT Plus where the patient is currently receiving buprenorphine products.

(4) Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed OBOT Plus facility, or its designated legal representative, or as approved by the SOTA, or as required by law. Information made available by the Central Registry to Facilities or their designated legal representatives or as approved by the SOTA shall also be treated as confidential.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-301, 33-2-302, 33-2-402, 33-2-403, 33-2-404, 33-2-407, and Chapter 978 of the Public Acts of 2018.

* 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)

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Department of Mental Health and Substance Abuse Services on 3/7/2019 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: *08/27/18*

Rulemaking Hearing(s) Conducted on: (add more dates). *10/30/18*

Date: 3/7/2019

Signature:

Name of Officer: Marie Williams, LCSW

Title of Officer: Commissioner

SUE B. HUNT
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF DAVIDSON

Subscribed and sworn to before me on: March 7, 2019

Notary Public Signature: Sue B. Hunt

My commission expires on: March 8, 2021

Agency/Board/Commission:

Rule Chapter Number(s):

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Herbert H. Slatery III
Herbert H. Slatery III
Attorney General and Reporter

3/29/2019
Date

Department of State Use Only

Filed with the Department of State on: 3/29/2019

Effective on: 6/27/2019

Tre Hargett
Secretary of State

SECRETARY OF STATE
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