G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Tennessee Corrections Institute
DIVISION:	
SUBJECT:	Minimum Qualifications for Correctional Personnel
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 41-7-106
EFFECTIVE DATES:	September 6, 2012 through March 5, 2013
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rule permits the Tennessee Corrections Institute (TCI) to establish criteria for determining whether to waive the minimum statutory qualifications required to be a jail administrator, corrections officer, or guard in a county jail or workhouse. Under the previous rule, TCI had no authority to grant waivers of any kind.

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)

(Insert statement here) **The proposed rules will have an impact on local governments.**

Department of State
Division of Publications
312 Rosa L. Parks, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 09-04-12
Rule ID(s): 5306
File Date (effective date): 9/6/12
End Effective Date: 3/5/13

Emergency Rule Filing Form

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

Agency/Board/Commission: Tennessee Corrections Institute
Division:
Contact Person: C. Edward Scudder, Jr.
Address: 500 James Robertson Parkway
Davy Crockett Tower, Legal Office
Nashville, Tennessee
Zip: 37243
Phone: (615) 532-5773
Email: ed.scudder@tn.gov

Rule Type:
X Emergency Rule

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

Statement of Necessity:
An immediate danger to public safety exists across the State of Tennessee. Many local correctional departments are woefully understaffed. A correctional facility that is short staffed can create an unsafe condition for the corrections officers, the inmates, and most importantly, the general public. Sheriffs and jail administrators strive to keep their correctional facilities fully staffed, but they face many obstacles in hiring new corrections officers. The ability to seek a waiver of certain statutory pre-employment conditions from the Board of Control of the Tennessee Corrections Institute will allow the sheriffs and jail administrators to hire applicants who are otherwise qualified.

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

Chapter Number	Chapter Title
1400-04	Criteria for Waivers
Rule Number	**Rule Title**
1400-04-.01	Submission of Waiver Request
1400-04-.02	Waiver of Pre-Employment Requirements

(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)

Substance of Proposed Rules

Chapter 1400-04

Criteria for Waivers

Table of Contents

1400-04-.01 Submission of Waiver Request
1400-04-.02 Waivers of Pre-employment Requirements

1400-04-.01 Submission of Waiver Request. A request for waiver of pre-employment requirements must be submitted by the prospective employing agency prior to the employment of the person requiring the waiver. Requests must be submitted no later than thirty (30) days prior to the next scheduled meeting of the Board of Control. Request for waiver filed/submitted by an individual will not be accepted by the Board of Control. The requesting department shall be represented by its designee before the Board of Control. Once a waiver has been granted for a previous pre-employment requirement for a particular employee, that requirement shall be considered waived for future applications for certification.

Authority: T.C.A. §§ 41-7-106 and 41-4-144.

1400-04-.02 Waiver of Pre-employment Requirements. A waiver of pre-employment requirements may be granted under the following circumstances:

(1) No person may be employed as a local correctional officer, who requires a waiver under this section, until such waiver is granted.

(a) Military History - The Board of Control may waive pre-employment requirements relating to the military history on an individual basis and depending on the circumstances.

1. Waivers may be granted from pre-employment requirements for the following separations from military service:

(i) an Entry Level Separation

(ii) a General Discharge under Honorable Conditions.

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

(i) Dishonorable Discharge

(ii) Bad Conduct Discharge

(iii) Other Than Honorable Discharge.

(b) Criminal Activity - The Board of Control may consider a waiver from pre-employment requirements relating to criminal activity on an individual basis and depending on the circumstances.

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

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

   (ii) controlled substances, as defined in the Tennessee Drug Control Act compiled in Title 39, Chapter 17, Part 4, when the offense was classed as a misdemeanor.

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

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

   (i) the amount of time since the offense;

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

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

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

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

(c) Mental Illness or Disorder – There is no waiver from the certification requirement set forth in T.C.A. § 41-4-144(a)(9).

Authority: T.C.A. §§ 41-7-106 and 41-4-144.

* 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)
Sheriff Bill Oldham	X				
Dr. Deborah Newman	X				
Sheriff Armando Fontes	X				
Commissioner Derrick Schofield	X				
Director Jeremy Harrell	X				
Director Bob McKee	X				
Dr. Deborah Burris-Kitchen	X				

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

Date: August 27, 2012

Signature: C. Edward Scudder, Jr.

Name of Officer: C. Edward Scudder, Jr.

Title of Officer: Assistant General Counsel

W. C. HENDERSON STATE OF TENNESSEE NOTARY PUBLIC WILSON COUNTY

Subscribed and sworn to before me on: August 27, 2012

Notary Public Signature: W C Henderson

My commission expires on: Sept 19, 2013

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.

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

8-31-12
Date

Department of State Use Only

RECEIVED
2012 SEP -6 PM 1:44
SECRETARY OF STATE
PUBLICATIONS

Filed with the Department of State on: 9/6/12

Effective for: 180 *days

Effective through: 3/5/13

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

Tre Hargett by Mona Hart, PDA

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	State
DIVISION:	Business Services
SUBJECT:	Workers' Compensation Exemption Fees
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 50-6-912
EFFECTIVE DATES:	December 3, 2012 through June 30, 2013
FISCAL IMPACT:	The agency anticipates: (1) A one-time increase of $2,529 in state expenditures from the Employee Misclassification Education and Enforcement Fund; (2) A recurring decrease in state revenues in fiscal year 2012-13 which exceeds $236,200 to the Employee Misclassification Education and Enforcement Fund; and (3) A recurring decrease in state revenues in fiscal year 2013-14 which exceeds $1,105,350 to the Employee Misclassification Education and Enforcement Fund.
STAFF RULE ABSTRACT:	This rule reduces the issuance and renewal fees for construction services provider registrations and construction services provider workers' compensation exemptions from $100 to $50, effective January 1, 2013. The agency reports that this fee reduction is authorized by Chapter 1030 of the Public Acts of 2012.

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)

If adopted, these rules will not have any impact on the expenditures or revenues of local governments.

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.

There were no comments, written or oral, filed at the rulemaking hearing for the above-referenced rules held at the Department of State on July 13, 2012.

Regulatory Flexibility Addendum

Pursuant to T.C.A. § 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

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

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

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

The rules are amended to mirror language that is contained in the statute based on passage of Chapter 1030 of the Tennessee Public Acts of 2012. Therefore, the rules are clear, concise, and are not ambiguous.

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

The rules use language that is contained in the statute based on passage of Chapter 1030 of the Tennessee Public Acts of 2012 to reduce the following fees from $100 to $50: 1) construction services provider registration; 2) construction services provider workers' compensation exemption; 3) construction services provider workers' compensation exemption renewal; and 4) construction services provider registration renewal.

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

The rules mirror the statute. The reduction of fees should assist small businesses with compliance.

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

Compliance is simplified because the reduction of fees will reduce the cost of compliance. Reporting requirements remain the same.

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

The rules do not impact performance, design, or operational standards for small businesses.

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

The rules do not create unnecessary entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs. The rules mirror the statutory language and reduce costs.

Department of State
Division of Publications
312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 09-01-12
Rule ID(s): 5305
File Date: 9/4/12
Effective Date: 12/3/12

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing. TCA Section 4-5-205

Agency/Board/Commission:	Department of State
Division:	Business Services
Contact Person:	Nathan Burton
Address:	312 Rosa L. Parks Ave., Snodgrass Tower, 6th Floor, Nashville, TN
Zip:	37243
Phone:	615-741-2819
Email:	nathan.burton@tn.gov

Revision Type (check all that apply):

X Amendment
___ New
___ Repeal

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

Chapter Number	**Chapter Title**
1360-09-01	Workers' Compensation Exemption Registration
Rule Number	**Rule Title**
1360-09-01-.05	Fees

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Chapter 1360-09-01
Workers' Compensation Exemption Registration
Amendments

Rule 1360-09-01-.05 Fees is amended by deleting the language "one hundred dollars ($100)" wherever it appears and by substituting instead the language "fifty dollars ($50)". Fees is further amended by inserting the following language as a new subdivision (4) so that, as amended, the existing subdivisions and the additional subdivision shall read as follows:

Rule 1360-09-01-.05 Fees.

(1) The following fees apply to documents issued or filed in writing or online:

(a) The fee for the issuance of a construction services provider registration to providers who have not been issued a license by the board is ~~one hundred dollars ($100)~~ fifty dollars ($50).

(b) The fee for the issuance of a construction services provider workers' compensation exemption is ~~one hundred dollars ($100)~~ fifty dollars ($50).

(c) The fee for the filing of correction information pursuant to T.C.A. §50-6-905(c) is twenty dollars ($20).

(d) The fee for the filing of change of address information pursuant to T.C.A. §50-6-905(d) is twenty dollars ($20).

(e) The fee for the filing of a construction services provider workers' compensation exemption renewal is ~~one hundred dollars ($100)~~ fifty dollars ($50).

(f) The fee for the filing of a construction services provider registration renewal to providers who have not been issued a license by the board is ~~one hundred dollars ($100)~~ fifty dollars ($50).

(g) The fee for the filing of a revocation pursuant to T.C.A. §50-6-908(a) is twenty dollars ($20).

(h) The fee for the issuance of a copy of the notice issued pursuant to T.C.A. §50-6-905(a)(1) is twenty dollars ($20).

(i) The fee for the issuance of a second or subsequent construction services provider workers' compensation exemption registration is twenty dollars ($20) per registration.

(j) The fee for the filing of a second or subsequent construction services provider workers' compensation exemption renewal is twenty dollars ($20) per renewal.

(2) In addition to the fees authorized in subsection (1), the secretary of state is authorized to charge an online transaction fee to cover costs associated with processing payments for applications submitted online.

(3) To facilitate credit card payment and fee collection the Secretary of State may establish a merchant ID or may cause one to be established in the Department of Labor and Workforce Development specifically for the Employee Misclassification Education and Enforcement Fund. If the merchant ID is established in the Department of Labor and Workforce Development all transaction and other fees associated with credit card payments will be paid directly from the Employee Misclassification Education and Enforcement Fund.

(4) The fees authorized by Tenn. Pub. Acts ch. 1030 (2012) in subdivisions (1)(a), (1)(b), (1)(e) and (1)(f) are effective on January 1, 2013 and apply to registrations or renewals on or after that date.

Authority: T.C.A. §50-6-912 and Tenn. Pub. Acts, ch. 1030 (2012).

* 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 State (board/commission/ other authority) on 7/13/12 (mm/dd/yyyy), and is in compliance with the provisions of TCA 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 05/22/12

Rulemaking Hearing(s) Conducted on: (add more dates). 07/13/12

Date: 7/13/12

Signature: Tre Hargett

Name of Officer: TRE HARGETT

Title of Officer: SECRETARY OF STATE

MONA LEE HART
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY, TENN.
My Commission Expires NOV. 7, 2012

Subscribed and sworn to before me on: July 13, 2012

Notary Public Signature: Mona Lee Hart

My commission expires on: Nov. 7, 2012

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

Robert E. Cooper, Jr.
Attorney General and Reporter

Date

Department of State Use Only

RECEIVED
2012 SEP -4 PM 2:13
SECRETARY OF STATE
PUBLICATIONS

Filed with the Department of State on: 9/4/12

Effective on: 12/3/12

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Environment and Conservation
DIVISION:	Water Supply
SUBJECT:	Underground Injection Control
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 69-3-101 et seq.
EFFECTIVE DATES:	December 11, 2012 through June 30, 2013
FISCAL IMPACT:	Minimal
STAFF RULE ABSTRACT:	This rulemaking renumbers the rule chapter regulating underground injection control from 1200-04-06 to 0400 45-06. No substantive changes are being made.

Impact on Local Governments

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

The Department does not anticipate an impact on local governments.

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.

There were no comments at public hearings regarding the proposed rule changes.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

Underground Injection Control Rules regulate entities that are discharging into ground water via large capacity septic systems (serving more than 20 persons per day), stormwater injection systems and waste injection. There are approximately 2000 currently regulated entities. Small businesses would include restaurants and other commercial and industrial establishments that have stormwater injection systems, injection wells or large capacity septic systems. There are no costs identified for small businesses. There were no substantive changes to the rules. The Department is re-numbering to the chapter 0400 series which is designated for Environment and Conservation from the chapter 1200 series of the Department of Health.

(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 are no costs identified for the proposed rule changes. There were no substantive changes to the rules. The Department is re-numbering to the chapter 0400 series which is designated for Environment and Conservation from the chapter 1200 series of the Department of Health.

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

There should not be any effect on small businesses and consumers from the rule changes.

(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 is no identified burden to small businesses. There are no substantive changes to the rules, only re-numbering to the 0400 series.

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

This is not applicable. There are no substantive changes in the proposed rules, merely re-numbering.

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

This is not applicable. There are no substantive changes in the proposed rules, merely re-numbering.

Department of State
Division of Publications
312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 09-05-12
Rule ID(s): 5307-5308
File Date: 9/12/12
Effective Date: 12/11/12

Rulemaking Hearing Rule(s) Filing Form

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

Agency/Board/Commission:	Environment and Conservation
Division:	Water Supply
Contact Person:	Tom Moss
Address:	6th Floor, L & C Tower 401 Church Street Nashville, Tennessee
Zip:	37243-1549
Phone:	615-532-0170
Email:	Tom.Moss@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
X Repeal

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

Chapter Number	**Chapter Title**
1200-04-06	Underground Injection Control
Rule Number	**Rule Title**
1200-04-06-.01	Authority and Purpose
1200-04-06-.02	General
1200-04-06-.03	Injection Prohibited
1200-04-06-.04	Prevention of Pollution of Ground Water and Identification of Underground Sources of Drinking Water and Exempted Aquifers
1200-04-06-.05	Injected Fluid Standards
1200-04-06-.06	Classification of Injection Wells
1200-04-06-.07	Permit Required
1200-04-06-.08	Authorization by Permit For Injection Wells Not Authorized By Rule
1200-04-06-.09	General Standards and Methods
1200-04-06-.10	Class I Wells
1200-04-06-.11	Class II Wells
1200-04-06-.12	Class III Wells
1200-04-06-.13	Class IV Wells
1200-04-06-.14	Class V Wells
1200-04-06-.15	Fees for Class I Injection Wells
1200-04-06-.16	Fees For Class II Injection Wells
1200-04-06-.17	Fees For Class III Injection Wells
1200-04-06-.18	Fees For Class V Injection Wells
1200-04-06-.19	Bonds Required for Permitted Wells

Chapter Number	Chapter Title
0400-45-06	Underground Injection Control
Rule Number	**Rule Title**
0400-45-06-.01	Authority and Purpose
0400-45-06-.02	General
0400-45-06-.03	Injection Prohibited
0400-45-06-.04	Prevention of Pollution of Ground Water and Identification of Underground Sources of Drinking Water and Exempted Aquifers
0400-45-06-.05	Injected Fluid Standards
0400-45-06-.06	Classification of Injection Wells
0400-45-06-.07	Permit Required
0400-45-06-.08	Authorization by Permit For Injection Wells Not Authorized By Rule
0400-45-06-.09	General Standards and Methods
0400-45-06-.10	Class I Wells
0400-45-06-.11	Class II Wells
0400-45-06-.12	Class III Wells
0400-45-06-.13	Class IV Wells
0400-45-06-.14	Class V Wells
0400-45-06-.15	Fees for Class I Injection Wells
0400-45-06-.16	Fees For Class II Injection Wells
0400-45-06-.17	Fees For Class III Injection Wells
0400-45-06-.18	Fees For Class V Injection Wells
0400-45-06-.19	Bonds Required for Permitted Wells

(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)

Repeal

Chapter 1200-04-06
Underground Injection Control

Chapter 1200-04-06 Underground Injection Control is repealed.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

New Rules

Chapter 0400-45-06
Underground Injection Control

Table of Contents

0400-45-06-.01	Authority and Purpose	0400-45-06-.11	Class II Wells
0400-45-06-.02	General	0400-45-06-.12	Class III Wells
0400-45-06-.03	Injection Prohibited	0400-45-06-.13	Class IV Wells
0400-45-06-.04	Prevention of Pollution of Ground Water And Identification of Underground Sources of Drinking Water and Exempted Aquifers	0400-45-06-.14	Class V Wells
		0400-45-06-.15	Fees for Class I Injection Wells
		0400-45-06-.16	Fees For Class II Injection Wells
		0400-45-06-.17	Fees For Class III Injection Wells
0400-45-06-.05	Injected Fluid Standards	0400-45-06-.18	Fees For Class V Injection Wells
0400-45-06-.06	Classification of Injection Wells	0400-45-06-.19	Bonds Required for Permitted Wells
0400-45-06-.07	Permit Required	Appendix A	
0400-45-06-.08	Authorization by Permit For Injection Wells Not Authorized By Rule		
0400-45-06-.09	General Standards and Methods		
0400-45-06-.10	Class I Wells		

~~1200-04-06-.01~~ 0400-45-06-.01 Authority and Purpose.

The purpose of these regulations is to protect the ground water resources of the State. The authority for this rule is included in the authority given the board to protect waters of the State pursuant to T.C.A. § 69-3-105. As provided in T.C.A. § 69-3-103(29), "Waters" means any and all water, public or private, on or beneath the surface of the ground, which are contained within, flow through, or border upon Tennessee or any portion thereof except those bodies of water confined to and retained within the limits of private property in single ownership which do not combine or effect a junction with natural surface or underground waters.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.02~~ 0400-45-06-.02 General.

(1) Use of Number and Gender

As used in these rules:

(a) Words in the masculine gender also include the feminine and neuter genders; and

(b) Words in the singular include the plural; and

(c) Words in the plural include the singular.

(2) Rule Structure

These rules are organized, numbered, and referenced according to the following outline form:

(1) paragraph

(a) subparagraph

1. part

(i) subpart

(I) item

I. subitem

A. section

(A) subsection

(3) Definitions

For the purposes of the Underground Injection Control program established in this chapter, the definition of any word or phrase used in these regulations shall be the same as given in T.C.A. § 69-3-103 except the following words or phrases shall have the following meanings:

"Aquifer" means a formation, group of formations, or part of a formation that contains a sufficient quantity of permeable material to yield significant quantities of water for wells and springs.

"Area of Review" (AOR) means the area surrounding an injection well described according to the criteria set forth in ~~Rule 1200-04-06-.09~~ paragraph (3) of Rule 0400-45-06-.09 or in the case of an area permit, the project area plus a circumscribing area the width of which is either a mile or a number calculated according to the criteria set forth in the formula for injection well AOR.

"Casing" means a tubular retaining structure which is installed in an excavated hole to maintain the well opening.

"Cementing" means the act of employing cementitious material in the annulus behind the well casing.

"Cesspool" means a drywell that receives untreated sanitary waste containing human excreta, and which sometimes has an open bottom and/or perforated sides.

"Commissioner" means the Commissioner of environment and conservation or the commissioner's duly authorized representative and, in the event of the commissioner's absence or a vacancy in the office of commissioner, the deputy commissioner.

"Compatibility" means substances capable of being mixed or existing together.

"Composite sample" means a mixture of grab samples collected at the same sampling point at different times.

"Confining unit or zone" means a geological formation, group of formations, or part of a formation that limits fluid movement from an injection zone.

"Confining bed" means a layer of distinctly less permeable material stratigraphically adjacent to one or more aquifers.

"Contamination" means the addition of any substance or matter to water.

"Draft permit" means a document prepared under ~~Rule 1200-04-06-.08~~ paragraph (7) of Rule 0400-45-06-.08 indicating the Commissioner's tentative decision to issue or deny, modify, revoke and reissue, terminate, or reissue a "permit." A notice of intent to terminate a permit, and a notice of intent to deny a permit, as discussed in ~~Rule 1200-04-06-.08~~ paragraph (9) of Rule 0400-45-06-.08 are types of "draft permits." A denial of a request for modification, revocation and reissuance, or termination, as discussed in ~~Rule 1200-04-06-.08~~ paragraph (9) of Rule 0400-45-06-.08 is not a "draft permit."

"Drilling mud" means a heavy suspension used in drilling an "injection well," introduced down the drill pipe and through the drill bit.

"Drywell" means a well, other than an improved sinkhole or subsurface fluid distribution system, completed above the water table so that its bottom and sides are typically dry except when receiving fluids.

"Enhanced recovery" means increased recovery from a pool achieved by artificial means or by the application of energy extrinsic to the pool.

"Emergency permit" means a UIC "permit" issued in accordance with ~~Rule 1200-04-06-.07~~ paragraph (8) of Rule 0400-45-06-.07.

"Environmental Protection Agency" ("EPA") means the United States Environmental Protection Agency.

"EPA" means the United States Environmental Protection Agency.

"Exempted aquifer" means an "aquifer" or its portion that meets the criteria in the definition of "underground source of drinking water" but which has been exempted according to the procedures in Rule ~~1200-04-06-.04~~ 0400-45-06-.04.

"Existing injection well" means an "injection well" that began injection of fluids into the subsurface prior to the effective date of this rule.

"Facility or activity" means any waste facility or activity (including land or appurtenance thereto) that is subject to regulation under the Tennessee Solid Waste Disposal Act, T.C.A §§ 68-211-101 et seq., the Tennessee Hazardous ~~Water~~ Waste Management Act, T.C.A. §§ 68-212-101 et seq., the Tennessee Water Quality Control Act of 1977, T.C.A. §§ 69-3-101 et seq., or the Tennessee Safe Drinking Water Act of 1983, T.C.A. §§ 68-221-701 et seq..

"Fluids" means materials or substances that flow or move whether semi-solid, liquid, sludge, gas or any other form or state.

"Formation" means a body or stratum of rock characterized by a degree of lithologic homogeneity and is mappable on the earth's surface or traceable in the subsurface.

"Formation fluid" means "fluid" present in a "formation" under natural conditions as opposed to fluids introduced into a formation by injection or emplacement by man. This term is synonymous with "native water."

"Grab sample" means a sample collected at a particular time and place that represents the composition of the source at that time and place.

"Ground water" means water below the land surface and free to move under the influence of gravity.

"Grout" means a fluid mixture of cement and water or other cementitious material of a consistency that can be forced through a pipe under hydraulic pressure.

"Hazardous waste" means a hazardous waste as defined by rule ~~1200-01-11-.02~~ subparagraph (1)(c) of Rule 0400-12-01-.02.

"Hydrofracture" means the application of pressure sufficient to cause rupture of a subsurface formation.

"Improved Sinkhole" means a naturally occurring karst depression modified by man in such a manner that the chemical, physical, biological, radiological, or bacteriological properties of the water or fluids moving into the subsurface through it have been or will be altered.

"Infiltration cell" means an unlined man-made structure designed for the distribution of fluids into or above a "USDW."

"Injection well" means structure or device which is used for the emplacement of fluids into a subsurface stratum including, but not limited to:

(a) a well used for the emplacement of fluids;

(b) a subsurface fluid distribution system;

(c) an improved sinkhole; or

(d) infiltration cell and any other structures or devices designed, constructed or used to emplace fluids into the subsurface, except as provided in ~~Rule 1200-04-06-.03~~ paragraph (3) of Rule 0400-45-06-.03; or

(e) modified recharge point.

"Injection zone" means the formation, group of formations, or part of a formation that receives fluids through an injection well.

"Injectivity index" means the rate of injection in gallons per minute per unit of applied injection pressure in pounds per square inch.

"Innovative technology" means an experimental or unproven procedure, which has not been demonstrated to be feasible under the conditions in which it is being tested.

"Lease" means real property upon which the right to extract oil and gas or other minerals has been granted under contract for a share of the value of the production or an annual rental for a specified period.

"Mechanical integrity" means mechanically complete, performs the function for which it was intended and is unimpaired.

"Modified recharge point" means a naturally occurring karst feature that has been modified by man with a structure or in any other manner that the chemical, physical, biological, radiological or bacteriological properties of the water or fluids moving into the subsurface through it or the ground water has been or will be altered.

"New injection well" means any well that begins injection of fluids into the subsurface after August 9, 1985.

"Owner or operator" means the owner or operator of any "facility or activity" subject to regulation under the UIC program.

"Packer" means a device placed in a well to produce a fluid-tight seal in a section of the well bore or the annulus between the well casing and the inner injection tubing.

"Permit" means an authorization, license, or equivalent control document issued by EPA or the ~~Department~~ Commissioner to implement the requirements of ~~this~~ these rules. "Permit" includes an area permit and an emergency permit. "Permit" as used in these UIC rules means an individual permit issued under the Water Quality Control Act and does not include an authorization by rule which is a type of general permit under the Water Quality Control Act.

"Person" means an individual, association, partnership, corporation, municipality, State, Federal, or Tribal agency, or an agency or employee thereof.

"Plugging" means the act or process of stopping the flow of water, oil, or gas into or out of a formation through a bore hole or well penetrating that formation.

"Point of Injection" means the last accessible point where a sample may be collected prior to waste fluids being released into the subsurface environment through a Class V injection well.

"Pollution" means such alteration of the physical, chemical, biological, bacteriological, or radiological properties of waters of this State including but not limited to changes in temperature, taste, color, turbidity, or odor of the waters:

(a) as will result or will likely result in harm, potential harm or detriment of the public health, safety, or welfare;

(b) as will result or will likely result in harm, potential harm or detriment to the health of animals, birds, fish, or aquatic life;

(c) as will render or will likely render the waters substantially less useful to domestic, municipal, industrial, agricultural, recreational, or other reasonable uses; or

(d) as will leave or will likely leave the waters in such condition as to violate any standards of water quality established by Water Quality Control Board.

"Project" means a group of wells in a single operation.

"Produced water" means those waters produced in conjunction with the production of crude oil or natural gas and commonly collected at field storage or disposal facilities including: lease tanks, commingled tank batteries, burn pits, and community or lease wastewater disposal systems.

"Public water system" means a system for the provision of piped water for human consumption if such system has at least fifteen (15) connections or regularly serves at least twenty five (25) individuals at least sixty (60) days out of the year.

"Radioactive material" means any material, solid, liquid, or gas, which emits radiation spontaneously.

"Radioactive waste" means any waste which contains radioactive material in concentrations which exceed those listed in Rule ~~1200-02-05-.161~~ 0400-20-05-.161, Schedule RHS 8-30, Table II, Column 2.

"Recharge point" means a naturally occurring sinkhole or other karst feature that accepts stormwater runoff from unimproved properties.

"Regional rock deformation" means folded, faulted, sheared, compressed or extended rocks which result from various earth forces.

"Sanitary waste" means liquid or solid wastes originating solely from humans and human activities, such as wastes from toilets, showers, wash basins, cleaning, clothes washing, or food preparation, together with any waters mixed with or used to convey such wastes, and provided that the waste or water is not mixed with industrial waste.

"Schedule of compliance" means a schedule of remedial measures included in a "permit," including an enforceable sequence of interim requirements (for example: actions, operations, or milestone events) leading to compliance with the "appropriate Act and regulations."

"Septic system" means a "well" that is used to emplace sanitary waste below the surface and is typically comprised of a septic tank and subsurface fluid distribution system or disposal system.

"Sewage" means water-carried waste or discharges from human beings or animals, from residences, public or private buildings, or industrial establishments, or boats, together with such other wastes and ground, surface, storm, or other water as may be present; (T.C.A. § 69-3-103(27)).

"Sinkhole" means a naturally occurring closed depression in a karst area characterized by inward drainage (inlets) accepting runoff from the surrounding area and having no visible surface outlet.

"Site" means the land or water area where any facility or activity is physically located or conducted including adjacent land used in connection with the facility or activity.

"Stratum" (plural strata) means a single sedimentary bed or layer, regardless of thickness, that consists of generally the same kind of rock material.

"Subsurface fluid distribution system" (SFDS) means an assemblage of perforated pipes, drain tiles, or mechanisms intended to distribute fluids below the surface of the ground.

"Total Dissolved Solids" means a material that passes through a standard glass fiber filter disk and remains after evaporation and drying to constant weight at 180°C.

"Transferee" means the owner or operator receiving ownership and/or operational control of the well.

"Transferor" means the owner or operator transferring ownership and/or operational control of the well.

"Tremie pipe" means a device, usually small diameter pipe, that carries grouting materials to the bottom of a drill hole and allows the emplacement of the grout from the bottom up without the introduction of appreciable air pockets.

"UIC" means the Underground Injection Control program.

"Underground injection" means a "well injection."

"Underground source of drinking water" (USDW) means an aquifer or its part that:

(a) currently supplies any public water system; or

(b) contains a sufficient quantity of ground water to supply a public water system; and

1. currently supplies drinking water for human consumption; or

2. contains fewer than 10,000 mg/L total dissolved solids; and

(c) which is not a portion of an aquifer which has been designated by the ~~Department~~ Commissioner as an Exempted Aquifer.

"Well" means a bored, drilled, driven or dug shaft or hole whose depth is greater than the largest surface dimension or an improved sinkhole; or a subsurface fluid distribution system.

"Well injection" means the subsurface emplacement of fluids through a "well."

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.03~~ 0400-45-06-.03 Injection Prohibited.

(1) Unless excluded under ~~Subsection~~ paragraph (3) of this rule, the construction of an injection well, the conversion of a well into an injection well, and the use or operation of an injection well is prohibited unless authorized by an injection well permit or by rule of the ~~Department~~ Commissioner.

(2) Wells may not be used for the disposal of radioactive or hazardous waste.

(3) The following activities are not within the scope of ~~subsection~~ paragraph (1) of this rule:

(a) Operation of domestic subsurface fluid distribution systems disposing exclusively of sanitary waste with the capacity of serving less than 20 persons;

(b) Operation of facilities injecting natural gas for the purpose of storage; or

(c) Operation of wastewater treatment ponds or lagoons permitted to discharge to surface waters under the National Pollutant Discharge Elimination System (NPDES) permitting program.

(4) These rules do not limit the authority of the ~~Department~~ Commissioner to abate and prevent pollution of surface or ground water resulting from any injection activity, or other discharge of pollutants, by requiring a permit, by instituting any type of enforcement action under the Water Quality Control Act of 1977, T.C.A. §§ 69-3-101 et seq. or other environmental statute, or by contracting for clean-up under the Tennessee

Hazardous Waste Management Act, T.C.A. §§ ~~68-46-201~~ 68-212-201 et seq., or by other appropriate action.

(5) The use of any well to dispose of water carrying human waste, household or business waste, raw sewage or the effluent from any septic tank or other sewer system of any kind, unless such well is a subsurface fluid distribution system (SFDS) which is part of a Subsurface Sewage Disposal System (SSDS) permitted under provisions of Rule ~~1200-1-6-.05~~ 0400-48-01-.05 (T.C.A. § 68-221-401 et seq.).

(6) After the effective date of this rule all classes of new injection wells located within Zone 1 of a community water system's wellhead protection area as defined in Rule ~~1200-05-01-.34~~ 0400-45-01-.34 under T.C.A. §§ 68-221-701 et seq., the Tennessee Safe Drinking Water Act are prohibited.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.04~~ 0400-45-06-.04 Prevention of Pollution of Ground Water and Identification of Underground Sources of Drinking Water and Exempted Aquifers.

(1) No owner or operator shall construct, operate, maintain, convert, plug, abandon, or conduct any other injection activity in a manner that allows the movement of fluid containing any contaminant into underground sources of drinking water, if the presence of that contaminant may cause a violation of any primary drinking water regulation or may otherwise adversely affect the health of persons. The applicant for a permit shall have the burden of showing that the requirements of this paragraph are met.

(2) For Class I, II and III wells, if any water quality monitoring of an underground source of drinking water indicates the movement of any contaminant into the underground source of drinking water, except as authorized under this rule, the Commissioner shall prescribe such additional requirements for construction, corrective action, operation, monitoring, or reporting (including closure of the injection well) as are necessary to prevent such movement. In the case of wells authorized by permit, the Commissioner may impose additional requirements by modifying the permit in accordance with Rule ~~1200-04-06-.08~~ paragraph (8) of Rule 0400-45-06-.08 or may terminate the permit in accordance with ~~Rule 1200-04-06-.08~~ paragraph (9) of Rule 0400-45-06-.08. Additionally, the Commissioner may assess civil penalties for all permit or rule violations in accordance with T.C.A § 69-3-115.

(3) For class V wells, if at any time the Commissioner learns that a Class V well may cause a violation of primary drinking water regulations he or she shall:

(a) Require the injector to obtain an individual permit; and/or

(b) Order the injector to take such actions (including, where required, closure of the injection well) as may be necessary to prevent the violation; and/or

(c) Take enforcement action.

(4) Whenever the Commissioner learns that a Class V well may be otherwise adversely affecting the health of persons, he or she may prescribe such actions as may be necessary to prevent the adverse effect, including any action authorized under paragraph (3) of this rule and assess civil penalties in accordance with T.C.A § 69-3-115.

(5) Notwithstanding any other provision of this rule, the Commissioner may take emergency action upon receipt of information that a contaminant which is present in or likely to enter a public water system or underground source of drinking water may present an imminent and substantial endangerment to the health of persons. The Commissioner must first determine that local authorities have not taken appropriate action to protect the health of such persons, before taking emergency action.

(6) Identification of Underground Sources of Drinking Water

(a) The Commissioner may identify (by narrative description, illustrations, maps, or other means) and shall protect, except where exempted under subparagraph (b) of this paragraph, as an underground source of drinking water, all aquifers or parts of aquifers which meet the definition of an "underground source of drinking water" in Rule ~~1200-04-06-.02~~ 0400-45-06-.02. Even if an

aquifer has not been specifically identified by the commissioner, it is an underground source of drinking water if it meets the definition in Rule ~~1200-04-06-.02~~ 0400-45-06-.02.

(b) 1. The Commissioner may identify (by narrative description, illustrations, maps, or other means) and describe in geographic and/or geometric terms (such as vertical and lateral limits and gradient) which are clear and definite, all aquifers or parts thereof which the Commissioner proposes to designate as exempted aquifers using the criteria in paragraph (7) of this rule.

2. No designation of an exempted aquifer submitted as part of a UIC Program shall be final until approved by the EPA Administrator.

3 Subsequent to program approval or promulgation by the EPA, the Commissioner may, after notice and opportunity for a public hearing, identify additional exempted aquifers.

(i) Exemption of aquifers identified under subparagraph (7)(b) of this Rule shall be treated as a program revision under 40 CFR 145.32.

(Note: 40 CFR 145.32 provides that:

(a) Either EPA or the approved state may initiate program revision. Program revision may be necessary when the controlling federal or state statutory or regulatory authority is modified or supplemented. The state shall keep EPA fully informed of any proposed modifications to its basic statutory or regulatory authority, its forms, procedures, or priorities.

(b) Revision of a state program shall be accomplished as follows:

(1) The state shall submit a modified program description, Attorney General's statement, Memorandum of Agreement, or such other documents as EPA determines to be necessary under the circumstances.

(2) Whenever EPA determines that the proposed program revision is substantial, EPA shall issue public notice and provide an opportunity to comment for a period of at least 30 days. The public notice shall be mailed to interested persons and shall be published in the Federal Register and in enough of the largest newspapers in the state to provide statewide coverage. The public notice shall summarize the proposed revisions and provide for the opportunity to request a public hearing. Such a hearing will be held if there is significant public interest based on requests received.

(3) The Administrator shall approve or disapprove program revisions based on the requirements of this part and of the Safe Drinking Water Act.

(4) A program revision shall become effective upon the approval of the Administrator. Notice of approval of any substantial revision shall be published in the Federal Register. Notice of approval of non-substantial program revisions may be given by a letter from the Administrator to the State Governor or his designee.)

(ii) Exemption of aquifers identified under subparagraph (7)(c) of this Rule shall become final if the Commissioner submits the exemption in writing to the EPA Administrator and the EPA Administrator has not disapproved the designation within 45 days. Any disapproval by the EPA Administrator shall state the reasons and shall constitute final Agency action for purposes of judicial review.

(c) 1. For Class III wells, the Commissioner shall require an applicant for a permit which necessitates an aquifer exemption under part (7)(b)1 of this rule to furnish the data necessary to demonstrate that the aquifer is expected to be mineral or hydrocarbon producing. Information contained in the mining plan for the proposed project, such as a map and general description of the mining zone, general information on the mineralogy and geochemistry of the mining zone, analysis of the amenability of the mining zone to the proposed mining method, and a time-table of planned development of the mining zone shall be considered by the Commissioner in addition to the information required.

2. For Class II wells, a demonstration of commercial producibility shall be made as follows:

(i) For a Class II well to be used for enhanced oil recovery processes in a field or project containing aquifers from which hydrocarbons were previously produced, commercial producibility shall be presumed by the Commissioner upon a demonstration by the applicant of historical production having occurred in the project area or field; and

(ii) For Class II wells not located in a field or project containing aquifers from which hydrocarbons were previously produced, information such as logs, core data, formation description, formation depth, formation thickness and formation parameters such as permeability and porosity shall be considered by the Commissioner, to the extent such information is available.

(7) Exempted Aquifers

An aquifer or a portion thereof which meets the criteria for an "underground source of drinking water" may be determined to be an "exempted aquifer" if it meets the following criteria:

(a) It does not currently serve as a source of drinking water; and

(b) It cannot now and will not in the future serve as a source of drinking water because:

1. It is mineral, hydrocarbon or geothermal energy producing, or can be demonstrated by a permit applicant as part of a permit application for a Class II or III operation to contain minerals or hydrocarbons that considering their quantity and location are expected to be commercially producible;

2. It is situated at a depth or location which makes recovery of water for drinking water purposes economically or technologically impractical;

3. It is so contaminated that it would be economically or technologically impractical to render that water fit for human consumption; or

4. It is located over a Class III well mining area subject to subsidence or catastrophic collapse;

or

(c) The total dissolved solids content of the ground water is more than 3,000 and less than 10,000 mg/l and it is not reasonably expected to supply a public water system.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.05~~ 0400-45-06-.05 Injected Fluid Standards.

(1) Any fluid injected into or above a USDW shall meet the following standards unless specific alternate standards are established by the ~~Department~~ Commissioner for the individual discharge based on hydrogeologic setting, character of the injectate, risk to the environment and persons utilizing the ground water resource and compliance with ~~1200-04-06-.05(1)~~ subparagraph (j) of this paragraph:

(a) Dissolved oxygen

The injected fluid shall contain dissolved oxygen in at least the amount that naturally occurs in that portion of the aquifer where the injection occurs.

(b) Oils and grease

The injected fluid shall contain no oil and grease other than that of natural origin in that portion of the aquifer where the injection occurs.

(c) Color and turbidity

The injected fluids shall contain no color or turbidity other than that of natural origin in that portion of the aquifer where the injection occurs.

(d) Coliform bacteria

The concentration of a fecal coliform group shall not exceed 200 per 100 ml. as a geometric mean based on a minimum of 10 samples collected from a given sampling point over a period of not more than 30 consecutive days with individual samples being collected at intervals of not less than 12 hours. For the purposes of determining the geometric mean, individual samples having a fecal coliform group concentration of less than 1 per 100 ml. shall be considered as having a concentration of 1 per 100 ml. In addition, the concentration of the fecal coliform group in any individual sample shall not exceed 1,000 per 100 ml.

(e) Taste and odor

The injected fluids shall have no taste or odor other than that which naturally occurs in that portion of the aquifer where the injection occurs.

(f) pH

The injected fluids shall have a pH level as naturally occurs in that portion of the aquifer where the injection occurs or as may result from normal agricultural, or silviculture activity provided all reasonable controls are used.

(g) Chemical constituents

The injected fluids shall be free from chemical constituents, other than those of natural origin, in that portion of the aquifer where the injection occurs, in concentrations specified in ~~1200-05-01-.19~~ Rule 0400-45-01-.19 or combinations which would be harmful to human, animal or aquatic life or detrimental to the most sensitive and governing water use. Criteria for chemical constituents contained in guidelines published by the US Environmental Protection Agency shall be considered.

(h) Solids, floating materials and deposits

The injected fluid shall be free of distinctly visible solids, scum, foam, or oily sleek other than those of natural origin in that portion of the aquifer where the injection occurs.

(i) Other pollutants

The injected fluid shall contain no other pollutants that may be detrimental to public health or impair the usefulness of the water for the most sensitive and governing water use.

(j) The operation of an underground injection system shall not cause any aquifer designated as a USDW to contain any substances, whether alone or in combination with other substances, that are toxic, carcinogenic, mutagenic, or teratogenic, other than those of natural origin, at levels and conditions which violate primary drinking water standards as given in ~~1200-05-01~~ Chapter 0400-45-01 or adversely affect health of persons.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.06~~ 0400-45-06-.06 Classification of Injection Wells.

Injection wells within the jurisdiction of the ~~Department~~ Commissioner are classified as follows:

(1) Class I

(a) Wells used by generators of hazardous waste or owners or operators of hazardous waste management facilities to inject hazardous waste, beneath the lowermost formation containing within a radius of one mile of the well bore, a USDW; or

(b) Other industrial and municipal disposal wells which inject fluids beneath the lowermost formation containing, within a radius of one mile of the well bore, a USDW.

(c) Radioactive waste disposal wells which inject fluids below the lowermost formation containing an underground source of drinking water within one mile of the well bore.

(2) Class II

Wells that inject fluids:

(a) Which are brought to the surface in connection with conventional oil or natural gas production and may be commingled with waste waters from gas plants which are an integral part of production operations, unless those waters are classified as a hazardous waste at the time of injection;

(b) For enhanced recovery of oil or natural gas; and

(c) For storage of hydrocarbons which are liquid at standard temperature and pressure.

(3) Class III

Wells that inject fluids for extraction of minerals including:

(a) Mining of sulfur by the Frasch process;

(b) In-situ production of uranium or other metals. This category includes only in-situ production from ore bodies which have not been conventionally mined. Solution mining of conventional mines such as stope leaching is included in Class V; or

(c) Solution mining of salts or potash.

(4) Class IV

(a) Wells used by generators of hazardous waste or of radioactive waste, by owners or operators of hazardous waste management facilities, or by owners or operators of radioactive waste disposal sites, to dispose of hazardous waste or radioactive waste into a formation which within one mile of the well contains a USDW; or

(b) Wells used by generators of hazardous waste or of radioactive waste, by owners or operators of hazardous waste management facilities, or by owners or operators of radioactive waste disposal sites, to dispose of hazardous waste or radioactive waste above a formation which within one mile of the well contains a USDW.

(c) Wells used by generators of hazardous waste or owners or operators of hazardous waste management facilities to dispose of hazardous waste, which cannot be classified under subparagraph (1)(a) of this rule or subparagraphs ~~(4)~~(a) and (b) of this ~~rule~~ paragraph.

(5) Class V

Injection wells or systems not included in Classes ~~I~~ I, II, III, or IV. Class V wells include:

(a) Air conditioning return flow wells used to return to the supply aquifer the water used for heating or cooling in a heat pump;

(b) Drainage wells used to drain surface fluid, primarily storm runoff, into a subsurface formation;

(c) Cooling water return flow wells used to inject water previously used for cooling;

(d) Recharge wells used to replenish the water in an aquifer;

(e) Sand backfill and other backfill wells used to inject a mixture of water and sand, mill tailings or other solids into mined-out portions of subsurface mines whether what is injected is a radioactive waste or not;

(f) Subsidence control wells (not used for the purpose of oil or natural gas production) used to inject fluids into a non-oil or gas producing zone to reduce or eliminate subsidence associated with the overdraft of fresh water;

(g) Injection systems associated with remedial activity. This subparagraph does not allow the injection of hazardous waste into a Class V well. Systems used to inject contaminated ground water that has been treated and is being reinjected into the same formation from which it was drawn are not prohibited by this rule if such injection is approved by state or federal agencies operating under the Tennessee Hazardous Waste Management Act, Part 1 or Part 2, T.C.A. ~~Sections~~ §§ 68-212-101 et seq. or 68-212-201 et seq., ~~or~~ Tennessee Petroleum Underground Storage Tank Act, T.C.A. ~~Sections~~ §§ 68-215-101 et seq., ~~or~~ ~~Tennessee~~ Water Quality Control Act of 1977, T.C.A. ~~Sections~~ §§ 69-3-101 et seq., ~~or~~ Resource Conservation and Recovery Act (RCRA); 42 U.S.C. §§6901-6992k, or Comprehensive Environmental Response and Liability Act of 1980; 42 U.S.C. §§9601-9675;

(h) Injection wells associated with the recovery of geothermal energy for heating, aquaculture and production of electric power;

(i) Wells used for solution mining of conventional mines such as stopes leaching;

(j) Injection wells used in innovative or experimental technologies;

(k) Injection wells used for in site recovery of lignite, coal, tar sands, and oil shale; and

(l) Wells used to inject spent brine into the same formation from which it was withdrawn after extraction of halogens or their salts.

(m) Large capacity subsurface fluid distribution systems with the capacity to serve more than 20 persons per day.

(n) Infiltration cells.

(o) Subsurface fluid distribution systems disposing of waste other than sanitary waste.

(p) Dry wells used for the injection of wastes into a subsurface formation;

(q) Modification of a recharge point or the area where the recharge originates; and

(r) Improved sinkholes.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.07~~ 0400-45-06-.07 Permit Required.

(1) Except for exclusions specified in paragraph ~~1200-04-06-.03~~(3) of Rule 0400-45-06-.03, all injection wells and activities must be authorized by permit or by rule.

(2) For new injection wells, a permit must be obtained before construction commences, unless the injection is authorized by rule as described in paragraph ~~1200-04-06-.14~~(2) of Rule 0400-45-06-.14.

(3) The owner or operator of an existing Class II or III injection well shall complete, sign and submit to the ~~Department~~ Commissioner an application for permit in conformance with this Chapter within six (6) months from the date of approval of these rules. The owner or operator must demonstrate to the satisfaction of the ~~Department~~ Commissioner that the existing well complies with all applicable rules of this Chapter.

(4) Continued injection into existing Class V Wells is authorized by virtue of this rule provided compliance with ~~Rule 1200-04-06-.05~~ paragraph (1) of Rule 0400-45-06-.05 and any other applicable rules of this Chapter are maintained. Owners/operators of existing Class V wells that fail to maintain compliance shall immediately cease operation and submit an application. An application must be submitted within the appropriate time frame for each grand division as specified in this rule. Within six (6) months of the effective date of this rule, owner/operators of injection wells within the Western Grand Division must submit an application. Within twelve (12) months of the effective date of this rule, owner/operators of injection wells within the Central Grand Division must submit an application. Within eighteen (18) months of the effective date of this rule, owner/operators of injection wells within the Eastern Grand Division must submit an application. If an application for an existing Class V well is not submitted within the specified timeframe, the owner/operator shall be subject to an application fee for a new well as specified in ~~1200-04-06-.18~~ paragraph (1) of Rule 0400-45-06-.18.

(5) The ~~Department~~ Commissioner may require the owner or operator of a Class V injection well authorized by rule to apply for and obtain an injection well permit. Cases for which a permit may be required include:

(a) The injection well is not in compliance with the standards required by this Chapter.

(b) Compliance with standards in addition to those listed in this Chapter is required to protect USDWs from pollution.

(6) Reserved.

(7) Class V wells utilizing innovative or experimental technologies may not be authorized by rule, but only by a permit. The permit shall require a surety bond.

(8) Emergency permits.

(a) Coverage

Notwithstanding any other provision of this rule the Commissioner may temporarily permit a specific underground injection if:

1. An imminent and substantial endangerment to the health of persons will result unless a temporary emergency permit is granted, provided the injection will not result in the movement of fluids into underground sources of drinking water; or

2. (i) A substantial and irretrievable loss of oil or gas resources will occur unless a temporary emergency permit is granted to a Class II well; and

(ii) Timely application for a permit could not be practically made; and

(iii) The injection will not result in the movement of fluids into underground sources of drinking water; or

3. A substantial delay in production of oil or gas resources will occur unless a temporary emergency permit is granted to a new Class II well and the temporary authorization will not result in the movement of fluids into an underground source of drinking water.

(b) Requirements for issuance

1. Any temporary permit under part (a)1 of this paragraph shall be for no longer term than required to prevent the hazard.

2. Any temporary permit under part (a)2 of this paragraph shall be for no longer than 90 days, except that if a permit application has been submitted prior to the expiration of the 90-day period, the Commissioner may extend the temporary permit until final action on the application.

3. Any temporary permit under part (a)3 of this paragraph shall be issued only after a complete permit application has been submitted and shall be effective until final action on the application.

4. Notice of any temporary permit under this paragraph shall be published in accordance with paragraph (7) of Rule ~~1200-04-06-.08~~ 0400-45-06-.08 within ten days of the issuance of the permit.

5. The temporary permit under this paragraph may be either verbal, or written. If verbal authorization, it must be followed within 5 calendar days by a written temporary emergency permit.

6. The Commissioner shall condition the permit in any manner he or she determines is necessary to ensure that the injection will not result in the movement of fluids into an underground source of drinking water.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.08~~ 0400-45-06-.08 Authorization by Permit

For Injection Wells Not Authorized By Rule.

(1) Permit Application

All permit applicants for injection wells not authorized by rule shall provide the following information to the ~~Department~~ Commissioner, using a form provided by the ~~Department~~ Commissioner:

(a) The activities conducted by the applicant which require it to obtain a UIC permit.

(b) Name, mailing address, and location of the facility for which the application is submitted.

(c) Up to four North American Industry Classification System (NAICS) codes which best reflect the principal products or services provided by the facility.

(d) The operator's name, address, telephone number, ownership status, and status as Federal, State, private, public, or other entity.

(e) Whether the facility is located on Indian lands.

(f) A listing of all permits or construction approvals received or applied for under any of the following programs:

1. Hazardous Waste Management program under federal or state law.

2. UIC program under federal or state law.

3. NPDES program under federal or state law.

4. Prevention of Significant Deterioration (PSD) program under federal or state law.

5. Nonattainment program under federal or state law.

6. National Emission Standards for Hazardous Pollutants (NESHAPS) preconstruction approval under federal or state law.

7. Ocean dumping permits under the Marine Protection Research and Sanctuaries Act.

8. Dredge and fill permits under section 404 of the Clean Water Act, 33 U.S.C. Section 1344.

9. Other relevant environmental permits.

(g) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source depicting the facility and each of its intake and discharge structures; each of its hazardous waste treatment, storage, or disposal facilities; each well where fluids from the facility are injected underground; and those wells, springs, surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant within a quarter mile of the facility property boundary.

(h) A brief description of the nature of the business.

(2) A permit application will be processed when:

(a) A completed application form, all information required by these rules and any supplemental information, as may be required, is submitted to the ~~Department~~ Commissioner. The application shall identify (by narrative description, illustrations, maps, or other suitable means) and describe by geographic or geometric terms (including lateral and vertical limits and gradients) the area intended to be used as an injection zone.

(b) The feasibility requirements that apply to the proposed injection well have been satisfied.

(3) Duration of permits

(a) Permits for Class I and V wells and authorizations for Class V wells shall be effective for a fixed term not to exceed five (5) years. Permits for Class II and III wells may be issued for a period up to the operating life of the facility. Each Class II or III well permit shall be reviewed at least once every five (5) years to determine whether it should be modified, revoked and reissued, or revoked as provided in paragraphs ~~1200-04-06-.08~~ (7) and (8) of this rule.

(b) Except as provided by the Uniform Administrative Procedures Act, T.C.A. §§ 4-5-101 et seq., the term of a permit shall not be extended by modification beyond the maximum duration specified in this rule.

(c) The ~~Department~~ Commissioner may issue any permit for a duration that is less than the full allowable term under this rule.

(4) Schedules of compliance

(a) The permit may when appropriate specify a schedule of compliance.

(b) Time for compliance

Any schedule of compliance shall require compliance as soon as possible but in no case later than three (3) years after the effective date of the permit.

(c) Interim dates

Except as provided in this ~~section~~ subparagraph, if a permit establishes a schedule of compliance which exceeds one (1) year from the date of permit issuance, the schedule shall set forth interim requirements and the dates for their achievements.

1. The time between interim dates shall not exceed one (1) year.

2. If the time necessary for completion of any interim requirement (such as the construction of a control facility) is more than one (1) year and is not readily divisible into stages for completion, the permit shall specify interim dates for the submission of reports of progress toward completion of the interim requirements and indicate a projected completion date.

(d) Reporting

Progress reports shall be submitted no later than thirty (30) days following each interim date and the final date of compliance.

(5) Effect of a permit

(a) A permit may be revoked, suspended or modified during its term for cause, under T.C.A. § 69-3-108(f).

(b) The issuance of a permit does not convey any property rights of any sort, or any exclusive privilege.

(c) The issuance of a permit does not authorize any injury to persons or property or invasion of other property rights, or any infringement of other State, Federal or local laws or regulations. In particular, the issuance of a permit does not relieve a Class I, Class IV or Class V permittee from any applicable requirement he may be subject to under the Tennessee Hazardous Waste Management Act (T.C.A. ~~6-46-101~~ §§ 68-212-101 et seq.)

(6) Transfer of permits

A permit may be transferred by the permittee to a new owner or operator as a minor modification if the permit has been modified or revoked and reissued.

(7) Public notice of permit actions and public comment period.

(a) Scope

The ~~Department~~ Commissioner shall give public notice that the following actions have occurred:

1. A draft permit has been prepared. A draft permit shall contain:

(i) All permit conditions

(ii) All compliance schedules for corrective action; and

(iii) All monitoring requirements

(b) Upon request, the ~~Department~~ Commissioner shall send to the requestor copies of the foregoing documents.

(c) Timing

1. Public notice of the preparation of a draft permit shall allow at least thirty (30) days for public comment.

2. Public notice of a public hearing shall be given at least thirty (30) days before the hearing. (Public notice of the hearing may be given at the same time as public notice of the draft permit and the two notices may be combined.)

(d) Methods

Public notices of permit actions shall be given by the following methods:

1. By mailing a copy of a notice to the following persons (any person otherwise entitled to receive notice under this paragraph may waive his or her rights to receive notice for any classes and categories of permits):

   (i) the applicant;

   (ii) any other agency which the ~~Department~~ Commissioner knows has issued or is required to issue a RCRA, PSD, NPDES or 404 permit for the same facility or activity;

   (iii) federal, state and local agencies with jurisdiction over fish, shellfish, and wildlife resources; the Advisory Council on Historic Preservation, state historic preservation officers, and other appropriate government authorities, including any affected States;

   (iv) persons on a mailing list developed by:

      (I) notifying the public of the opportunity to be put on the mailing list through periodic publication in the public press and in other publications such as ~~Regional~~ regional and ~~State~~ state funded newsletters, environmental bulletins, or State law journals; and

      (II) including those who request in writing to be on the list. (The ~~Department~~ Commissioner may update the mailing list from time to time by requesting written indication of continued interest from those listed. The ~~Department~~ Commissioner may delete from the list the name of any person who fails to respond to such a request.)

2. By publication of a notice in a daily or weekly newspaper within the area to be affected by the facility or activity;

3. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

(e) Contents

All public notices of permit actions shall contain the following minimum information:

1. Name and address of the ~~Department~~ Commissioner office processing the permit action for which notice is being given;

2. Name and address of the permittee or permit applicant and, if different, of the facility or activity regulated by the permit;

3. A brief description of the business conducted at the facility or activity described in the permit application;

4. A description of the type and quantity of wastes, fluids, or pollutants which are proposed to be injected;

5. A brief summary of the basis for the permit conditions;

6. Reasons why any requested variances do or do not appear justified;

7. Name, address, and telephone number of a person from whom interested persons may obtain further information including copies of the draft permit, fact sheet when prepared, and the application;

8. A brief description of the applicable comment procedures including, the beginning and ending dates of the comment period, procedures for requesting a hearing, and any other procedures by which the public may participate in the final decision;

9. Reference to the date of previous public notices relating to the permit;

10. Date, time, and place of the hearing;

11. A brief description of the nature and purpose of the hearing including the applicable rules and procedures; and

12. Any additional information considered necessary or proper.

(f) Public comments and requests for public hearings

During the public comment period, any interested person may submit written comments on the permit application or draft permit and may request a public hearing. A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised.

(g) Public hearings

The ~~Department~~ Commissioner shall hold a public hearing whenever, as evidenced by requests, there is public interest in a draft permit. A public hearing may also be held at the ~~Department~~ Commissioner's discretion to clarify issues in the permit.

(h) Consideration of comments and response

1. All comments submitted during the public comment period and all hearing testimony shall be considered in making the final decision.

2. If a decision is reached to issue a final permit, the ~~Department~~ Commissioner shall respond to comments when the permit is issued. This response shall:

(i) Be made available to the public;

(ii) Specify which provisions, if any, of the draft permit have been changed in the final permit, and the reasons for the change; and

(iii) Briefly describe and respond to all significant comments on the draft permit raised during the public comment period, or during any hearing.

(i) Notice of final permit decision

1. After the close of the comment period, the Commissioner shall notify the applicant and each person who has submitted written comments, or requested notice, of the final permit decision. This notice shall contain reference to the procedures for appealing a permit decision.

2. A final permit decision shall become effective thirty (30) days after service of notice on the applicant of the final permit decision, unless a later date is specified in the notice, or a petition is filed pursuant to ~~paragraph~~ subparagraph (j) or (k) ~~below~~ of this paragraph.

(j) Within thirty (30) days of receipt of notice of a final permit decision, or prior to any later date specified in the notice, any person other than the applicant who has filed comments on that permit, or its drafts, may petition the Board for a hearing on the permit or any condition of the permit. The petition shall include a statement of all of the permit conditions which are challenged and the reasons supporting the challenge. This hearing shall be legislative in nature and shall not be a contested case within the meaning of T.C.A. § 4-5-102 of the Uniform Administrative Procedures Act. The Board shall make a recommendation on issuance or denial of the permit or permit conditions to the Commissioner that shall become final and effective in thirty (30) days if the Commissioner takes no action.

(k) Within thirty (30) days of receipt of notice of a final permit decision, the permit applicant may file a petition with the Board for a contested case hearing pursuant to T.C.A. §§ 69-3-105 and 4-5-301 et seq.

(8) Modification or revocation and reissuance of permits

When the ~~Department~~ Commissioner determines that one or more causes exist for modification or revocation and reissuance of a permit, the ~~Department~~ Commissioner may modify or revoke and reissue the permit accordingly, subject to the limitations of subparagraph (c) of this paragraph, and may request an updated application if necessary. When a permit is modified, only the conditions subject to modification are reopened. If a permit is revoked and reissued, the entire permit is reopened and subject to revision and the permit is reissued for a new term. If a permit modification satisfies the criteria for minor modifications, the permit may be modified without a draft permit or public review. Otherwise, a draft permit must be prepared and public review procedures as set out herein must be followed.

(a) Causes for modification

The following are causes for modification and may be causes for revocation and reissuances.

1. Alterations

There are material and substantial alterations or additions to the permitted facility or activity which occurred after permit issuance which justify the application of permit conditions that are different or absent in the existing permit.

2. Information

The ~~Department~~ Commissioner has received information that was not available at the time of permit issuance (other than revised regulations, guidance, or test methods) and would have justified the application of different permit conditions at the time of issuance. This cause shall include any information indicating that cumulative effects on the environment are unacceptable.

3. New regulations

The standard or regulations on which the permit was based have been changed by promulgation of amended standards or regulations or by judicial decision after the permit was issued. Permits other than for Class ~~II~~ II or III wells may be modified during their terms for this cause, only as follows:

(i) For promulgation of amended standards or regulations, when:

(I) The permit condition requested to be modified was based on a Departmental regulation;

(II) The ~~Department~~ Commissioner has revised withdrawn, or modified that portion of the regulation on which the permit condition was based; and

(III) A permittee requests modification within thirty (30) days after public notice of the action on which the request is based.

(ii) For judicial decisions, a court of competent jurisdiction has remanded and stayed Department promulgated regulations if the remand and stay concern that portion of the regulations on which the permit condition was based and a request is filed by the permittee in accordance with these regulations within thirty (30) days of judicial remand.

4. Compliance schedules

The ~~Department~~ Commissioner determines good cause exists for modification of a compliance schedule, such as an act of God, strike, flood, or materials shortage or other events over which the permittee has little or no control and for which there is no reasonably available remedy.

(b) Causes for modification or revocation and reissuance

The following are causes to modify or, alternatively, revoke and reissue a permit:

1. Cause exists for revocation and the ~~Department~~ Commissioner determines that modification or revocation and reissuance is appropriate; and

2. The ~~Department~~ Commissioner has received notification of a proposed transfer of the permit.

(c) Facility siting

Suitability of the Facility location will not be considered at the time of permit modification or revocation and reissuance unless new information or standards indicate that a threat to human health or the environment exists which was unknown at the time of permit issuance.

(9) Revocation of permits or denial of renewal application

(a) The ~~Department~~ Commissioner may revoke a permit during term, or deny a permit renewal application for the following causes:

1. Noncompliance by the permittee with any condition of the permit;

2. The permittee's failure in the application or during the permit issuance process to disclose fully all relevant facts, or the permittee's misrepresentation of any relevant facts at any time; or

3. A determination that the permitted activity endangers human health or the environment and can only be regulated to acceptable levels by permit modification or revocation.

(b) Notice of intent to revoke and reissue, or terminate. If the ~~Department~~ Commissioner tentatively decides to revoke and reissue a permit, a notice of intent to revoke and reissue, or notice of intent to terminate shall be issued.

(10) Minor Modifications

Upon the consent of the permittee, the ~~Department~~ Commissioner may modify a permit to make the corrections or allowances for changes in the permitted activity listed in this paragraph without following the entire permitting procedure. Minor modifications may only:

(a) Correct typographical errors;

(b) Require more frequent monitoring or reporting by the permittee;

(c) Change an interim compliance date in a schedule of compliance, provided the new date is not more than 120 days after the date specified in the existing permit and does not interfere with attainment of the final compliance date requirement;

(d) Change quantities or types of fluids injected which are injected within the capacity of the facility as permitted and, in the judgment of the ~~Department~~ Commissioner would not interfere with the operation of the facility or its ability to meet conditions described in the permit and would not change its classification;

(e) Change a construction requirement approved by the ~~Department~~ Commissioner, provided that any such alteration shall comply with all requirements of this rule; ~~or~~

(f) Amend a plugging and abandonment plan; or

(g) Allow for a change in ownership or operational control of a facility where the Commissioner determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility, coverage, and liability between the current and new permittees has been submitted to the commissioner.

(11) Confidentiality of information

The handling of confidential information shall be governed by T.C.A. § 69-3-113.

(12) Signatories to applications and reports

(a) Applications

All permit applications, shall be signed as follows:

1. For a corporation: by a responsible corporate officer. For the purpose of this part, a responsible corporate officer means:

~~(1)~~ (i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function or any other person who performs similar policy or decision making functions for the corporation, or

~~(II)~~ (ii) The manager of one or more manufacturing, production or operation facilities employing more than 250 persons or having gross annual sales or expenditures exceeding 25 million dollars (in second quarter 1980 dollars), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.

(Note: The ~~Department~~ Commissioner does not require specific assignments or delegations of authority to responsible corporate officers identified in ~~subpart (f)~~ this part The ~~Department~~ Commissioner will presume that these responsible corporate officers have the requisite authority to sign permit applications unless the corporation has notified the Commissioner to the contrary. Corporate procedures governing authority to sign permit applications may provide for assignment or delegation to applicable corporate positions under ~~item (II)~~ subpart (ii) of this part rather than the specific individuals.)

2. For a partnership or sole proprietorship: by a general partner or the proprietor, respectively; or

3. For a municipality, State, Federal, or other public agency: by either a principal executive officer or ranking elected official.

(b) Reports

All reports required by permits, and other information requested by the ~~Department~~ Commissioner, shall be signed by a person described in subparagraph (a) ~~above~~ of this paragraph or by a duly authorized representative of that person. A person is a duly authorized representative only if:

1. The authorization is made in writing by a person described in subparagraph (a) of this paragraph;

2. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity, such as the position of plant manager, operator of a well or well field, superintendent, or position of equivalent responsibility (A duly authorized representative may thus be either a named individual or any individual occupying a named position.); and

3. The written authorization is submitted to the ~~Department~~ Commissioner.

(c) Changes to authorization

If an authorization under subparagraph (b) of this paragraph is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements of subparagraph (b) of this paragraph must be submitted to the ~~Department~~ Commissioner prior to or at the time any reports, information, or applications signed by an authorized representative are submitted.

(d) Certification

Any person signing a document under this ~~section~~ paragraph shall make the following certification.

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

(13) Permit Requirements

All UIC permits shall contain permit conditions established by the Commissioner as necessary to fulfill the purposes of the Tennessee Water Quality Control Act, T.C.A. §§ 69-3-101 et seq., a description of the injection zone being permitted, and any necessary corrective action as stated under ~~Rule 1200-04-06-.09~~ paragraph (5) of Rule 0400-45-06-.09. The permit conditions shall be set at levels to prevent adverse effects to persons utilizing the ground water resource after consideration of at least the following factors: any guidelines set for certain pollutants by U.S.E.P.A., the flow characteristics of ground water, risk to humans and the risk of migration. The ~~following conditions~~ requirements of subparagraphs (a) through (n) of this paragraph apply to all UIC permits. All conditions applicable to all permits shall be incorporated into the permits either expressly or by reference. If incorporated by reference, a specific citation to these regulations must be given in the permit.

(a) The permittee must comply with all conditions of this permit and all applicable laws and regulations. Any permit noncompliance constitutes a violation of the Tennessee Water Quality Control Act and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.

(b) If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must apply for and obtain a new permit prior to expiration of this permit.

(c) It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

(d) The permittee shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from non-compliance with this permit.

(e) The permittee shall at all times properly operate and maintain all facilities and systems of related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance includes effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems only when necessary to achieve compliance with the conditions of the permit.

(f) This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance, does not stay any permit condition.

(g) This permit does not convey any property rights of any sort, or any exclusive privilege.

(h) The permittee shall furnish to the ~~Department~~ Commissioner, within a time specified, any information which the ~~Department~~ Commissioner may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The permittee shall also furnish to the ~~Department~~ Commissioner, upon request, copies of records required to be kept by this permit.

(i) The permittee shall allow ~~Department personnel~~ the Commissioner, or an authorized representative of the ~~Department~~ Commissioner, upon the presentation of credentials to:

1. Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

3. Inspect at reasonable times any facility, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

4. Sample or monitor at reasonable times, for the purposes or assuring permit compliance or as otherwise authorized by the Tennessee Water Quality Control Act, any substances or parameters at any location.

(j) Monitoring and records

1. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity. The permittee shall monitor injection fluids, injection operations, and local ground water supplies, in accordance with the requirements for the applicable class of well stated in Rules ~~1200-04-06-.10~~ 0400-45-06-.10 through ~~1200-04-06-.14~~ 0400-45-06-.14.

2. The permittee shall retain records of all monitoring information, including the following:

   (i) Calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement, report, or application. This period may be extended by request of the ~~Department~~ Commissioner at any time; and

   (ii) The nature and composition of all injected fluids until three years after the completion of any plugging and abandonment procedures. The ~~Department~~ Commissioner may require the owner or operator to deliver the records to the Department at the conclusion of the retention period.

3. Records of monitoring information shall include:

   (i) The date, exact place, and time of sampling or measurements;

   (ii) The individual(s) who performed the sampling or measurements;

   (iii) The date(s) analyses were performed;

   (iv) The individual(s) who performed the analyses;

   (v) The analytical techniques or methods used; and

   (vi) The results of such analyses.

(k) All applications, reports, or information submitted to the ~~Department~~ Commissioner shall be signed and certified.

(l) Reporting requirements

~~(i)~~ 1. Planned Changes

The permittee shall give notice to the ~~Department~~ Commissioner as soon as possible of any planned physical alterations or additions to the permitted facility.

~~(ii)~~ 2. Anticipated noncompliance

The permittee shall give advance notice to the ~~Department~~ Commissioner of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

~~(iii)~~ 3. Transfers

See ~~subsections~~ paragraphs (5), (7), (8) and (9) of this rule.

~~(iv)~~ 4. Monitoring reports

Monitoring results shall be reported at the intervals specified elsewhere in this permit.

~~(v)~~ 5. Compliance schedules

Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 30 days following each schedule date.

~~(vi)~~ 6. Twenty-four hour reporting

The permittee shall report any noncompliance which may endanger health or the environment, including:

~~(I)~~ (i) Any monitoring or other information which indicates that any contaminant may cause an endangerment to USDWs; or

~~(II)~~ (ii) Any noncompliance with a permit condition or malfunction of the injection system which may cause fluid migration into or between USDWs.

Any such information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within 72 hours of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause, the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance.

~~(vii)~~ 7. Other noncompliance

The permittee shall report all instances of noncompliance not reported under ~~paragraphs i, iv, v, and vi of this section~~ parts 1, 4, 5, and 6 of this subparagraph, at the time monitoring reports are submitted. The reports shall contain the information listed in ~~paragraph (l)(vi)~~ part 6 of this ~~section~~ subparagraph.

~~(viii)~~ 8. Other information

Where the permittee becomes aware that it failed to submit any relevant acts in a permit application, or submitted incorrect information in a permit application or in any report to the ~~Department~~ Commissioner, it shall promptly submit such facts or information.

(m) Requirements prior to commencing injection

Except for all new wells authorized by an area permit under Rules ~~1200-04-06-.11~~ 0400-45-06-.11 and ~~1200-04-06-.12~~ 0400-45-06-.12, a new injection well may not commence injection until construction is complete, and

1. The permittee has submitted notice of completion of construction to the ~~Director~~ Commissioner; and

2. (i) The ~~Department~~ Commissioner has inspected or otherwise reviewed the new injection well and finds it is in compliance with the conditions of the permit; or

   (ii) The permittee has not received notice from the ~~Director~~ Commissioner of his or her intent to inspect or otherwise review the new injection well within 13 days of the date of the notice in ~~paragraph (m)(l) of this section~~ part 1 of this subparagraph, in which case prior inspection or review is waived and the permittee may commence injection. The ~~Director~~ Commissioner shall include in his notice a reasonable time period in which he shall inspect the well.

(n) The permittee shall notify the ~~Department~~ Commissioner at such times as the permit requires before conversion or abandonment of the well, or in the case of area permits, before closure of the project.

(o) The permittee shall at all times maintain sufficient financial resources to allow for the proper plugging and abandonment of the well. In the event of a change of ownership or other transfer of permit, the transferee shall provide proof of financial responsibility before continued operation.

1. For Class I and III wells, a surety bond or cash bond shall be filed with the ~~Department~~ Commissioner prior to permit issuance. At the ~~Department~~ Commissioner's discretion, other forms of financial assurance for Class I wells may be acceptable.

2. Class II wells shall have a surety bond or cash bond for a total of $4,000 per well. If there is an existing $2,000 bond with the Tennessee Oil and Gas Board, the bond under this rule shall be $2,000. If no bond currently exists, the bond shall be for $4,000.

3. At the ~~Department~~ Commissioner's discretion, a bond may be required for Class V wells.

(p) The owner or operator of a Class I, II or III well permitted under this part shall establish prior to commencing injection or on a schedule determined by the ~~Department~~ Commissioner, and thereafter maintain mechanical integrity for the well. When the ~~Department~~ Commissioner determines that a Class I, II, or III well lacks mechanical integrity, the ~~Department~~ Commissioner shall give written notice of the determination to the owner or operator. Unless the ~~Department~~ Commissioner requires immediate cessation, the owner or operator shall cease injection into the well within 48 hours of receipt of the ~~Department~~ Commissioner's determination. The ~~Department~~ Commissioner may allow plugging of the well pursuant to the requirements of this rule or require the permittee to perform such additional construction, operation, monitoring, reporting and corrective action as is necessary to prevent the movement of fluid into or between USDWs caused by the lack of mechanical integrity. The owner or operator may resume injection upon written notification from the ~~Department~~ Commissioner that the owner or operator has demonstrated mechanical integrity pursuant to this rule. The ~~Department~~ Commissioner may allow the owner or operator of a well which lacks mechanical integrity to continue or resume injection, if the owner or operator has made a satisfactory demonstration that there is no movement of fluid into or between USDWs.

(q) A Class I, II or III permit shall include and a Class V permit may include, conditions to insure that plugging and abandonment of the well will not allow the movement of fluids into or between USDWs. Where the ~~Department~~ Commissioner's review of an application indicates that the permittee's plan is inadequate, the ~~Department~~ Commissioner may require the applicant to revise the plan, prescribe conditions meeting the requirements of this paragraph, or deny the permit.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.09~~ 0400-45-06-.09 General Standards and Methods.

(1) Applicability

The provisions of this ~~subchapter~~ rule set forth standards and requirements that apply to all classes of injection wells unless specifically excluded or contradicted by provisions applicable to a particular class of well.

(2) Supervisory Standard

All phases of well construction, testing and operation shall be supervised by a person who is knowledgeable and experienced in practical drilling engineering and who is familiar with the special conditions and requirements of injection well construction.

(3) Area of Review

(a) Descriptions of the area of review are subject to approval by the ~~Department~~ Commissioner according to either subpart 4(i) or (ii) of this subparagraph. The Commissioner may solicit input from the owners and operators of injection wells within the State as to which method is most appropriate for each geographic area or field. In no event shall the boundary of an area of review be less than a radius of one (1) mile from any injection well covered by the appropriate authorization. The following factors are to be included in the description:

1. Chemistry of the injection and formation fluids;

2. Hydrogeology, including the direction of ground water movement;

3. Ground water use and dependence; past, present, and future, as documented by public record; and

4. The area of potential impact as determined by either subpart (i) of this part the calculated zone of endangering influence or subpart (ii) of this part a fixed radius.

(i) Zone of endangering influence

(I) The zone of endangering influence shall be:

I. In the case of application(s) for well permit(s) under Rule ~~1200-04-06-.08~~ 0400-45-06-.08, that area the radius of which is the lateral distance in which the pressures in the injection zone may cause the migration of the injection and/or formation fluid into an underground source of drinking water; or

II. In the case of an application for an area permit, the project area plus a circumscribing area the width of which is the lateral distance from the perimeter of the project area, in which pressures in the injection zone may cause the migration of the injection and/or formation fluid into an underground source of drinking water.

(II) Computation of the zone of endangering influence may be based upon the parameters listed below and should be calculated for an injection time period equal to the expected life of the injection well or pattern. The following modified Theis equation illustrates one form which the mathematical model may take.

$$r = \left(\frac{2.25KHt}{S10^{x}}\right)^{1/2}$$

where:

$X = \frac{4\pi KH(h_w - h_{bo}XS_pG_b}{2.3Q}$

r = Radius of endangering influence from injection well (length)
K = Hydraulic conductivity of the injection zone (length/time)
H = Thickness of the injection zone (length)
t = Time of injection (time)
S = Storage coefficient (dimensionless)
Q = Injection rate (volume/time)
h_{bo} = Observed original hydrostatic head of injection zone (length) measured from the base of the lowermost underground source of drinking water
h_w = Hydrostatic head of underground source of drinking water (length) measured from the base of the lowermost underground source of drinking water
S_pG_b = Specific Gravity of fluid in the injection zone (dimensionless)
Π (pi) = 3.142 (dimensionless)

The above equation is based on the following assumptions:

I. The injection zone is homogeneous and isotropic;

II. The injection zone has infinite areal extent;

III. The injection well penetrates the entire thickness of the injection zone;

IV. The well diameter is infinitesimal compared to "r"; when injection time is longer than a few minutes; and

V. The emplacement of fluid into the injection zone creates instantaneous increase in pressure.

(ii) Fixed radius

(I) In the case of application(s) for a well permit(s), a fixed radius around the well of not less than one mile may be used.

(II) In the case of an application for an area permit, a fixed width of not less than one mile for the circumscribing area may be used.

In determining the fixed radius, the following factors shall be taken into consideration: chemistry of the injected and formation fluids; hydrogeology; population and ground-water use and dependence; and historical practices in the area.

(b) The ~~Department~~ Commissioner may require an owner or operator of an existing or proposed injection well to submit information necessary to establish the area of review.

(4) Mechanical Integrity Sandards

(a) An injection well has mechanical integrity if there is no significant leak in the casing, tubing or packer, and if there is no significant fluid movement into USDWs through vertical channels in and adjacent to the injection well bore hold.

(b) The following tests shall be used to evaluate the mechanical integrity of an injection well:

1. Monitoring of annulus pressure, or pressure test with liquid or gas to detect any leaks in casing, tubing, or packer;

2. Appropriate geophysical logs to detect any fluid movement through vertical channels in and adjacent to the injection well borehole.

(c) The ~~Department~~ Commissioner may allow the use of tests to evaluate mechanical integrity other than those listed in this rule if such tests have been approved in writing by the ~~Department~~ Commissioner and, if the ~~Department~~ Commissioner receives authority for an underground injection control program from the U.S. E.P.A., the E.P.A. Administrator or his designee.

(d) Methods and standards generally accepted in the industry shall be applied in conducting and evaluating the tests required by this ~~section~~ paragraph.

(5) Corrective Action Standards

(a) Standards

1. Applicants for injection well permits shall identify the location of all known wells within the area of review which penetrate the injection zone, or in the case of Class II wells operating over the fracture pressure of the injection formation, all known wells within the area of review penetrating formations affected by the increase in pressure. For such wells which are improperly sealed, completed or abandoned, the applicant shall also submit a plan consisting of such steps or modifications as are necessary to prevent movement of fluids into USDWs.

(b) Requirements

1. Any permit issued for an existing injection well (other than a Class II well) requiring corrective action shall include a compliance schedule requiring any corrective action accepted or prescribed shall be completed as soon as possible.

2. No permit for a new injection well may authorize injection until all required corrective action has been taken.

(c) Injection pressure limitation

The ~~Department~~ Commissioner may require as a permit condition that injection pressure be so limited that pressure in the injection zone does not exceed hydrostatic pressure at the site of any improperly completed or abandoned well within the area of review. This pressure limitation shall satisfy the corrective action requirement. Alternatively, such injection pressure limitation can be part of a compliance schedule and last until all other required corrective action has been taken.

(d) In determining the adequacy of corrective action to prevent fluid movement into or between formations containing USDWs, the following criteria and factors shall be considered by the ~~Department~~ Commissioner:

1. Nature and volume of the injected fluid;

2. Nature of native fluids, and by-products of injection;

3. Potentially affected population;

4. Geology;

5. Hydrology;

6. History of the injection operation;

7. Completion and plugging records;

8. Abandonment procedures in effect at the time the well was abandoned; and

9. Hydraulic connections with formations containing USDWs.

(e) Class III wells only

When setting corrective action requirements, the Commissioner shall consider the overall effect of the project on the hydraulic gradient in the potentially affected USDWs, and the corresponding changes in potentiometric surface(s) and flow direction(s) rather than the discrete effect of each well. If a decision is made that corrective action is not necessary based on the determinations ~~above~~ of this paragraph, the monitoring program required in Rule ~~1200-04-06-.12~~ 0400-45-06-.12 shall be designed to verify the validity of such determinations.

(6) Plugging and Abandonment Standards

(a) An injection well, or a test or monitor well associated with an injection well, must be abandoned and plugged when:

1. the well is no longer usable for its intended purpose or other purpose as approved by the ~~Department~~ Commissioner;

2. the well poses a potential threat to the quality of the waters of the state; or

3. the well has not been operated for two (2) years.

(b) When it is necessary to plug and abandon a well covered by these regulations, an application for a plugging and abandonment permit will be submitted to the ~~Department~~ Commissioner on the form prescribed. The application will include:

1. Reasons for abandonment;

2. A copy of the approved plugging and abandonment plan which was submitted with the application for construction or operation permits; and

3. Any modifications deemed necessary to the previously approved plugging and abandonment plan.

(c) The owner/operator of an abandoned injection well or facility may be required to submit all pertinent records of construction, operation and abandonment to the ~~Department~~ Commissioner within a period of not less than one year following the date of abandonment.

(d) Any well that is to be permanently plugged and abandoned shall be completely filled and sealed in such a manner that vertical movement of fluid either into or between formation(s) containing USDWs through the bore hole is not allowed. The proposed method of filling and the type of material to be used shall be approved by the ~~Department~~ Commissioner.

(e) As a minimum, permanent seals must be placed in the bore hole opposite (1) the lowermost confining bed, and (2) each intermediate confining bed between successive formation(s) containing USDWs.

(f) Seals intended to prevent vertical movement of water in a well bore hole shall be composed of cement, sand-and-cement, or concrete or other sealing materials demonstrated to the satisfaction of the ~~Department~~ Commissioner to be effective.

(g) The minimum length of a seal required in subparagraph (f), ~~above~~ of this paragraph, shall be 20 feet.

(h) The bore hole above the uppermost formation(s) containing a USDW shall be filled with materials less permeable than the surrounding undisturbed formations, the uppermost five (5) feet of the bore hole (at land surface) shall be filled with a material appropriate to the intended use of the land.

(i) The materials used to fill spaces between well seals shall be filled with disinfected dimensionally stable materials, compacted mechanically if necessary to avoid later settlement except that cement, cement and sand, and concrete do not require disinfection. Disenfection of well filling materials shall be accomplished by using chlorine compounds such as sodium hypochlorite or calcium hypochlorite.

(j) Temporary bridges may be used to avoid having to fill very deep holes below the deepest point at which a permanent seal is required. Temporary bridges used to provide a base for a permanent seal shall consist of materials approved by the ~~Department~~ Commissioner.

(k) After a cessation of operations of two years, the owner or operator shall plug and abandon the well in accordance with the plan unless he:

1. Provides notice to the ~~commissioner~~ Commissioner; and

2. Describes actions or procedures, satisfactory to the Commissioner that the owner or operator will take to ensure that the well will not endanger USDWs during the period of temporary abandonment. These actions and procedures shall include compliance with the technical requirements applicable to active injection wells unless waived by the commissioner.

(7) Placement of sealing materials

(a) Approved sealing materials used in abandonment operations shall be introduced at the bottom of the well or interval to be sealed and placed progressively upward to the top of the well. All such sealing materials shall be placed in such a way as to avoid segregation or dilution of the sealing materials. The method of emplacing materials shall be approved by the ~~Department~~ Commissioner. Dumping sealing material from the top of the well shall not be allowed.

(b) Permanent seals shall be placed in wells or bore holes opposite confining beds between aquifers which are identifiable as, or are suspected of being, hydraulically separated under natural, undisturbed conditions. After the required seal has been installed, the remainder of the confining zone between formations containing USDWs may be filled with sand, sand and gravel, or other rock material acceptable to the ~~Department~~ Commissioner.

(8) Special Conditions

(a) The permanent sealing of flowing wells or wells that have a positive shut-in pressure head at the land surface shall be accomplished only after the wells have been prepared in such a way as to prevent any backflow of water or other fluids at the land surface. This can be accomplished by introducing high specific gravity fluids at the bottom of the bore hole and filling the hole with the fluid until all flow ceases or the shut-in pressure is reduced to zero. If the displaced fluid constitutes a contaminant, special handling will be required to avoid any threat to USDWs.

(b) Prior to abandonment, any Class I or Class III well or any monitoring well that extends to the top of the shallowest injection zone shall be sealed from the top of the shallowest injection zone to the land surface with neat cement grout or an approved equivalent cementitious material such as neat cement with a maximum of 5 percent by weight of commercially processed bentonite.

(c) The following shall be considered in determining the adequacy of a plugging and abandonment plan for injection wells:

1. The type and number of plugs to be used;

2. The placement of each plug including the elevation of the top and bottom;

3. The type, grade and quantity of plugging material to be used;

4. The method of placement of the plugs;

5. The procedure used to plug and abandon the well;

6. Any newly constructed or discovered wells, or information, including existing well data, within the area of review;

7. Geologic formations present including but not limited to type of strata, structure and location of any aquifer;

8. Economic conditions; and

9. Such other factors that may affect the adequacy of the plan.

(9) Verification of Procedures

(a) Except under emergency conditions the ~~Department~~ Commissioner is to receive thirty (30) days advance notice of the intent to plug and abandon either an injection or monitoring well in order to permit Departmental personnel to witness the procedure.

(b) Within ninety (90) days after completion of plugging, the permittee shall provide to the ~~Department~~ Commissioner documentation that the well was adequately plugged and abandoned.

(10) Evidence of financial responsibility shall be demonstrated to accomplish all actions required under these rules, including all plugging and abandonment activities. This financial responsibility requirement does not apply to those Class V wells which are permitted by rule.

(11) The Commissioner may require, by written notice on a selective well-by-well basis, an owner or operator of an injection well to establish and maintain records, make reports, conduct monitoring, and provide other information as is deemed necessary to determine whether the owner or operator has acted or is acting in compliance with T.C.A. § 69-3-101 et seq., Tennessee Water Quality Control Act or its implementing regulations.

(12) All injection wells must be placed on a plat with the Register of Deeds by the seller of the individual properties that the injection well is located on or the injection zone is beneath. The owner/operator of the injection well shall have contractual agreement for access to the injection well at all reasonable times.

(13) Any person owning or operating an injection well shall keep the ~~Department~~ Commissioner advised of his or her current address and must readily accept all mail sent by the ~~Department~~ Commissioner. For the purposes of this rule, registered or certified mail sent with proper postage to the registered owner or operator's last known address shall be considered adequate notification regardless of whether the mail is accepted or returned unclaimed.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.10~~ 0400-45-06-.10 Class I Wells.

(1) The following are prohibited:

(a) Subsurface emplacement of fluids containing hazardous waste into ground water.

(b) Subsurface emplacement of waste fluids into ground water in a location containing extractable energy-related resources including but not limited to oil, gas, oilshale, coal and lignite. (See attached ~~Figure~~ Appendix A)

(c) Subsurface emplacement of waste fluids into ground water in areas characterized by regional rock deformation such as of the magnitude that occurs in eastern Tennessee. (See attached ~~Figure~~ Appendix A)

(d) Subsurface emplacement of waste fluids into or beneath aquifers composed of uncemented sand such as occurs in western Tennessee. (See attached ~~Figure~~ Appendix A)

(e) The application of pressures sufficient to initiate new fractures or propagate existing fractures in the injection or confining zone.

(2) Permit Application for Class I Wells

(a) Three separate and independent permits will be needed for Class I Wells. They are:

1. Construction permits;

2. Operating permits; and

3. Abandonment and plugging permits.

(b) The counties in the following list generally do not have the characteristics enumerated in ~~rule 1200-04-06-.10~~ paragraph (1) ~~above~~ of this rule. However, if such characteristics do exist in a particular location the prohibitions in ~~section~~ paragraph (1) ~~above~~ of this rule would apply.

~~Bedford~~	~~Houston~~	Perry
Cannon	Humphreys	Robertson
Cheatham	Lawrence	Rutherford
Coffee	Lewis	Smith
Davidson	Lincoln	Stewart
DeKalb	Macon	Sumner
Dickson	Maury	Trousdale
Franklin	Marshall	Warren
Giles	Moore	Williamson
Hickman	Montgomery	Wilson

(3) Construction Permit Requirements

(a) Feasibility Study

An application for a permit to construct a new Class I injection well or for a permit modification to inject a fluid which has not been authorized by the existing permit shall be considered only after a thorough evaluation of all reasonable disposal methods. This requirement shall be satisfied as follows:

1. Submission to the ~~Department~~ Commissioner of a technical report providing:

(i) a characterization of the fluid to be injected;

(ii) the source of the fluid to be injected;

(iii) an evaluation of all reasonable methods of disposal which may be used for each fluid to be injected;

(iv) a demonstration of the effect of the fluid on the host rock and the ground water; and

(v) documentation that underground injection is a feasible means of the permitting process or disapprove the proposed injection well.

2. After a review, the ~~Department~~ Commissioner, will either approve continuation of the permitting process or disapprove the proposed injection well.

(b) Description of Area

If the ~~Department~~ Commissioner approves the feasibility study, a hydrogeologic description of the area surrounding the site of the proposed injection facility must be submitted. The study area shall extend for at least a two and one-half miles (2½) radius of the site. The description shall include but not be limited to the following:

1. A set of inventories and maps that shall provide the following information to the extent that such information is known to the applicant or is available in public records.

   (i) A tabulation of data on all wells of public record (to include water wells) located within the study area, to include:

      (I) method of construction,

      (II) date drilled,

      (III) location,

      (IV) depth,

      (V) record of plugging or completion, and

      (VI) the present use of the well.

   (ii) A tabulation of surface waters located within the study area to include:

      (I) type

      (II) location, and

      (III) use.

   (iii) A map(s) showing the location of:

      (I) wells,

      (II) surface waters, and

      (III) other pertinent surface features such as roads, mines, quarries, residences and planned developments, within the study area.

2. Hydrogeological data including maps and cross sections showing local and regional geological structure, the horizontal and vertical extent of formation(s) containing a USDW, the proposed injection zone, and the direction of flow of water in each formation(s) containing a USDW and proposed injection zone.

3. After a review, the ~~Department~~ Commissioner will either approve continuation of the permitting process or disapprove the proposed injection well.

(c) Construction Plans

Application for a permit to construct a Class I Well shall contain a proposed step-by-step drilling plan. The drilling plan must specify the proposed drilling, sampling, coring, and testing program and adhere to the design criteria and construction standards provided in this rule. If the ~~Department~~ Commissioner determines that the construction permit application meets the requirements of ~~subsections~~ subparagraphs (d), (e), and (f) of this ~~rule~~ paragraph, the construction permit shall be issued.

(d) Design Criteria

1. All Class I wells shall be designed and constructed in such a fashion they inject into a formation which is beneath the lowermost formation containing a USDW.

2. All Class I wells shall be cased and cemented to prevent the movement of fluids into or between formation(s) containing a USDW and to maintain the quality of aquifers above the injection zone that may be used for monitoring or other purposes.

3. A deviation survey will be run at sufficiently frequent intervals to ensure that the casing can be set and centered for cementing.

4. The ~~Department~~ Commissioner may require directional surveys, if, after an analysis of the well design and drilling program, it is deemed necessary.

5. The construction should be supervised by a person knowledgeable and experienced in drilling and completion of injection wells.

6. All Class I injection wells shall inject fluids through tubing with a packer set immediately above the injection zone, or tubing with an approved fluid seal as an alternative. The tubing, packer, and fluid seal shall be designed for the expected service.

(e) Casings

1. The casings used in the construction of each newly drilled Class I well shall be designed for the life expectancy of the well.

2. The number, thickness, type of materials, and length of casing shall be sufficient to protect the USDWs and the integrity of the well and the confining strata.

3. Exact setting depths for all casings shall be determined in the field, based on all available information, in order to best protect USDWs.

(f) Cementing

The applicant shall submit the proposed cementing program with the drilling plan. The proposed program should insure that an adequate bond can be achieved between the casing and the borehole.

1. The cementitious material used in the construction of each newly drilled well shall be designed for the life expectancy of the well. In determining and specifying casing and cementing requirements, the following factors shall be considered:

   (i) depth to the injection zone;

   (ii) depth to the bottom of all formation(s) containing USDWs;

   (iii) injection pressure, external pressure, internal pressure, and axial loading;

   (iv) hole size;

   (v) size and grade of all casing strings (wall thickness, diameter, nominal weight, length, joint specification and construction material);

   (vi) corrosiveness of injected fluid, formation fluids, and temperatures;

   (vii) lithology of injection and confining zones;

   (viii) type, grade, and amount of cementitious material.

2. Cementitious material must be compatible with the injected fluid, native fluids, and the formations penetrated by the bore hole.

3. Use of additives to the cementitious materials used for mixing shall be determined by the applicant, provided the integrity, containment, corrosion protection, and structural strength of the cementitious material are not significantly affected. Accurate records shall be kept and recorded of all additives used.

4. Prior to cementing, the hole shall be conditioned in such a way as to optimize bonding of the cement to the casing and formation, and to prevent channeling.

5. Placement of cementitious material shall be in such a manner that the purposes and characteristics of the cement are retained, and shall be subject to ~~Department~~ Commissioner approval.

6. The applicant shall submit a cement testing program with the permit application for ~~Department~~ Commissioner approval. The purpose of the cement testing program is to insure that the cement seal is adequate to prevent migration of fluids in channels, microannular spaces, or voids in the cement. The following methods of testing, as a minimum, shall be considered:

   (i) pressure testing of casing - to not less than 1.5 times the expected injection pressure;

   (ii) temperature log - must be run within forty-eight (48) hours after cementing; and

   (iii) cement bond log.

(g) Testing during drilling and construction of new Class I wells

Appropriate logs and other tests shall be conducted during the drilling and construction of new Class I wells. A descriptive report interpreting the results of such logs and tests shall be prepared by a qualified log analyst and submitted to the ~~Department~~ Commissioner. At a minimum, such logs and tests shall include:

1. Directional surveys on all holes that are constructed by first drilling a pilot hole, and then enlarging the pilot hole by reaming or another method. Construction of pilot holes is not encouraged.

2. Such other logs and tests as may be needed after taking into account the availability of similar data in the area of the drilling site, the construction plan, and the need for additional information. In determining which logs and tests shall be required, the following logs shall be considered for use in the following situations:

   (i) For surface casing intended to protect USDWs:

      (I) resistivity, spontaneous potential, and caliper logs before the casing is installed; and

      (II) a cement bond, temperature, or density log after the casing is set and cemented.

   (ii) For intermediate and long strings of casing intended to facilitate injection:

      (I) resistivity, spontaneous potential, porosity, and gamma ray and caliper logs before the casing is installed;

      (II) fracture finder logs; and

      (III) a cement bond, temperature, or density log after the casing is set and cemented.

3. The following information concerning the proposed injection zone shall be determined or calculated for new Class I wells:

   (i) hydrostatic pressure head;

   (ii) temperature of the native fluid;

   (iii) geostatic pressure;

(iv) other physical and chemical characteristics of the proposed injection zone;

(v) physical and chemical characteristics of the native fluids;

(vi) generalized direction of fluid flow in the proposed injection zone; and

(vii) other information as deemed necessary by the ~~Department~~ Commissioner.

(h) Testing Integrity of Completed Class I Well(s)

1. The completed well(s) will be tested to assure that the well(s) will function as built. Tests to be considered shall include, but not be limited to, the followings:

(i) cement bond log;

(ii) temperature log;

(iii) pressure test of final casing to at least 1.5 times the expected injection pressure for one hour, with no pressure drop after temperature correction;

(iv) casing inspection log from top to bottom of the well for baseline monitoring purposes;

(v) injection tests; and

(vi) withdrawal tests - if necessary.

(i) Construction Reports

1. The ~~Department~~ Commissioner shall be notified when drilling is to commence.

2. The ~~Department~~ Commissioner will require periodic data reports and progress reports that may include, but not be limited to, the following:

(i) driller's log;

(ii) geophysical logs;

(iii) core analyses;

(iv) lithologic log;

(v) drill stem test data;

(vi) injection or withdrawal test data;

(vii) pressure test data; and

(viii) construction progress reports.

3. Interpretation of data will be required in the data reports or progress reports at each milestone phase of construction such as completion of the pilot hole, completion of test well, and completion of well performance tests.

4. The applicant shall submit final reports of pertinent data collected with interpretations to the ~~Department~~ Commissioner with the application for an Injection Well Operation Permit.

(4) Operating Permits

(a) Application for permit to operate any Class I well shall be complete and contain any information necessary to provide:

1. A feasibility study including all of the items required in ~~rule 1200-04-06-.10~~ subparagraph (3)(a) of this rule. An up-to-date feasibility study must also be submitted with any request for renewal of an operating permit. If the feasibility study is not included, the application for renewal of an operating permit will not be complete.

2. A description of the area of review which applies to each Class I injection well in a manner acceptable to the ~~Department~~ Commissioner. The description shall take into account the zone of endangering influence. A radius around the injection well field of not less than one mile shall be used as a minimum area of review. A determination of the area of review shall include, but not be limited to, the following information:

   (i) the geologic and hydrologic characteristics of the host rock, and the confining unit separating the injection zone from the lowermost formation(s) containing a USDW;

   (ii) the characteristics of the injection fluids and native fluids;

   (iii) number of people residing in the area of review; and

   (iv) ground water use and dependence; past, present, and future to the extent such information is known to the applicant or is on public record.

3. The compatibility of the non-hazardous injected fluid with both the native fluid and the host rock of the in tended injection zone must be demonstrated using laboratory or field data.

4. Contingency plans to prevent pollution of any USDWs or surface water which may be caused by failure of the well or associated equipment.

5. A plan for plugging and abandonment of the proposed injection well. Plugging shall be accomplished so that the injection zones are completely isolated and the movement of fluids into any formation(s) containing a USDW or between formation(s) containing a USDW is prevented. Plugging shall also be accomplished so that surface water cannot enter the well.

6. A report on the status of any corrective action required under these rules.

(b) Operating Requirements for Class I Wells

1. Injection pressure shall not exceed a maximum of 0.60 psi/foot of depth from the land surface to the shallowest injection zone unless the applicant can demonstrate, to the satisfaction of the ~~Department~~ Commissioner that a higher pressure can be used and will not initiate new fractures or propagate existing fractures in the injection zone.

2. Total pressure shall not exceed the maximum allowable stress of the materials used to construct the well.

3. Injection of wastewater between the outermost casing protecting USDWs and the inner tubing is prohibited.

4. All waste fluids to be emplaced shall be injected through tubing.

5. The annulus between the tubing and the long string of casing shall be filled with a fluid approved by the ~~Department~~ Commissioner. A pressure, also approved by the ~~Department~~ Commissioner shall be maintained on the annulus sufficient to allow for continuous monitoring of the mechanical integrity of the well.

6. The ~~Department~~ Commissioner shall be notified when operation is to commence.

7. Other operational limitations shall be established as necessary on a case-by-case basis.

(c) Operation and maintenance Manual

1. Operation and maintenance procedure manual(s) shall be prepared for injection well disposal facilities, or parts thereof. The manual shall, at a minimum, contain appropriate information discussed in the remainder of this ~~section~~ subparagraph. The ~~Department~~ Commissioner may require that the manual be submitted as part of the application for an operating permit.

2. The required procedure shall provide for the reliable and efficient operation and maintenance of the injection well disposal facility, in accordance with the requirements of this rule.

3. The detail of the required manual shall be consistent with the complexity of the system. The manual shall be developed in accordance with the unique requirements of the individual injection well disposal facility and shall provide the operator with sufficient information and description regarding the design, operation, and maintenance criteria and features of the disposal facility involved.

4. Basic hydraulic and engineering design criteria for the injection well disposal facility shall be included in the manual, as well as information and procedures required for normal control and distribution of effluent within the injection well disposal facility.

5. Information concerning process control and performance evaluation for the facility shall be included, as well as equipment and procedural descriptions for emergency operating conditions, alternate discharge as a back-up procedure, and listing of spare parts to have on hand. Regular maintenance of all equipment, repair, safety, and monitoring procedures, laboratory, lab testing equipment, and personnel requirements, and a "trouble shooting" problem guide shall also be included in the manual.

6. A copy of the manual shall be provided to the operator of the injection facility by the permittee. The manual shall be available for reference at the facility or other approved site. The permittee shall maintain at least one copy of the manual.

7. The ~~Department~~ Commissioner may require revisions to the manual to reflect any facility modifications performed in order to comply with the requirements of this chapter, or to reflect experience resulting from facility operation.

(d) Abnormal Events

1. In the event the permittee is temporarily unable to comply with any of the conditions of a permit that may result in imminent harm to the public health or to the environment due to breakdown of equipment, power outages, destruction by hazard of fire, wind, or by other cause, the permittee of the facility shall immediately cease injection and shall notify the ~~Department~~ Commissioner. Notification shall be made in person, by telephone, or by telegraph to the nearest office of the Department within 24 hours of breakdown or malfunction.

2. A written report shall be required by the ~~Department~~ Commissioner within 72 hours of the notification referenced in ~~(d)(1), above~~ part 1 of this subparagraph. The report shall describe the nature and cause of the breakdown or malfunction, the steps being taken or planned to be taken to correct the problem and prevent its reoccurrence, emergency procedures in use pending correction of the problem, and the time when the facility will again be operating in accordance with permit conditions.

3. Under emergency conditions in which the permittee is unable to use the permitted well, the permittee may use an alternate discharge only with prior approval of the ~~Department~~ Commissioner. The applicant shall address the alternate disposal method in the permit application and the operating manual.

4. In the event a well must be developed the applicant shall address disposal of backwashed fluids. The disposal method shall be approved by the ~~Department~~ Commissioner.

(e) Operational Monitoring Requirements

1. In determining the type, number, depth, and location of monitoring wells to be used and the parameters to be measured, the following criteria shall, as a minimum, be considered:

   (i) the local geology and hydrology,

   (ii) the extent of the area of review;

   (iii) the proximity of the injection operation to points of withdrawal of drinking water;

   (iv) the operating pressures and attendant hydraulic gradients;

   (v) the physical and chemical character of the injected fluid; and

   (vi) the number, type, location, and depth of water wells in the area of review.

2. The ~~Department~~ Commissioner shall be allowed access at reasonable times to the permittee's property and records for the purpose of inspections and the collection of samples for analyses from the wastewater streams associated with the permitted wells.

3. The physical and chemical quality of the native fluid in the injection zone and in the zone(s) to be monitored shall be established prior to injection.

4. The injected fluid shall be analyzed with sufficient frequency to yield representative data on its characteristics.

5. Continuous indicating and recording devices shall be used to monitor fluid level or closed-in surface pressure in monitor wells other than the injection wells.

6. The mechanical integrity of the injection well system shall be examined and evaluated at least once every three years in accordance with the standards contained in this rule.

(f) Class I injection wells shall be monitored as follows:

1. Continuous indicating and recording devices shall be installed and used to monitor the following:

   (i) injection rate and daily volume of injected fluids;

   (ii) injection pressure; and

   (iii) pressure maintained on the annulus between the injection tubing and the long string of casing.

2. Determination shall be made at least twice monthly of the injectivity index of each well used for injection. The method of determination shall be subject to the approval by the ~~Department~~ Commissioner.

(g) Sampling frequency and procedure for monitoring wells other than the injection well shall include, but not be limited to:

1. The fluids in the zone to be monitored shall be sampled and analyzed with sufficient frequency to yield representative data on its characteristics. The frequency shall be at least monthly.

2. Constituents to be monitored shall be those determined appropriate based on the nature of the waste being injected.

3. Samples must be collected by a method insuring that the sample is representative of the fluid in the zone to be monitored. The method shall be subject to approval by the ~~Department~~ Commissioner.

(h) Operation Reports

1. The applicant must submit, for ~~Department~~ Commissioner approval, his proposed methodology for collection and reporting of operational data, to insure that data is collected, correlated, and reported in a fashion that would enable the agency to evaluate well performance.

2. Reporting requirements shall, at a minimum, include:

(i) Quarterly reporting to the ~~Department~~ Commissioner;

(ii) Monthly average, maximum and minimum values for injection pressure, flow rate, volume, and annular pressure; and

(iii) Results of mechanical integrity and any other periodic test required by the ~~Department~~ Commissioner shall be reported with the first regular quarterly report after the completion of the test.

3. The results of analyses of representative samples of the injected fluid and water from the monitoring wells shall be submitted on a quarterly basis to the ~~Department~~ Commissioner. Parameters for such analyses shall be established on an individual basis.

(i) Ambient Monitoring

1. Based on a site-specific assessment of the potential for fluid movement from the well or injection zone and on the potential value of monitoring wells to detect such movement, the ~~Department~~ Commissioner shall require the owner or operator to develop a monitoring program. At a minimum, the ~~Director~~ Commissioner shall require:

(i) Monitoring of the pressure buildup in the injection zone annually, including a shut down of the well for a time sufficient to conduct a valid observation of the pressure fall-off curve; and

(ii) Periodic monitoring of the ground water quality in the first aquifer overlying the injection zone.

2. When prescribing a monitoring system the ~~Department~~ Commissioner may also require:

(i) Continuous monitoring for pressure changes in the first aquifer overlying the confining zone. When such a well is installed, the owner or operator shall, on a quarterly basis, sample the aquifer and analyze for constituents specified by the ~~Department~~ Commissioner;

(ii) The use of indirect, geophysical techniques to determine the position of the waste front, the water quality in a formation designated by the ~~Department~~ Commissioner, or to provide other site specific data;

(iii) Periodic monitoring of the ground water quality in the lowermost USDW; and

(iv) Any additional monitoring necessary to determine whether fluids are moving into or between USDWs.

(5) Plugging and Abandonment Permits

(a) Upon the occurrence of any of the conditions stated in ~~rule 1200-04-06-.09~~ subparagraph (6)(a) of Rule 0400-45-06-.09, the owner or operator of the well shall submit an application for a permit for plugging and abandonment of the well.

(b) Before any injection well is plugged, the owner or operator shall obtain a permit for the plugging of the well.

(c) The application shall include the items stated in ~~rule 1200-04-06-.09~~ subparagraph (6)(b) of Rule 0400-45-06-.09.

(d) If the ~~Department~~ Commissioner finds that the application meets all requirements of these rules, then the permit for plugging and abandonment of the well shall be ~~issues~~ issued.

(e) Upon completion of plugging and abandonment of a well or wellfield, the permittee shall submit to the ~~Department~~ Commissioner a Final Report, in accordance with the standards described in ~~rule 1200-04-06-.09~~ paragraph (6) Rule 0400-45-06-.09, which shall include, but will not be limited to, the following:

1. Daily construction reports;

2. Certification of completion in accordance with approved plans and specifications by a person knowledgeable and experienced in the field; and

3. Evidence, such as a sealed copy or certification from the county clerk, that a surveyor's plot of the location of the abandoned wells has been recorded in the county courthouse property records.

(f) The ~~Department~~ Commissioner shall require post-closure monitoring of Class I wells for at least three (3) years. Results of such monitoring shall be reported quarterly to the ~~Department~~ Commissioner.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.11~~ 0400-45-06-.11 Class II Wells.

A permit must be obtained from the ~~Department~~ Commissioner prior to the operation of any Class II injection well except for existing Class II enhanced recovery wells and hydrocarbon storage wells. This requirement is in addition to and separate from any approval or regulatory procedure required by the Tennessee Oil and Gas Board, Department of Environment and Conservation.

(1) Permit Applications

(a) For Class II wells, the ~~Department~~ Commissioner shall require an applicant to furnish a demonstration of commercial producibility which shall be made as follows:

1. For a Class II well to be used for enhanced oil recovery processes in a field or project containing aquifers from which hydrocarbons were previously produced, commercial producibility shall be presumed by the ~~Department~~ Commissioner upon evidence that production has occurred in the project area or field.

2. For Class II wells not located in a field or project from which hydrocarbons were previously produced, information such as logs, core data, formation description, formation depth, formation thickness, and formation parameters such as permeability and porosity shall be considered by the ~~Department~~ Commissioner to the extent such information is available.

(b) Permit applications for Class II wells shall be submitted by the applicant using the appropriate permit application form promulgated by the Department and shall contain any attachments necessary to provide:

1. facility name and location;

2. name and address of legal contacts (agents of process);

3. ownership of facility, including address;

4. a map and a tabulation of data as required by ~~rule 1200-04-06-.10~~ part (3)(b)1 of Rule 0400-45-06-.10.

5. a description of the proposed injection system including type and construction of injection wells, nature of injected fluid and any proposed pretreatment;

6. a statement of estimated daily volume of fluid to be injected and maximum injection pressure;

7. appropriate logs of the well with the proposed injection zone marked, in the case of a well already drilled, or; in the case of undrilled wells a statement of the proposed zone to be used for disposal and the approximate depth of said zone;

8. a schematic diagram of the proposed Class II well showing the casing and cementing program together with an explanation thereof; and

9. a statement by the applicant that the proposed Class II well(s) will be completed in such a manner to insure that the injected substances are injected into the proposed injection zone and that provisions have been made for adequate protection of formation(s) containing USDWs and any other zone of commercial value.

10. proposed formation testing program to obtain the information required by ~~rule 1200-04-06-.11~~ subparagraph (5)(b) of this rule.

11. proposed stimulation program.

12. proposed injection procedure.

13. proposed contingency plans, if any, to address well failures so as to prevent migration of contaminating fluids into a USDW.

14. plans for meeting the monitoring requirements of ~~rule 1200-04-06-.11~~ paragraph (6) of this rule.

(c) Reserved

(d) Additional requirements for Class II enhanced recovery wells

Applications for Class II enhanced recovery wells must include a description of the reservoir to be enhanced and a state statement relative to the necessity for the use of wells to enhance production of oil or natural gas.

(e) Additional Requirements for Class II Hydrocarbon Storage Wells

Applications for Class II hydrocarbon storage wells must include the following:

1. a map showing the known areal extent of the reservoir to be used for storage and the location of all wells or test holes known to extend into or through the proposed reservoir.

2. a series of maps and geologic cross-sections showing the known subsurface position and structure of the reservoir, the nature of the horizontal and vertical boundaries of the reservoir, and the thickness of the reservoir.

3. a tabulation of the type, construction, depth and current condition of each well or test hole located within the area covered by the reservoir map required ~~above~~ in part 1 of this subparagraph.

4. a description of the procedures to be used to plug or work over existing wells or test holes to prevent migration of injected substances into any aquifer other than the proposed storage reservoir.

5. a description of the method, procedures and devices for testing the integrity of the proposed reservoir to contain the injected substances within the bounds of the reservoir.

(f) The ~~Department~~ Commissioner may issue a permit on an area basis rather than for each Class II well individually provided that the injection wells are:

1. described and identified by location in permit application(s) if they are existing wells, except that the ~~Department~~ Commissioner may accept a single description of wells with substantially the same characteristics;

2. within the same well field, facility site, reservoir, project, or similar unit in the same State;

3. operated by a single owner or operator; and

4. used to inject other than hazardous waste.

(g) Area permits shall specify:

1. the area within which underground injections are authorized; and

2. the requirements for construction, monitoring, reporting, operation, and abandonment, for all wells authorized by the permit.

(h) The area permit may authorize the permittee to construct and operate, convert, or plug and abandon wells within the permit area provided:

1. the permittee notifies the ~~Department~~ Commissioner at such time as the permit requires;

2. the additional well satisfies the criteria in ~~paragraph~~ subparagraph (f) of this ~~section~~ paragraph and meets the requirements specified in the permit under ~~paragraph~~ subparagraph (g) of this ~~section~~ paragraph; and

3. the cumulative effects of drilling and operation of additional injection wells are considered by the ~~Department~~ Commissioner during evaluation of the area permit application and are acceptable to the ~~Department~~ Commissioner.

(i) If the ~~Department~~ Commissioner determines that any well constructed under an area permit does not satisfy any of the requirements of this ~~section~~ paragraph, the ~~Department~~ Commissioner may modify the permit, terminate, or take enforcement action. If the ~~Department~~ Commissioner determines that cumulative effects of additional wells are unacceptable, the permit may be modified or revoked.

(2) Construction of Class II Wells

(a) All Class II wells shall be cased and cemented to prevent the movement of fluids into or between USDWs and to maintain the quality of aquifers above the injection zone that may be used for monitoring or other purposes.

(b) All Class II wells shall be designed and constructed in such a fashion that they inject into a formation which is beneath the lower-most formation(s) containing USDWs. Class II wells shall be sited in such a fashion that they inject into a formation which is separated from any formation(s) containing USDWs by a confining zone that is free of known open faults or fractures within the area of review.

(c) In the design specifications for Class II wells, the applicant shall address the problem of corrosion, proposed protective measure(s), and if appropriate, proposed methods of monitoring

the extent of corrosion subject to ~~Department~~ Commissioner approval. The applicant shall consider thickness and type of cement, number and thickness of casings, casing material, casing coatings, native fluid quality, injection fluid quality and life expectancy of the well.

(d) Class II wells shall inject fluids through tubing with a packer set immediately above the injection zone, or tubing with an approved fluid seal as an alternative. The tubing, packer, and fluid seal shall be designed for the expected service.

1. The use of other alternatives may be allowed with the written approval of the ~~Department~~ Commissioner and if the ~~Department~~ Commissioner receives authority from U.S. E.P.A. for an underground injection control program, the EPA Administrator or his designee. To obtain approval, the applicant shall submit a written request to the ~~Department~~ Commissioner, which shall set forth the proposed alternative and all technical data supporting its use. The ~~Department~~ Commissioner will approve the request if the alternative method is deemed capable of providing a comparable level of protection to USDWs.

2. In determining and specifying requirements for tubing, packer, or alternatives, the following factors shall be considered:

(i) depth of setting;

(ii) characteristics of injection fluid (chemical content and corrosiveness);

(iii) injection rate and pressure;

(iv) annular pressure;

(v) temperature, volume, viscosity, and density of injected fluid; and

(vi) type and size of casing.

(e) ~~Department~~ Commissioner approval is required prior to any remedial procedures that alter the basic design specifications, materials, or character of the well.

(3) Casings

(a) The casings used in the construction of each newly drilled Class II well shall be designed for the life expectancy of the well.

(b) The number, thickness, type of materials, and length of casing shall be sufficient to protect the quality of drinking water resources and the integrity of the well and the confining strata.

(c) Exact setting depths for all casings shall be determined in the field, based on all available information, and subject to the ~~Department~~ Commissioner's approval.

(4) Cementing

(a) The cementitious material used in the construction of each newly drilled well shall be designed for the life expectancy of the well. In determining and specifying casing and cementing requirements, the following factors shall be considered:

1. depth to the injection zone;

2. depth to the bottom of all formation(s) containing USDWs;

3. injection pressure and external loading;

4. hole size;

5. size and grade of all casing strings (wall thickness, diameter, nominal weight, length, joint specification and construction material);

6. corrosiveness of injected fluid, formation fluids, and temperatures;

7. lithology of injection and confining zones; and

8. type or grade of cementitious material.

(b) In addition, the ~~Department~~ Commissioner may consider the following factors:

1. nature of formation fluids, and

2. external pressures, internal pressure and axial loading.

(c) Cementitious material must be compatible with the injected fluid, native fluids, and the formation.

(d) Use of the cementitious materials used for mixing shall be determined by the applicant, provided the integrity, containment, corrosion protection, and structural strength of the cement are not significantly affected. Accurate records shall be kept and recorded of all additives used.

(e) Prior to cementing, the hole shall be conditioned in such a way as to optimize bonding of the cement to the casing and formation, and to prevent channeling.

(f) Placement of cementitious material shall be in such a manner that the purposed and characteristics of the cement are retained, and shall be subject to ~~Department~~ Commissioner approval.

(g) The applicant shall submit his cement testing program with the permit application for ~~Department~~ Commissioner approval. The purpose of the cement testing program is to insure that the cement seal is adequate to prevent migration of fluids in channels, microannular space, or voids in the cement. The following methods of testing, as a minimum, shall be considered:

1. pressure testing of casing - to not less than 1.5 times the expected injection pressure;

2. temperature log; and

3. cement bond log.

(5) Testing for Class II Wells

(a) Appropriate logs and other tests shall be conducted during the drilling and construction of new Class II wells. A descriptive report interpreting the results of that portion of those logs and tests which specifically relate to (1) a USDW and the confining zone adjacent to it, and (2) the injection zone and adjacent formations shall be prepared by a knowledgeable log analyst and submitted to the ~~Department~~ Commissioner. At a minimum, these logs and tests shall include:

1. Deviation checks on all holes constructed by first drilling a pilot hole and then enlarging the pilot hole, by reaming or another method. Such checks shall be at sufficiently frequent intervals to assure that vertical avenues for fluid movement in the form of diverging holes are not created during drilling.

2. Such other logs and tests as may be needed after taking into account the availability of similar data in the area of the drilling site, the construction plan, and the need for additional information that may arise from time to time as the construction of the well progresses. In determining which logs and tests shall be required, the following shall be considered by the ~~Department~~ Commissioner in setting logging and testing requirements:

(i) For surface casing intended to protect USDWs in areas where the lithology has not been determined:

(I) electric and caliper logs before casing is installed; and

(II) a cement bond, temperature, or density log after the casing is set and cemented.

(ii) For intermediate and long strings of casing intended to facilitate injection:

(I) electric, porosity and gamma ray logs before the casing is installed;

(II) fracture finder logs; and

(III) a cement bond, temperature, or density log after the casing is set and cemented.

(b) At a minimum, the following information concerning the injection formation shall be determined or calculated for new Class II wells or projects:

1. fluid pressure;

2. estimated fracture pressure; and

3. physical and chemical characteristics of the injection zone.

(c) Prior to commencement of injection, wells shall be tested to assure the initial integrity of the casing, tubing and packer, if used, including pressure testing of the casing-tubing annulus.

(d) At least once every five years thereafter, injection wells shall be tested to assure their continued mechanical integrity. The results of these tests shall be reported to the ~~Department~~ Commissioner. Tests demonstrating continued mechanical integrity shall include the following:

1. measurement of annular pressures in wells injecting at positive pressures under a packer or a balanced-fluid seal;

2. pressure testing of the casing-tubing annulus for wells injecting under vacuum conditions; and

3. such other tests which are demonstrably effective and which may be approved for use by the ~~Department~~ Commissioner.

(e) Notwithstanding the test procedures ~~outlined above~~ of subparagraph (d) of this paragraph, the ~~Department~~ Commissioner may require more comprehensive testing of the injection wells when deemed advisable, including the use of tracer surveys, noise logs, temperature logs, or other test procedures or devices.

(f) The ~~Department~~ Commissioner may order special tests to be conducted prior to the expiration of five years if conditions are believed to so warrant. Any such special test which demonstrates continued mechanical integrity of a well shall be considered the equivalent of an initial test for test scheduling purposes, and the regular five-year testing schedule shall be applicable thereafter.

(g) The injection well operator shall advise the ~~Department~~ Commissioner of the date and the time that initial, a five-year, or special tests are to commence in order that such tests may be witnessed.

(h) Injection pressure at the wellhead shall not exceed a maximum which shall be calculated so as to assure that the pressure during injection does not initiate new fractures or propagate existing fractures in the confining zone adjacent to USDWs. In no case shall injection pressure cause the movement of injection or formation fluids into USDWs.

(i) Injection between the outermost casing protecting USDWs and the well bore is prohibited.

(6) Monitoring Requirements

(a) Class II wells shall be so equipped that the flow rate, injection pressure and annular pressure can be determined at any time for each well.

(b) The permittee shall monitor the nature of injected fluids at time intervals sufficiently frequently to yield data representative of their characteristics;

(c) The permittee shall make observation of injection pressure, flow rate, and cumulative volume at least daily.

(d) The results of all monitoring shall be maintained by the operator and made available to the ~~Department~~ Commissioner upon request.

(e) The ~~Department~~ Commissioner may grant administrative exception to the requirement set forth in ~~paragraph~~ subparagraph (c) of this ~~subsection~~ paragraph.

(f) Hydrocarbon storage and enhanced recovery may be monitored on a field or project basis rather than on an individual well basis by manifold monitoring. Manifold monitoring may be used in cases of facilities consisting of more than one injection well, operating with a common manifold. Separate monitoring systems for each well are not required provided the owner/operator demonstrates that manifold monitoring is comparable to individual well monitoring.

(g) Monitoring requirements shall, at a minimum, include:

1. Monitoring of the nature of injected fluids at time intervals sufficiently frequent to yield data representative of their characteristics;

2. Observation of injection pressure, flow rate, and cumulative volume at least with the following frequencies:

(i) Weekly for produced fluid disposal operations;

(ii) Monthly for enhanced recovery operations;

(iii) Daily during the injection of liquid hydrocarbons and injection for withdrawal of stored hydrocarbons;

(iv) Daily during the injection phase of cyclic steam operations; and

(v) Recording of one observation of injection pressure, flow rate and cumulative volume at reasonable intervals no greater than 30 days.

3. Maintenance of the results of all monitoring until the next permit review.

(7) Commencement, Discontinuance, and Abandonment of Injection Operations

The following provisions shall apply to all Class II wells.

(a) Notice of Commencement and Discontinuance

1. Immediately upon the commencement of injection operations in any well, the operator shall notify the Division of the date such operations began.

2. Within 30 days after permanent cessation of hydrocarbon storage operations or within 30 days after discontinuance of injection operations into any other well, the operator shall notify the ~~Department~~ Commissioner of the date of such discontinuance and the reasons therefore. No injection well may be temporarily abandoned for a period exceeding six months unless the owner/operator demonstrates to the satisfaction of the ~~Department~~ Commissioner that there is a continuing need for such a well, that the well exhibits mechanical integrity, and that continued temporary abandonment will not endanger USDWs. Written permission is required.

(b) Abandonment of Injection Operations

1. Whenever there is a continuous two year period of non-injection into any Class II well, such project or well must be plugged and abandoned, and the authority for injection shall automatically terminate, unless the owner/operator demonstrates to the satisfaction of the ~~Department~~ Commissioner that there is a continuing need for such a well, that the well exhibits mechanical integrity, and that continued temporary abandonment will not endanger USDWs. Written permission is required.

2. Before any injection well is plugged, the operator shall obtain approval for the well's plugging program from the ~~Department~~ Commissioner.

3. For good cause shown, the ~~Department~~ Commissioner may grant an administrative extension or extensions of injection authority as an exception to ~~paragraph (1) above~~ part 1 of this subparagraph.

(c) Prior to granting approval for the plugging and abandonment of a Class II well the ~~Department~~ Commissioner shall consider the following information:

1. The type, and number of plugs to be used;

2. The placement of each plug including elevaton top and bottom;

3. The type, grade, and quantity of cement to be used; and

4. The method of placement of the plugs.

5. The procedure used to meet the requirements of Rule ~~1200-04-06-.04~~ 0400-45-06-.04.

(8) Reporting Requirements

(a) Annual reporting to the ~~Department~~ Commissioner summarizing the results of monitoring required under paragraph (6) of this ~~section~~ rule is required. Such summary shall include monthly records of injected fluid, and any major changes in characteristics or sources of injected fluid.

(b) Owners or operators of hydrocarbon storage and enhanced recovery projects may report on a field or project basis rather than an individual field basis where manifold monitoring is used.

(c) The ~~Department~~ Commissioner may require a demonstration of mechanical integrity prior to approving transfer of authority to inject. Prior to approval to inject, the permittee must supply to the ~~Department~~ Commissioner the following:

1. the anticipated maximum pressure and flow rate at which the well will operate;

2. the results of the formation testing program;

3. the actual injection procedure; and

4. for new wells, the status of corrective action on defective wells in the area of review.

(9) Removal of Produced Water from Leases and Field Facilities

(a) Produced water shall not be stored or disposed of in any unlined pit, pond, lake or depression or in any other place in a manner that will constitute a hazard to USDWs.

(b) Transportation of any produced water by motor vehicle from any lease, central tank battery, or other facility, without approval of the ~~Department~~ Commissioner is prohibited.

(c) Authorization to transport produced water may be obtained by submitting a request to the ~~Department~~ Commissioner.

(d) No owner or operator shall permit produced water to be removed from its leases or field facilities by motor vehicle except by a person possessing ~~Department~~ Commissioner approval.

(10) Disposition of Transported Produced Water

(a) No person transporting produced water may dispose of such water on the surface of the ground, or in any pit, pond, lake, depression, draw, or in any watercourse, or in any other place or in any manner which will constitute a hazard to any USDW.

(b) Delivery of produced water to approved wastewater disposal facilities, enhanced recovery injection facilities, or to a drill site for use in drilling fluid will not be construed as constituting a hazard to USDWs provided the produced waters are placed in tanks or other impermeable storage at such facilities.

(c) The ~~Department~~ Commissioner may grant temporary exceptions for emergency situations, for use of produced water in road construction or maintenance or for use of produced waters for other construction purposes upon request and a proper showing by a holder of a ~~Department~~ Commissioner approval to move produced water.

(11) Existing Class II enhanced recovery wells and hydrocarbon storage wells.

Class II wells in current operation upon the effective date of this rule shall file an application within 6 months of the effective date of this rule. No application fee will be required. Failure to file an application by the required date shall make the wells in violation of ~~Rule~~ this Chapter ~~1200-04-06~~ and subject to the new application fee or closure.

(a) An existing Class II enhanced recovery or hydrocarbon storage injection well is authorized by rule, if the owner or operator injects into the existing well within one year after the date which the State of Tennessee's UIC program is authorized under the Federal Safe Drinking Water Act and becomes effective. An owner or operator of a well which is authorized by rule pursuant to this paragraph shall re-work, operate, maintain, plug, abandon or inject into the well in compliance with applicable regulations.

(b) Duration of well authorization by rule

Well authorization under this paragraph expires upon the effective date of a permit issued after plugging and abandonment in accordance with an approved plugging and abandonment plan pursuant to these rules and upon submission of a plugging and abandonment report.

(c) Prohibitions on injection

An owner or operator of a well authorized by rule pursuant to this paragraph is prohibited from injecting into the well:

1. Upon the effective date of an applicable permit denial;

2. Upon failure to submit a permit application in a timely manner;

3. Upon failure to submit inventory information in a timely manner;

4. Upon failure to comply with a request for information in a timely manner;

5. Upon failure to provide alternative financial assurance;

6. Forty-eight hours after receipt of the determination by the Commissioner that the well lacks mechanical integrity, unless the Commissioner requires immediate cessation; or

7. Upon receipt of notification from the Commissioner that the transferee has not demonstrated financial responsibility.

(d) Requirements

The owner or operator of a well authorized under this paragraph shall comply with the applicable requirements of this rule. Such owner or operator shall comply with the casing and cementing requirements no later than 1 year and other requirements no later than 1 year after authorization.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.12~~ 0400-45-06-.12 Class III Wells.

(1) Permit Application

(a) For Class III wells, the ~~Department~~ Commissioner shall require an applicant to furnish a feasibility study demonstrating the applicability of the injection well method of mining.

(b) A permit must be obtained from the ~~Department~~ Commissioner prior to the operation of any Class III well. Prior to granting approval for operation of a Class III well or project, the ~~Department~~ Commissioner shall consider all relevant information developed during the construction phase as well as any information submitted in the permit application and supporting documents.

(c) Permit applications for Class III wells shall be submitted by the applicant using the appropriate permit application form promulgated by the Department and shall contain any attachments necessary to provide:

1. facility name and location;

2. name and address of legal contacts (agents of process);

3. ownership of facility, including address;

4. a map and a tabulation of data as required by ~~rule 1200-04-06-.10~~ part (3)(b)1 of Rule 0400-45-06-.10.

5. a description of the proposed injection system including type and construction of injection wells, nature of injected fluid and any proposed pretreatment;

6. a statement of estimated daily volume of fluid to be injected and maximum injection pressure;

7. an electric log of the well with the proposed injection zone marked, in the case of a well already drilled, or; in the case of undrilled wells a statement of the proposed zone to be mined and the approximate depth, top and bottom, of said zone;

8. a schematic diagram of the proposed Class III well showing the casing and cementing program together with an explanation thereof; and

9. a statement by the applicant that the proposed Class III well(s) will be completed in such a manner to insure that the injected substances are injected into the proposed injection zone and that provision has been made for adequate protection of USDWs and any other zones of commercial value.

(d) The ~~Department~~ Commissioner may issue a permit on an area basis rather than for each Class III well individually provided that the injection wells are:

1. described and identified by location in permit application(s) if they are existing wells, except that the ~~Department~~ Commissioner may accept a single description of wells with substantially the same characteristics;

2. within the same well field, facility site, reservoir, project, or similar unit in the same State;

3. operated by a single owner or operator; and

4. used to inject other than hazardous waste.

(e) Area permits shall specify:

1. the area within which underground injections are authorized; and

2. the requirements for construction, monitoring, reporting, operation, and abandonment, for all wells authorized by the permit.

(f) The area permit may authorize the permittee to construct and operate, convert, or plug and abandon wells within the permit area provided:

1. the permittee notifies the ~~Department~~ Commissioner at such time as the permit requires;

2. the additional well satisfies the criteria in ~~paragraph~~ subparagraph (d) of this ~~section~~ paragraph and meets the requirements specified in the permit under ~~paragraph~~ subparagraph (e) of this ~~section~~ paragraph; and

3. the cumulative effects of drilling and operation of additional injection wells are considered by the ~~Department~~ Commissioner during evaluation of the area permit application and are acceptable to the ~~Department~~ Commissioner.

(g) If the ~~Department~~ Commissioner determines that any well constructed under an area permit does not satisfy any of the requirements of this ~~section~~ paragraph, the ~~Department~~ Commissioner may modify the permit, terminate, or take enforcement action. If the ~~Department~~ Commissioner determines that cumulative effects of additional wells are unacceptable, the permit may be modified or revoked.

(2) Well Construction Standards for Class III Wells

(a) General Design Considerations

1. All Class III wells shall be cased and cemented to prevent the movement of fluids into or between USDWs and to maintain the quality of aquifers above the injection zone that may be used for monitoring or other purposes.

2. In the design specification for Class III wells, the applicant shall address the problem of corrosion, proposed protective measure(s), and if appropriate, proposed methods of monitoring the extent of corrosion subject to ~~Department~~ Commissioner approval. The applicant shall consider thickness and type of cement, number and thickness of casings, casing material, casing coatings, native fluid quality, injection fluid quality and life expectancy of the well.

3. Class III wells shall inject fluids through tubing with a packer set immediately above the injection zone, or tubing with an approved fluid seal as an alternative. The tubing, packer, and fluid seal shall be designed for the expected service.

(i) The use of other alternatives may be allowed with the written approval of the ~~Department~~ Commissioner. To obtain approval, the applicant shall submit a written request to the ~~Department~~ Commissioner, which shall set forth the proposed alternative and all technical data supporting its use. The ~~Department~~ Commissioner will approve the request if the alternative method is deemed capable of providing a comparable level of protection to USDWs.

(ii) In determining and specifying requirements for tubing, packer, or alternatives the following factors shall be considered:

(I) depth of setting;

(II) characteristics of injection fluid (chemical content and corrosiveness);

(III) injection rate and pressure;

(IV) annular pressure;

(V) temperature, volume, viscosity and density of injected fluid; and

(VI) type and size of casing.

4. ~~Department~~ Commissioner approval is required prior to any remedial procedures that alter the basic design specifications, materials, or character of the well.

(b) Casings

1. The casings used in the construction of each newly drilled Class III well shall be designed for the life expectancy of the well.

2. The number, thickness, type of materials, and length of casing shall be sufficient to protect the quality of USDW waters and the integrity of the well and the confining strata.

3. Exact setting depths for all castings shall be determined in the field, based on all available information, and subject to the ~~Department~~ Commissioner's approval.

(c) Cementing

1. The cementitious material used in the construction of each newly drilled well shall be designed for the life expectancy of the well. In determining and specifying casing and cementing requirements, the following factors shall be considered by the applicant:

(i) depth to the injection zone;

(ii) depth to the bottom of all formations containing USDWs;

(iii) injection pressure, external pressure, internal pressure, and axial loading;

(iv) hole size;

(v) size and grade of all casing strings (wall thickness, diameter, nominal weight, length, joint specification and construction material);

(vi) corrosiveness of injected fluid, formation fluids, and temperatures;

(vii) lithology of injection and confining zones; and

(viii) type or grade of cementitious material.

2. Cementitious materials must be compatible with the injected fluid, native fluids, and the formations penetrated by the bore hole.

3. Use of additives used for mixing shall be determined by the applicant, provided the integrity, containment, corrosion protection, and structural strength of the cement are not significantly affected. Accurate records shall be kept and recorded of all additives used.

4. Placement of cementitious material shall be in such a manner that the purposes and characteristics of the cement are retained, and shall be subject to ~~Department~~ Commissioner approval.

5. The applicant shall submit his cement testing program with the permit application for ~~Department~~ Commissioner approval. The purpose of the cement testing program is to insure that the cement seal is adequate to prevent migration of fluids in channels, micro-

annular spaces, or voids in the cement. The following methods of testing, as a minimum, shall be considered:

(i) pressure testing of casing - to not less than 1.5 times the expected injection pressure;

(ii) temperature log; and

(iii) cement bond log.

(d) Testing

1. Appropriate logs and other tests shall be made during the drilling and construction of new Class III wells. Upon completion of construction, the completed well system will be tested to assure that the well system will function as designed at the design operation pressures. A descriptive report interpreting the results of such logs and tests shall be prepared by a qualified log analyst and submitted to the ~~Department~~ Commissioner. The logs and tests appropriate to each type of Class III well shall be determined based on the intended function, depth, construction and other characteristics of the well, availability of similar data in the area of the drilling site and the need for additional information that may arise from time to time as the construction of the well progresses. At a minimum, such logs and tests shall include deviation checks conducted on all holes where pilot holes and reaming are used, at sufficiently frequent intervals to assure that vertical avenues for fluid migration in the form of diverging holes are not created during drilling.

2. Where the injection zone is a water bearing formation, the following information concerning the injection zone shall be determined or calculated by the applicant for new Class III wells:

(i) hydrostatic pressure head;

(ii) fluid pressure;

(iii) fracture pressure;

(iv) other physical and chemical characteristics of the injection zone;

(v) physical and chemical characteristics of the native fluids; and

(vi) compatibility of injected fluids with formation fluids.

3. Where the injection formation is not a water bearing formation, the fracture pressure shall be determined or calculated.

(e) Environmental Concerns During Construction

1. The disposal of drilling fluids or cuttings and the disposal of wastes during testing shall be in a sound environmental manner that avoids violation of surface and ground water quality standards. The proposed disposal method must be approved by the ~~Department~~ Commissioner prior to start of construction.

2. For Class III wells, the applicant is advised that other permits may be required for surface facilities associated with the mining activity.

(f) Operating Requirements

1. Total pressure shall not exceed the maximum allowable stress of the materials used to construct the well and shall not initiate new fractures or propagate existing fractures in the confining zone or in the injection zone or cause migration of fluids into USDWs.

2. Injection between the outermost casing protecting USDWs and the inner tubing is prohibited.

3. The ~~Department~~ Commissioner shall be allowed access at reasonable time to the permittee's property and records for the purpose of inspections and the collection of samples for analyses from the process and wastewater streams associated with the permitted wells.

4. Other operational limitations shall be established as necessary on a case-by-case basis.

(g) Monitoring Requirements

1. Monitoring Well Design

(i) Monitor wells shall be located in such a fashion as to detect any excursion of injected fluids or process by-products outside the mining area or zone.

(ii) Where injection is into a formation which contains water with less than 10,000 mg/L Total Dissolved Solids, monitoring wells shall be completed into the injection zone and into the deepest aquifer above the injection zone and may also be required below the injection zone.

(iii) Where injection is into a formation which contains water with more than 10,000 mg/L Total Dissolved Solids, monitoring wells will be required above and may be required in the injection zone.

(iv) Where the injection wells penetrate USDWs in an area subject to subsidence or catastrophic collapse, an adequate number of monitoring wells shall be completed into USDWs to detect any movement of injected fluids, process by-products or native fluids into the USDWs. The monitoring wells shall be located outside the physical influence of the subsidence or catastrophic collapse.

(v) Class III wells may be monitored on a field or project basis rather than an individual well basis provided the owner or operator demonstrates to the satisfaction of the ~~Department~~ Commissioner that the proposed monitoring system is comparable to individual well monitoring.

(vi) In determining the type, number, depth, and location of monitoring wells to be used and the parameters to be measured, the following criteria shall, as a minimum, be considered by the applicant:

(I) the local geology and hydrology;

(II) the population relying on USDWs within the area of review;

(III) the proximity of the injection operation to points of withdrawal of drinking water;

(IV) the operating pressures and attendant hydraulic gradients;

(V) the nature and volume of the injected fluid, the formation water and process by-products; and

(IV) the number, type, location, and depth of injection wells in the system, field or project.

(h) Monitoring Well Construction Requirements

Any monitoring well which penetrates the confining zone must be designed and constructed using the same standards that apply to the type of injection well to be monitored.

(i) Monitoring Criteria

1. The physical and chemical quality of the native fluid in the zones to be monitored shall be established prior to injection.

2. The injected fluid shall be analyzed with sufficient frequency to yield representative data on its physical and chemical characteristics. Parameters for such analysis shall be established on an individual basis.

3. The mechanical integrity of the injection well system shall be examined and evaluated at least once every three years. The methods and procedures to be used shall be subject to review by the ~~Department~~ Commissioner.

4. Samples must be collected by a method insuring that the sample is representative of the fluid in the zone to be monitored. The method shall be subject to approval by the ~~Department~~ Commissioner.

5. Continuous indicating and recording devices shall be installed and used to monitor the injection pressure and flow rate, and the volume of fluids injected and withdrawn.

6. Determination shall be made at least semi-monthly of the parameters chosen to measure water quality in the injection zone.

7. Determination shall be made at least semi-monthly of the fluid level or pressure head in each well used for monitoring.

8. The ~~Department~~ Commissioner may require that the applicant continue to monitor in the area affected by mining for a period of time after mining operations cease. If the monitoring reveals violations, the permittee must investigate and take corrective action.

9. The ~~Department~~ Commissioner may require a certificate that the applicant has assured, through a performance bond or other appropriate means, the resources necessary to cover post-closure monitoring and any corrective action resulting from this monitoring.

10. Wells specified in subpart ~~1200-04-06-.12(2)~~ (g)1(iv) of this paragraph shall be monitored once every three months.

(j) Reporting Requirements

The content and frequency of reports that will be required by the ~~Department~~ Commissioner shall be specified in the permit for each Class III well or project. Minimum requirements are as follows:

1. Construction Reports

   (i) The ~~Department~~ Commissioner will require periodic data progress reports during the construction of Class III injection or monitor wells.

   (ii) Interpretation of data will be required in the progress reports at each milestone phase of construction.

   (iii) The applicant shall submit final reports of all data collected with interpretations to the ~~Department~~ Commissioner. The final report shall include all information and data collected during construction with appropriate interpretations.

2. Operation Reports

   (i) An updated map of the area of review showing locations of all newly constructed or newly discovered wells not included in the technical report accompanying the permit application or in later reports shall be submitted annually to the ~~Department~~ Commissioner.

(ii) The applicant must submit, for ~~Department~~ Commissioner approval, his proposed methodology for collection and reporting of operational data, to insure that data is collected, correlated, and reported in a fashion that would enable the agency to evaluate well performance.

(iii) Except for routine monitoring required in subparagraph (g) of this ~~rule~~ paragraph results of required monitoring shall be maintained on site and reported to the ~~Department~~ Commissioner with the first quarterly report after the completion of the test.

(iv) Results of mechanical integrity and any other periodic test required by the ~~Department~~ Commissioner shall be reported upon request or as specified in the permit.

(v) Monitoring may be reported on a project or field basis rather than on an individual well basis where field or project monitoring has been approved.

(vi) Routine monitoring data required shall be reported quarterly to the ~~Department~~ Commissioner. These reports must be postmarked no later than the tenth day of the month following the end of the quarter.

(vii) In the event an excursion is verified in a designated monitor well, the permittee shall submit a written remedial action report at least every month to include for each well affected:

(I) An explanation of required and other actions since the verifying analysis was taken. The explanation should include the date on which actions were initiated and completed;

(II) A description of actions to be taken during the following report period;

(III) Sample analysis results for control parameters;

(IV) Permittee's efforts to define the extent and probable cause of the presence of mining solutions in a designated monitor well; and

(V) The first report shall include a groundwater analysis in the manner required by this rule. All such reports shall be mailed to the ~~Department~~ Commissioner, postmarked within two days of the end of each report period. The first report period shall begin with the day the presence of mining solution in a designated monitor well is verified. The permittee shall continue to make remedial action reports until clean-up is accomplished.

(k) Plugging and Abandonment Operation

1. Upon the occurrence of any of the conditions stated in ~~rule 1200-04-06-.09~~ subparagraph (6)(a) of Rule 0400-45-06-.09, the owner or operator of the well shall submit an application for a permit for plugging and abandonment of the well.

2. Before any injection well is plugged, the operator shall obtain approval for the wells plugging program from the ~~Department~~ Commissioner.

3. The owner or operator of an abandoned injection well or facility must retain all pertinent records of construction, operation and abandonment for a period of not less than three years following the date of abandonment of the well or facility.

4. Within one-hundred twenty (120) days after acknowledgment of completion of mining activities or, if final restoration of the mine area aquifer is required, upon final completion of the final restoration, the permittee shall accomplish closure of the mining facilities in accordance with Plugging and Abandonment Standards.

(l) Abandonment Reports

1. Upon completion of plugging and abandonment of a well or wellfield, the permittee shall submit to the ~~Department~~ Commissioner a Final Report which shall include, but will not be limited to, the following:

(i) daily construction reports;

(ii) certification of completion in accordance with approved plans and specifications by the engineer of record; and

(iii) evidence, such as a sealed copy or certification from the county clerk, that a surveyor's plot of the location of the abandoned wells has been recorded in the county courthouse property records.

2. Results of post-closure monitoring, if required by the abandonment permit, shall be reported quarterly to the ~~Department~~ Commissioner.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.13~~ 0400-45-06-.13 Class IV Wells.

(1) The construction or operation of a well used for the disposal of any hazardous waste or radioactive waste into or above a USDW is prohibited.

(2) The operator or the owner of an existing Class IV well must, within six (6) months after the effective date of this rule, submit a Plugging and Abandonment Plan for the ~~Department~~ Commissioner's approval. The owner or operator of an existing Class IV well shall complete plugging and abandonment in accordance with the approved Plugging and Abandonment Plan not later than six (6) months after the ~~Department~~ Commissioner's approval of the plan.

(3) Wells used to inject contaminated ground water that has been treated and is being re-injected into the same formation from which it was drawn are not prohibited by this rule if such injection is approved by EPA or the ~~Department~~ Commissioner, pursuant to provisions for cleanup of releases under the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), 42 U.S.C. 9601-9657, or pursuant to requirements and provisions under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901 – 6987.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.14~~ 0400-45-06-.14 Class V Wells.

This ~~section~~ rule sets forth Criteria and Standards to regulate all injection systems not regulated as Class I through IV.

(1) The following are prohibited:

(a) The use of any well to dispose of water carrying human waste, household or business waste, raw sewage or the effluent from any septic tank or other sewer system of any kind, unless such well is a subsurface fluid distribution system (SFDS) which is part of a Subsurface Sewage Disposal System (SSDS) permitted under the provisions of T.C.A. §§ 68-221-401 et seq. or a drip disposal system permitted pursuant to T.C.A. §§ 69-3-108 et seq.

(b) The use of any Class V injection well in such a manner as to cause any USDW to contain any substances, that are toxic, carcinogenic, mutagenic, or teratogenic, other than those of natural origin, at levels and conditions which violate primary drinking water standards as given in ~~1200-05-01~~ Chapter 0400-45-01 or adversely affect the health of persons.

(c) Large capacity cesspools; and

(d) Cesspools, other than large capacity cesspools, not authorized under T.C.A. 68-221-401 et seq.

(e) Motor Vehicle Waste Disposal Wells (MVWDWs) are prohibited and must be properly closed and abandoned.

(2) Construction and operation of a Class V well is authorized by virtue of this rule provided:

(a) the use of any Class V injection well does not present a hazard to any existing or future use of a USDW,

(b) The owner or operator shall within six (6) months after the promulgation of this rule supply a list of all wells owned or operated along with the following information for each well to include the following:

1. facility name and location, including a plot plan showing location of well(s);

2. name and address of legal contact;

3. ownership of facility;

4. nature and type of injection wells, including installed dimensions of wells and construction materials;

5. operating status of injection wells, including history of injection;

6. volume of injected fluid;

7. nature of injected fluid to include physical, chemical, biological or radiological characteristics; and

8. description of injection well, including monitoring well(s); and

9. other information as required by the ~~Department~~ Commissioner.

(c) The plans for the construction of any new, or modification of any existing Class V injection well which have been approved by the ~~Department~~ Commissioner.

(d) Injectate fluid from commercial or industrial processes shall not be co-mingled with any sanitary waste or septic system effluent in any subsurface fluid distribution system, unless it can be demonstrated to the ~~Department~~ Commissioner's satisfaction that a beneficial reaction will occur between the waste streams which will enhance the degradation of either or both waste streams.

(e) The injection well will not adversely impact a wellhead protection area designated by Rule ~~1200-05-01-.34~~ 0400-45-01-.34 promulgated under T.C.A. §§ 68-13-701 et seq., the Tennessee Safe Drinking Water Act. Motor vehicle waste disposal wells are prohibited in wellhead protection areas. All other motor vehicle waste disposal wells must meet the effluent standards set forth in ~~1200-04-06-.05~~ paragraph (1) of Rule 0400-45-06-.05 at the point of injection.

(f) Prohibition of injection

An owner or operator of a well which is authorized by rule pursuant to this paragraph is prohibited from injecting into the well:

1. Upon the effective date of an applicable permit denial;

2. Upon failure to submit a permit application in a timely manner;

3. Upon failure to submit inventory information in a timely manner; or

4. Upon failure to comply with a request for information in a timely manner.

(3) The owner of a Class V well shall be responsible for notifying the ~~Department~~ Commissioner of change in ownership.

(4) No authorization by permit or rule shall be allowed where a Class V well causes or allows a violation of the provisions of ~~rule 1200-04-06-.14~~ paragraph (1) of this rule or pollution of any ground or surface water.

(5) If at any time the ~~Department~~ Commissioner learns that an existing Class V system may cause a violation of these regulations, the ~~Department~~ Commissioner shall:

(a) require the injector to apply for an individual permit;

(b) order the injector to take such actions including, where required, closure of the injection well as may be necessary to prevent the violation; or

(c) take enforcement action.

(6) Notwithstanding any other provision of this ~~section~~ rule, the ~~Department~~ Commissioner may take emergency action upon receipt of information that a contaminant from a Class V injection system is likely to enter a public water system and present an imminent and substantial endangerment to the health of persons.

(7) Construction Standards for Class V Wells

(a) The variety of Class V well and their uses dictate a variety of construction designs consistent with those uses, and precludes specific construction standards. However, a well must be designed and constructed for its intended use, in accordance with good engineering practices, and the design and construction must be approved by the ~~Department~~ Commissioner.

(b) Class V wells shall be constructed so that their intended use does not violate the water quality standards.

(8) Operating Requirements for Class V Wells

(a) All Class V injection wells shall be operated in such a manner that they do not violate the provisions of ~~rule 1200-04-06-.14~~ paragraph (1) of this rule.

(b) Use of a pretreatment system may be necessary to insure that the water discharged meets the applicable water quality standards.

(c) Initial and/or periodic testing may be required for Class V injection wells.

(d) Upon completion of the well, the owner or operator must certify to the ~~Department~~ Commissioner that the well has been completed in accordance with the approved construction plan, and must submit any other additional information required.

(e) After the effective date of this rule, the operator, if not the property owner, for all Class V injection wells shall have access to the "point of injection" for the Class V wells. This is to be maintained by easement or deed restrictions on all injection points.

(9) Monitoring Requirements for Class V Injection Systems

(a) The ~~Department~~ Commissioner may require monitoring of Class V injection wells; the nature of which will be determined by the type of well, nature of the injected fluid, and water quality of the receiving aquifer.

(b) The ~~Department~~ Commissioner shall determine the extent and frequency of monitoring based on the type of injection well and the nature of the injected fluid.

(10) Reporting Requirements for Class V Wells will be determined by the type of injection well and nature of injected fluid.

(a) All municipalities and other governmental entities with storm water injection wells under their control either by ownership or easement shall submit an annual report describing the location and status of each injection well and any other information the ~~Department~~ Commissioner determines to be necessary. Such reports shall include a locational map.

(11) Plugging and Abandonment Standard

(a) The ~~Department~~ Commissioner will order that a Class V injection well be plugged and abandoned when the use of the system is determined to be a hazard to the ground water resource.

(b) Prior to abandoning a Class V injection well, the well shall be plugged with cement in a manner which will not allow movement of fluids between USDWs. The proposed plugging method and type of cement shall be approved by the ~~Department~~ Commissioner. Placement of the cement plug shall be accomplished by any recognized method which is acceptable to the ~~Department~~ Commissioner.

(c) The owner or operator shall notify the ~~Department~~ Commissioner of his intention to abandon the system when a Class V injection well is no longer used or is usable for its intended purpose.

(d) The owner of any Class V injection well shall apply for a Plugging and Abandonment Permit when the well is no longer used or usable for its intended purpose or any other purpose approved by the ~~Department~~ Commissioner. The application shall include justification for abandonment, the approved plugging and abandonment plan and any proposed modification to the original plugging plan as approved by the ~~Department~~ Commissioner.

(e) Closure does not mean that the owner or operator will need to cease operations at the facility, only that the owner or operator will need to close the well. A number of alternatives are available for the disposal of waste fluids. Examples of alternatives that may be available to motor vehicle stations include: recycling and reusing wastewater as much as possible; collecting and recycling petroleum-based fluids, coolants, and battery acids drained from vehicles; washing parts in a self-contained, recirculating solvent sink, with spent solvents being recovered and replaced by the supplier; using absorbents to clean up minor leaks and spills, and placing the used materials in approved waste containers and disposing of them properly; using a wet vacuum or mop to pick up accumulated rain or snow melt, and, if allowed, connecting floor drains to a municipal sewer system or holding tank, and, if allowed, disposing of the holding tank contents through a publicly owned treatment works ("POTW"). The owner/operator should check with the POTW to see if the POTW would accept the wastes. Alternatives that may be available to owners and operators of a large-capacity cesspool include: conversion to a septic system; connection to sewer; and installation of an on-site treatment unit.

(12) Prohibition of fluid movement.

(a) Injection activity prohibitions

1. No injection activity can allow the movement of fluid containing any contaminant into USDWs, if the presence of that contaminant may cause a violation of any primary drinking water standard, or other health based standards, or may otherwise adversely affect the health of persons. This prohibition applies to well construction, operation, maintenance, conversion, plugging, closure or any other injection activity.

2. If the ~~Department~~ Commissioner learns that an injection activity may endanger USDWs, the ~~Department~~ Commissioner may require the closure of the well a permit or permit modification, or other appropriate action.

(b) Closure requirements

The owner/operator must close the well in a manner that complies with the ~~above~~ prohibition of fluid movement in subparagraph (a) of this paragraph. Also, the owner/operator must dispose or otherwise manage any soil, gravel, sludge, liquids, or other materials removed from or adjacent to the well in accordance with all applicable Federal, State and local regulations and requirements.

(13) Authorization by Rule Requirements

All Class V UIC well authorizations by rule shall comply with this rule and all conditions established by the Commissioner as necessary to fulfill the purposes of the Tennessee Water Quality Control Act, T.C.A. §§ 69-3-101 et seq., contain a description of the injection zone being authorized, and contain any necessary corrective action as stated under ~~rule 1200-04-06-.09~~ paragraph (5) of Rule 0400-45-06-.09. The authorization conditions shall be set at levels to prevent adverse effects to persons utilizing the ground water resource after consideration of at least the following factors: any guidelines set for certain pollutants by U.S.E.P.A.; the flow characteristics of ground water risk to humans; and the risk of migration. The following conditions, subparagraphs (a) through (n) of this paragraph, apply to all Class V UIC authorizations. All conditions applicable to all authorizations shall be incorporated into the authorizations either expressly or by reference. If incorporated by reference, a specific citation to these regulations must be given in the authorizations.

(a) An applicant must comply with all conditions of this authorization and all applicable laws and regulations. Any authorization noncompliance constitutes a violation of the Tennessee Water Quality Control Act and is grounds for enforcement action; for authorization termination, revocation and reissuance, or modification; or for denial of an authorization renewal application.

(b) If the applicant wishes to continue an activity regulated by this authorization after the expiration date of this authorization, the applicant must apply for and obtain a new authorization prior to expiration of this authorization.

(c) It shall not be a defense for an owner or operator in an enforcement action that it would have been necessary to halt or reduce the authorized activity in order to maintain compliance with the conditions of this rule.

(d) The owner or operator shall take all reasonable steps to minimize or correct any adverse impact on the environment resulting from non-compliance with this rule.

(e) The owner or operator shall at all times properly operate and maintain all facilities and systems of related appurtenances which are installed or used by the applicant to achieve compliance with the conditions of this rule and authorization. Proper operation and maintenance includes effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems only when necessary to achieve compliance with the conditions of this rule.

(f) The authorization may be modified, revoked and reissued, or terminated for cause. The filing of a request by the owner or operator for a modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance, does not stay any authorization condition.

(g) This rule and the authorizations issued under it do not convey any property rights of any sort, or any exclusive privilege.

(h) The owner or operator shall furnish to the ~~Department~~ Commissioner, within a time specified, any information which the ~~Department~~ Commissioner may request to determine whether cause exists for modifying, revoking and reissuing, or terminating the authorization, or to determine compliance with this rule. The applicant shall also furnish to the ~~Department~~ Commissioner, upon request, copies of records required to be kept by this rule or the authorization.

(i) The owner or operator shall allow ~~Department personnel~~ the Commissioner, or an authorized representative of the ~~Department~~ Commissioner, upon the presentation of credentials to:

1. Enter upon the owner or operator's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this rule or the authorization;

2. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this rule or the authorization;

3. Inspect at reasonable times any facility, equipment (including monitoring and control equipment), practices, or operations regulated or required under this rule or the authorization; and

4. Sample or monitor at reasonable times, for the purposes or assuring compliance or as otherwise authorized by the Tennessee Water Quality Control Act or these rules, any substances or parameters at any location.

(j) Monitoring and records

1. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity. The owner or operator shall monitor injection fluids, injection operations, and local ground water supplies, in accordance with the requirements for the applicable class of well stated in this rule.

2. The owner or operator shall retain records of all monitoring information, including the following:

(i) Calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this authorization, and records of all data used to complete the application for the authorization under this rule, for a period of at least 3 years from the date of the sample, measurement, report, or application. This period may be extended by request of the ~~Department~~ Commissioner at any time; and

(ii) The nature and composition of all injected fluids until three years after the completion of any plugging and abandonment procedures. The ~~Department~~ Commissioner may require the owner or operator to deliver the records to the ~~Department~~ Commissioner at the conclusion of the retention period.

3. Records of monitoring information shall include:

(i) The date, exact place, and time of sampling or measurements;

(ii) The individual(s) who performed the sampling or measurements;

(iii) The date(s) analyses were performed;

(iv) The individual(s) who performed the analyses;

(v) The analytical techniques or methods used; and

(vi) The results of such analyses.

(k) All applications, reports, or information submitted to the ~~Department~~ Commissioner shall be signed and certified.

(l) Reporting requirements

1. Planned Changes

The owner or operator shall give notice to the ~~Department~~ Commissioner as soon as possible of any planned physical alterations or additions to the permitted facility.

2. Anticipated noncompliance

The owner or operator shall give advance notice to the ~~Department~~ Commissioner of any planned changes in the permitted facility or activity which may result in noncompliance with authorization requirements.

3. Transfers

See paragraphs (6), (7), (8) and (9) of Rule ~~1200-04-06-.08~~ 0400-45-06-.08.

4. Monitoring reports

Monitoring results shall be reported at the intervals specified elsewhere in this rule or the authorization.

5. Compliance schedules

Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 30 days following each schedule date.

6. Twenty-four hour reporting

The owner or operator shall report any noncompliance which may endanger health or the environment, including:

(i) Any monitoring or other information which indicates that any contaminant may cause an endangerment to USDWs; or

(ii) Any noncompliance with a permit condition or malfunction of the injection system which may cause fluid migration into or between USDWs.

Any such information shall be provided orally within 24 hours from the time the owner or operator becomes aware of the circumstances. A written submission shall also be provided within 72 hours of the time the owner or operator becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause, the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance.

7. Other noncompliance

The owner or operator shall report all instances of noncompliance not reported under parts 1, 4, 5, and 6 of this subparagraph, at the time monitoring reports are submitted. The reports shall contain the information listed in part 6 of this subparagraph.

8. Other information. Where the owner or operator becomes aware that the owner or operator has failed to submit any relevant acts in a permit application, or submitted incorrect information in a permit application or in any report to the ~~Department~~ Commissioner, the owner or operator shall promptly submit such facts or information.

(m) Requirements prior to commencing injection

Except for all new wells authorized by an area permit under Rules ~~1200-04-06-.11~~ 0400-45-06-.11 and ~~1200-04-06-.12~~ 0400-45-06-.12, a new injection well may not commence injection until construction is complete, and

1. The owner or operator has submitted notice of completion of construction to the ~~Director~~ Commissioner; and

2. (i) The ~~Department~~ Commissioner has inspected or otherwise reviewed the new injection well and finds it is in compliance with the conditions of this rule and the authorization; or

(ii) The owner or operator has not received notice from the ~~Director~~ Commissioner of his or her intent to inspect or otherwise review the new injection well within 13 days of the date of the notice in part 1 of this subparagraph, in which case prior inspection or review is waived and the owner or operator may commence injection. The ~~Director~~ Commissioner shall include in his notice a reasonable time period in which he shall inspect the well.

(n) The owner or operator shall notify the ~~Department~~ Commissioner at such times as this rule or the authorization requires before conversion or abandonment of the well, or in the case of area permits, before closure of the project.

(o) A Class V authorization may include, conditions to insure that plugging and abandonment of the well will not allow the movement of fluids into or between USDWs. Where the ~~Department~~ Commissioner's review of an application indicates that the applicant's plan is inadequate, the ~~Department~~ Commissioner may require the applicant to revise the plan, prescribe conditions meeting the requirements of this paragraph, or deny the authorization.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.15~~ 0400-45-06-.15 Fees for Class I Injection Wells.

(1) Permit Application Fees

Applications for permits to construct, operate or abandon a Class I injection well shall be accompanied by the following fees:

(a)	Construction Permit (New wells)	$2,500~~.00~~
(b)	Operating Permit (Initial)	$2,500~~.00~~
(c)	Abandonment Permit	$2,500~~.00~~
(d)	Operating Permit (Renewal)	$2,500~~.00~~

(2) Operational Fees

Owners or operators of Class I injection wells shall pay the following fees to the Department.

(a)	Waste fluid injection fee	$0.50 per 1,000 gallons
(b)	Annual permit maintenance fee	$7,500~~.00~~ per well
(c)	Permit modification and reissuance fee	$7,500~~.00~~ per well

(d) Waste fluid injection fees must be paid after the effective date of the regulations regardless of the status of the permit.

(3) All fees are due and payable as follows:

(a) Application fees must be received with applications.

(b) Operational fees

1. Fees for waste injection must be paid quarterly and are due at the time of submission of the quarterly monitoring reports as specified in the operating permit.

2. Annual permit maintenance fees are due on the date these rules become effective or on the date the permittee commences injection, whichever is later, and on each successive anniversary unless the permit expires or is revoked.

3. Permit modification and reissuance fees are due at the time of submission of the request by the permittee or thirty (30) days after notice of the need for modification has been sent to the permittee by the ~~Department~~ Commissioner.

(4) If any part of any fee imposed under this paragraph is not paid within fifteen days of the due date, a penalty of five percent (5%) of the amount due shall at once accrue and be added thereto. Thereafter, on the first day of each month during which any part of any fee or any prior accrued penalty remains unpaid, an additional penalty of five percent (5%) of the unpaid balance shall accrue and be added thereto. In addition, the fees not paid within fifteen (15) days after the due date shall bear interest at the maximum lawful rate from the due date to the date paid.

(5) The owner or operator of a Class I well who is required to pay fees set forth under this paragraph and who disagrees with the calculation or applicability of the fee may petition the Water Quality Control Board for a hearing. In order to perfect the hearing, a petition for a hearing together with the total amount of fee due must be received by the Department not later than fifteen (15) days after the due date. If it is finally determined that the amount in dispute was improperly assessed, the ~~Department~~ Commissioner shall return the amount determined to be improperly assessed with interest.

(6) The ~~Department~~ Commissioner shall review permit applications for a Class I well to determine if the application contains all of the information required by the ~~Department~~ Commissioner.

(a) If the application is deficient the ~~Department~~ Commissioner will specify the deficiency(ies) in writing and inform the applicant by certified mail within ninety (90) days after the effective date of this rule or the date of receipt of the application whichever is later.

(b) If the application is complete the ~~Department~~ Commissioner will notify the applicant by certified mail and initiate the permit evaluation process within ninety (90) days after the effective date of this rule or the date of receipt of the application whichever is later.

(c) If the application review is not completed within 90 days in accordance with ~~1200-04-06-.15(6)~~ subparagraphs (a) and (b) of this paragraph, the application fee shall be returned.

(7) After notification that an application is complete, the ~~Department~~ Commissioner shall complete its evaluation of an application for a Class I well as follows:

(a)	Construction permit		180 days
(b)	Operating permit		
	1.	Existing well	180 days
	2.	New well	90 days
(c)	Renewal permit		90 days
(d)	Abandonment permits		90 days

(8) Upon completion of the review, the ~~Department~~ Commissioner will either deny the application or issue a draft permit for processing in accordance with ~~rule 1200-04-06-.08~~ paragraph (7) of this rule. To achieve a final permit decision, an additional ninety (90) days will be required.

(9) The time periods provided in paragraphs (6), (7), and (8) of this rule shall be stayed if:

(a) A legal action concerning the permit is pending before any board, court or independent agency.

(b) The applicant requests that review be suspended.

(c) The ~~Department~~ Commissioner issues a written notice of deficiency and until the applicant addresses said deficiency to the satisfaction of the ~~Department~~ Commissioner.

Authority: T.C.A. §§ 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.16~~ 0400-45-06-.16 Fees For Class II Injection Wells.

(1) Permit Application Fees

Applications for permits to operate a Class II injection well shall be accompanied by the following fees:

Application review fee	$2,500.~~00~~
Permit renewal fee (every 5 years)	$1,000.~~00~~

(2) Operational Fees

Owners or operators of Class II injection wells shall pay the following fees to the Department:

Annual maintenance fee	$500.~~00~~
Permit modification and reissuance fee	$250.~~00~~

(3) Annual permit maintenance fees are due on the date these rules become effective or on the date the permittee commences injection, whichever is later, and on each successive anniversary unless the permit expires or is revoked.

(4) Permit modification and reissuance fees are due at the time of submission of the request by the permittee or thirty (30) days after notice of the need for modification has been sent to the permittee by the ~~Department~~ Commissioner.

(5) If any part of any fee imposed under this ~~section~~ rule is not paid within fifteen days of the due date, a penalty of five percent (5%) of the amount due shall at once accrue and be added thereto. Thereafter, on the first day of each month during which any part of any fee or any prior accrued penalty remains unpaid, an additional penalty of five percent (5%) of the unpaid balance shall accrue and be added thereto. In addition, the fees not paid within fifteen (15) days after the due date shall bear interest at the maximum lawful rate from the due date to the date paid.

(6) The ~~Department~~ Commissioner shall review permit applications for a Class II well to determine if the application contains all of the information required by the ~~Department~~ Commissioner.

(a) If the application is deficient the ~~Department~~ Commissioner will specify the deficiency(ies) in writing and inform the applicant by certified mail within sixty (60) days after the date of receipt of the application.

(b) If the application is complete the ~~Department~~ Commissioner will notify the applicant by certified mail and initiate the permit evaluation process within sixty days (60) days after the date of receipt of the application.

(c) The time periods provided in ~~paragraphs~~ subparagraphs (a) and (b) of this paragraph shall be stayed if:

1. A legal action concerning the permit is pending before any board, court or independent agency.

2. The applicant requests that review be suspended.

3. The ~~Department~~ Commissioner issues a written notice of deficiency and until the applicant addresses said deficiency to the satisfaction of the ~~Department~~ Commissioner.

(d) If the application review is not completed within 60 days in accordance with ~~1200-04-06-.16(6)~~ subparagraphs (a) and (b) of this paragraph, the application fee shall be returned.

Authority: T.C.A. §§ 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.17~~ 0400-45-06-.17 Fees For Class III Injection Wells.

(1) Permit Application Fees

Applications for permits to operate a Class III injection well shall be accompanied by the following fees:

Application review fee ..... $2,500~~.00~~
Permit renewal fee (every 5 years) ..... $1,500~~.00~~

(2) Operational Fees

Owners or operators of Class III injection wells shall pay the following fees to the Department:

Annual maintenance fee ..... $1,000~~.00~~
Permit modification and reissuance fee ..... $250~~.00~~

(3) Annual permit maintenance fees are due on the date these rules become effective or on the date the permittee commences injection, whichever is later, and on each successive anniversary unless the permit expires or is revoked.

(4) Permit modification and reissuance fees are due at the time of submission of the request by the permittee or thirty (30) days after notice of the need for modification has been sent to the permittee by the ~~Department~~ Commissioner.

(5) If any part of any fee imposed under this ~~section~~ rule is not paid within fifteen days of the due date, a penalty of five percent (5%) of the amount due shall at once accrue and be added thereto. Thereafter, on the first day of each month during which any part of any fee or any prior accrued penalty remains unpaid, an additional penalty of five percent (5%) of the unpaid balance shall accrue and be added thereto. In addition, the fees not paid within fifteen (15) days after the due date shall bear interest at the maximum lawful rate from the due date to the date paid.

(6) The ~~Department~~ Commissioner shall review permit applications for a Class III well to determine if the application contains all of the information required by the ~~Department~~ Commissioner.

(a) If the application is deficient the ~~Department~~ Commissioner will specify the deficiency(ies) in writing and inform the applicant by certified mail within ninety (90) days after the date of receipt of the application.

(b) If the application is complete the ~~Department~~ Commissioner will notify the applicant by certified mail and initiate the permit evaluation process within ninety days (90) days after the date of receipt of the application.

(c) The time periods provided in ~~paragraphs~~ subparagraphs (a) and (b) of this paragraph shall be stayed if:

1. A legal action concerning the permit is pending before any board, court or independent agency.

2. The applicant requests that review be suspended.

3. The ~~Department~~ Commissioner issues a written notice of deficiency and until the applicant addresses said deficiency to the satisfaction of the ~~Department~~ Commissioner.

(d) If the application review is not completed within 60 days in accordance with ~~1200-04-06-.17(6)~~ subparagraphs (a) and (b) of this paragraph, the application fee shall be returned.

Authority: T.C.A. §§ 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.18~~ 0400-45-06-.18 Fees For Class V Injection Wells.

(1) Application Fees

Applications for authorizations or permits for the following Class V injection wells shall be accompanied by the following one-time application review fees:

(a)	Innovative technology wells	$1,000~~.00~~ (per project)
(b)	Storm water drainage wells.	
	Subdivision	$500~~.00~~ (per project)
	Commercial/industrial facilities	$750~~.00~~ (per project)
(c)	Commercial/industrial geothermal wells	
	Open loop systems	$750~~.00~~ (per facility)
(d)	Commercial/industrial SFDS and infiltration cells	$500~~.00~~ (per facility)
(e)	Large capacity septic systems	$250~~.00~~ (per facility)
	Churches	$100~~.00~~ (per facility)
(f)	Remediation wells	
	Oversight under this rule	$1,000~~.00~~ (per project)
	Oversight by the ~~Department~~ Commissioner not under this rule	None
(g)	Change of ownership	$75
(h)	Modification of recharge point	$350 (per project)

(2) Renewal Fee

The following Class V wells shall submit the following fees with the renewal application:

(a)	Storm water drainage wells	
	Commercial/industrial facilities:	$350~~.00~~ (per facility)
(b)	Commercial/industrial geothermal wells	
	Open loop	$350~~.00~~ (per facility)
(c)	Commercial/industrial SFDS and infiltration cells:	$250~~.00~~ (per facility)
(d)	Large capacity septic systems	$250~~.00~~ (per facility)
	Churches	$50~~.00~~ (per facility)

(3) If the application is deficient the ~~Department~~ Commissioner will specify the deficiency(ies) in writing and inform the applicant within sixty (60) days after the date of receipt of the application.

(4) If the application is complete the ~~Department~~ Commissioner will notify the applicant and initiate the permit evaluation process within sixty (60) days after the date of receipt of the application.

~~(a)~~ (5) The time periods provided in paragraphs ~~(4)~~ (3) and ~~(5)~~ (4) of this rule shall be stayed if:

1. A legal action concerning the permit is pending before any board, court or independent agency.

2. The applicant requests that review be suspended.

3. The ~~Department~~ Commissioner issues a written notice of deficiency and until the applicant addresses said deficiency to the satisfaction of the ~~Department~~ Commissioner.

~~(b)~~ (6) If the application review is not completed within sixty (60) days in accordance with ~~1200-04-06-.18~~ paragraphs (3) ~~&~~ and (4) of this rule, the application fee shall be returned.

Authority: T.C.A. §§ 69-3-101 et seq., 68-203-101 et seq. and 4-5-201 et seq.

~~1200-04-06-.19~~ 0400-45-06-.19 Bonds Required for Permitted Wells

(1) A surety bond or cash bond is required from the owner or operator of an injection well for Class I, II and III wells adequate to allow proper plugging and abandonment of the well(s) and may be required for Class V wells at the ~~Department~~ Commissioner's discretion. Such bonds are penal in nature. Such surety bond or cash bond is required to be in force for a well from the time a permit has been granted until the well has been properly abandoned. Bonds shall be in favor of the ~~Department~~ Commissioner, conditioned that the well shall meet all the requirements of this ~~rule~~ Chapter and be plugged and abandoned in accordance with this ~~rule~~ Chapter. An individual well bond shall be released upon the proper plugging of the well and the filing of a plugging and abandonment report, driller's log, downhole surveys, and other data as required.

(2) At any time other than after the issuance of a notice of noncompliance or forfeiture, the surety may notify the ~~Director~~ Commissioner ~~of the Division of Water Supply~~ in writing of its desire to terminate its liability under the bond by giving written notice to the ~~Director~~ Commissioner. The ~~Director~~ Commissioner shall thereupon require the principal in the bond to file a new bond, or to effect a change of owners on the well within sixty (60) days. If the principal can no longer be contacted, then any interested party may seek to change ownership on the well. If a new bond is filed by the principal, or a change in ownership is approved by the ~~Director~~ Commissioner, liability under the original bond shall cease and terminate as to acts and operations occurring after the effective date of the new bond or approval of change in ownership and the original bond shall be released upon written request from the surety. If a new bond is not filed within sixty (60) days, or a change in ownership has not been approved, the ~~Director~~ Commissioner shall revoke the permit secured by the bond and require the principal to plug and abandon the well in accordance with the Underground Injection Control rules. In the event of the failure of the principal to plug the well, the surety may either cause the well to be plugged, or forfeit the amount of the bond to the ~~Department~~ Commissioner. This action will be initiated by the issuance of a notice of noncompliance. The surety will then have thirty (30) days in which to plug the well. If the well has not been plugged within that time limit, then a notice of forfeiture will be issued. The surety will then have twenty-one (21) days within which to petition the Tennessee Water Quality Control Board for a hearing relative to the bond forfeiture, pursuant to the Administrative Procedures Act, T.C.A. §§ 4-5-101 et seq. If a hearing is requested, no further action will be taken against the bond until such hearing has taken place and a final order given by the Board. If the well has been plugged in the interim, then notice of forfeiture will be cancelled and the bond released.

(3) Any of the following shall serve as bonds:

(a) A surety bond executed by the well operator as principal and by a corporate surety authorized to do business in Tennessee; or

(b) cash; or

(c) a certified check; or

(d) a certificate of Deposit, if made out exactly as follows: "Owner Name and Tennessee Department of Environment and Conservation or Tennessee Department of Environment and Conservation"; and does not contain any terms or conditions that provide that the issuing bank may charge against the deposit any debt of the depositor(s) owing to it (set-off terms); or any terms or conditions that provide anyone whose signature appears on the signature card to withdraw from funds the account. The owner shall be entitled to any interest earned on a certificate of deposit as the same becomes due and payable. The treasurer of the State of Tennessee shall receive and hold originals of such certificates in the name of the State of Tennessee, in trust, for the purpose for which such deposit is made, and shall at all times be responsible for the custody and safekeeping of such deposits; provided, however, that the certificate may be returned to the issuing financial institution as may be necessary for renewal from time to time; or

(4) Forfeiture

(a) The ~~Director~~ Commissioner shall cause a notice of noncompliance to be served upon the owner/operator and surety if the requirements for proper plugging and abandonment of a well or wells have not been complied with within the time limits set forth by this rule. Compliance for proper plugging and abandonment shall include the submission of all required records and data.

(b) The notice shall specify in what respects the owner has failed to comply with this rule or orders of the Water Quality Control Board.

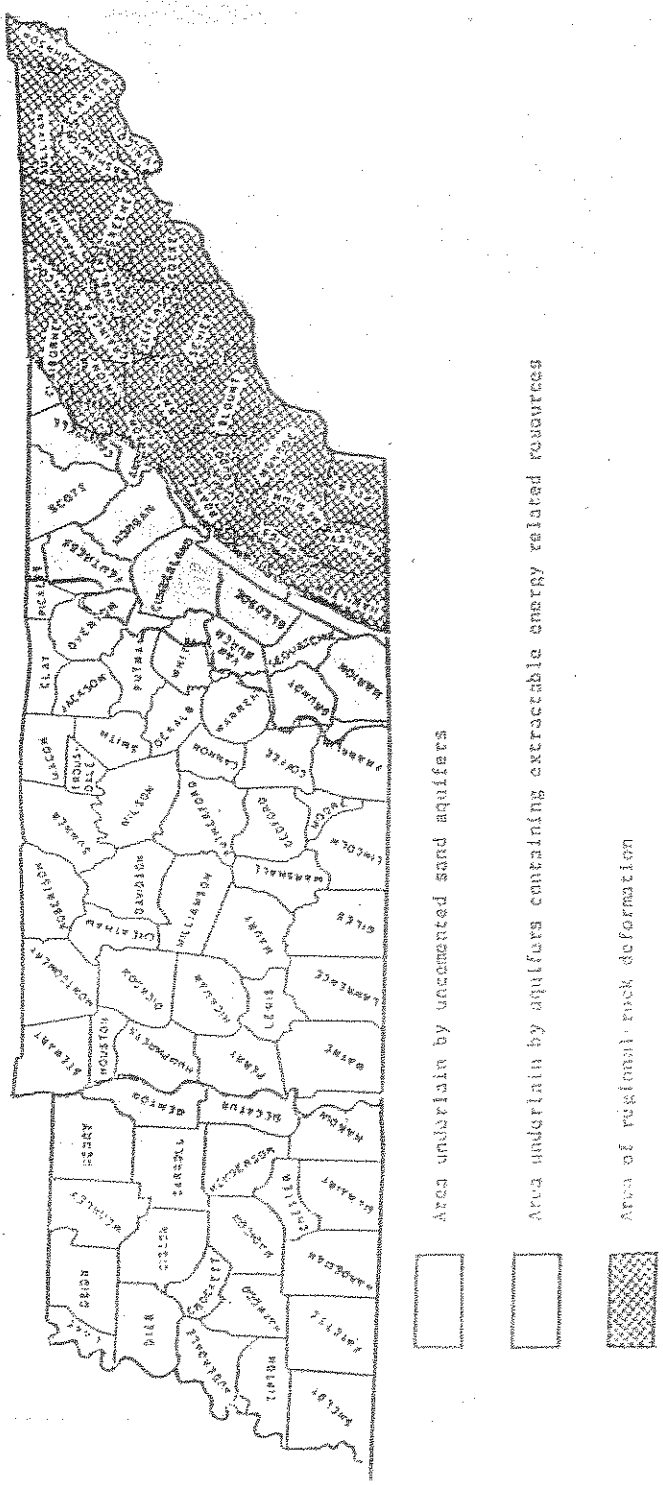
(c) If the owner has not reached an agreement with the ~~Director~~ Commissioner, or has not complied with the requirements set forth within thirty (30) days after the mailing of the notice, the bond shall then be forfeited to the ~~Department~~ Commissioner, and the money used to properly plug the well(s). Such bonds are penal in nature, and the full amount of the bond shall be forfeited.

(5) Notice of Noncompliance

(a) At any time the ~~Director~~ Commissioner causes a notice of noncompliance to be served upon the principal, the surety shall be afforded the opportunity to act in behalf of the principal within the time set forth in regard to proper plugging of the well or wells and submission of required well records, downhole data and plugging reports. Should the principal and surety fail to comply within the time provided, then and only in that event, the bond shall be forfeited and used to plug the well. When a bond is forfeited under this rule, the ~~Director~~ Commissioner shall give notice to the Attorney General, who shall institute proceedings to collect the forfeiture.

Authority: T.C.A. §§ 69-3-101 et seq. and 4-5-201 et seq.

APPENDIX A


Area underlain by uncemented sand aquifers
Area underlain by aquifers containing extractable energy related resources
Area of regional rock deformation

* 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)
Elaine Boyd				✓	
James W. Cameron III	✓				
Jill E. Davis	✓				
Geneil H. Dillehay				✓	
C. Monty Halcomb	✓				
Charlie R. Johnson	✓				
Judy Manners	✓				
John McClurkan	✓				
Frank McGinley	✓				
D. Anthony Robinson	✓				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Water Quality Control Board on May 15, 2012 (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: 10/18/11

Rulemaking Hearing(s) Conducted on: (add more dates). 12/13/11, 12/14/11 and 12/16/11

Date: May 15, 2012

Signature: C. Monty Halcomb

Name of Officer: C. Monty Halcomb

Title of Officer: Board Chairman

GLENDA SUE STILES
STATE OF TENNESSEE NOTARY PUBLIC
RUTHERFORD COUNTY
My Commission Expires December 22, 2013

Subscribed and sworn to before me on: 5-15-12

Notary Public Signature: Glenda Sue Stiles

My commission expires on: 12-22-2013

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

R E Cooper Jr

Robert E. Cooper, Jr.
Attorney General and Reporter

9-11-12
Date

Department of State Use Only

Filed with the Department of State on: 9/12/12

Effective on: 12/11/12

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Mental Health and Substance Abuse Services
DIVISION:	Office of Licensure
SUBJECT:	Non-Residential Opioid Treatment Program Facilities
STATUTORY AUTHORITY:	Tennessee Code Annotated, Section 4-3-1601
EFFECTIVE DATES:	December 19, 2012 through June 30, 2013
FISCAL IMPACT:	Minimal

STAFF RULE ABSTRACT:

In light of the prescription drug epidemic confronting our state and the vulnerable nature of the individuals served by Non-Residential Opioid Treatment Program Facilities (OTP), the department believes that OTPs are in need of clearer operational guidelines and better reporting mechanisms in order to ensure the safety and health of their service recipients and to track the nature and scope of the medications the OTPs dispense. The agency reports that new OTP rules capture the best practices in the area of opioid treatment and represent a positive step forward in the area of OTP regulation. The agency also reports that these rules provide Tennessee citizens continued access to an important treatment option with increased safety and public accountability measures.

The following is a description of the relevant changes in previous regulations effectuated by this rule:

1. The most evident change to the rules is the formatting of the rules. The previous version of the rules was based on the original Department of Health (DOH) rules. The DOH rules were self-contained with rule sections encompassing many issues. The new OTP rules are re-formatted to mirror other Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) Licensing rules. For example, the former Policy and Procedures section (0940-5-42.04) was "taken apart, with each subsection being made into a stand-alone section.

2. The new OTP rules make various housekeeping/technical/stylistic changes that update/synch rule language with proper terminology and definitions.

3. The new OTP rules incorporate new/modified definitions (0940-05-42-.01):

    A. Adds a definition for buprenorphine (commercial name Suboxone) and more scientifically descriptive language to expand coverage to generic forms of drugs as well

as commercial forms (0940-05-42-.01 (2)(c)).

B. Changes the definition of counseling session to require a counseling session to be at least 30 minutes, face-to-face, in a private location (0940-05-42-.01(2)(e)).

C. Changes the definition of detoxification to add additional forms of detoxification, which should address more than just the use of methadone (0940-05-42-.01(2)(g)).

D. Adds term "opiate/opioids" to the definitions to include more than just Methadone (0940-05-42- .0 1).

4. The new OTP rules provide for the designation of the State Opioid Treatment Authority (SOTA) and the duties of that office (0940-05-42-04). These rules:

A. Designate a SOTA position (0940-05-42-04(1)).

B. Give general overview of the authority of the SOTA, leaving open the ability for the SOTA to develop rules and policies regarding the operations, including best practices, for these agencies
(0940-05-42-04(2)).

5. The new OTP rules revise regulations regarding patient intake, admission and discharge (0940-05-42- .06). Highlights include:

A. Clarifies the responsibility of the medical director or program physician (0940-05-42-06(1) and (4));

B. Imposes a prohibition on any standardized routines or schedules of medication, emphasizing the need for individualized treatment) (0940-05-42-06(3));

C. Develops specific requirements for an initial assessment of a potential patient (0940-05-42- .06(8));

D. Develops specific requirements for a comprehensive assessment of a potential patient (0940- 05-42-06(9));

E. Develops additional requirements for information to be gathered from the potential patient prior to admissions (0940-05-42-06(2)); and

F. Develops specific timelines for completion of the assessments and adds the requirement that the information required by Section 0940-05-42-.06 be attached to the patient's file (0940-05- 42-.06(2),(8) and (9)).

6. The new OTP rules require a prospective adult service recipient at an OTP (18 years of age of older) to verify his or her dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years OR verify one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. These requirements can be waived for service recipients released from penal institutions, for pregnant service recipients with a verified pregnancy, and for previously treated service recipients (0940-05-42-.07(2)(a)(9)).

7. The new OTP rules require a prospective juvenile service recipient at an OTP (under 18 years of age) to verify two documented unsuccessful attempts at detoxification within a twelve month period (0940-05- 42-.07(2)(a)(1 0)).

8. The new OTP rules require that the patient acknowledge in writing that he or she has been offered detoxification services as an admission alternative and that certain issues have been discussed with the patient (0940-05-42-.06(2)(c) and -.18(1)).

9. The new OTP rules require that attention be given to those patients with pain management/chronic pain issues as well as those with mental health needs (0940-05-42-12(1) and (2)).

10. The new OTP rules require counselors to document in more detail their counseling encounters and increase the number and frequency of counseling sessions (0940-05-42-14(3) and (6)).

11. The new OTP rules revise the requirements for addressing a situation in which a patient receives a positive drug screen, increases the frequency of additional drug screening after a positive drug screening, and provides for the possibility of discharging a patient if the patient receives a 4th positive screen within a 6 month period (0940-05-42-. 17(9)).

12. The new OTP rules expand OTP hours of operation for dosing to seven (7) days a week (0940-05-42- .26).

13. The new OTP rules add the requirement that all OTP staff be trained in the areas of chronic pain and pain management (0940-05-42-.29(5)(b)(11)).

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)

TDMHSAS estimates that this rule will have a minimal fiscal impact on state and local government revenues and expenditures.

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.

TDMHSAS Responses to Comments about
Rules Chapter 0940-05-42 Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities made prior to, during, or after the
Rulemaking Hearing Held on January 5, 2012

GENERAL COMMENTS

BEHAVIORAL HEALTH GROUP (BHG)

On behalf of our client, Behavioral Health Group, we write to convey our opposition to several of the above referenced Department's proposed rules that were the subject of public hearing on January 5, 2012 and to comment on certain other rules. While our specific objections to the proposed rules are set forth separately below, it is appropriate to begin by expressing our surprise and disagreement with the Department's express purpose for the proposed rules as announced at the beginning of the January 5 public hearing. At that time, the Department stated its "summary of factual information" as required by T.C.A. § 4-5-204(a)(4). In essence, the Department stated that it is philosophically opposed to the long-term treatment provided by non-residential opioid treatment centers, which treatment modality it sees as contrary to the Department's "primary mission" of "encouraging patients to become drug-free." With all due respect, that philosophy is fundamentally flawed, scientifically unfounded and contrary to long-established best practice standards of medical care with respect to patients suffering from the disease of opioid addiction. The Department's position in this matter is at odds with that of the Center for Disease Control and Prevention (CDC), the Drug Enforcement Administration (DEA), the National Institutes of Health (NIH), the Center for Substance Abuse Treatment (CSAT) and the Substance Abuse and Mental Health Services Administration (SAMHSA) and with voluminous medical and scientific research, some of which is noted in this letter.

I. EFFECTIVENESS OF METHADONE MAINTENANCE TREATMENT

The opening comments at the hearing, as required by statute to provide the factual basis for the published rules, acknowledged that the major sentiment underlying these rules is opposition toward opioid treatment programs' (OTPs') "emphasis on maintenance effort," and referenced becoming "drug-free" as the "commonly accepted philosophy and belief of . . . drug abuse treatment." By use of the phrase "commonly accepted," the Department appears to be adopting "long-standing myths and misconceptions about opioid-based medications" in the general public, which "misinformation has the potential to discourage the appropriate use of these medications even though, properly administered, they have demonstrated efficacy and safety in millions of patients worldwide." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 8 (2004). (attached as Exhibit A); see also *Effective Medical Treatment of Opiate Addiction,* NIH Consensus Statement, Nov. 17-19, 1997 at 18 (noting that "[m]any of the barriers to effective use of MMT in the treatment of opiate dependence stem from misperceptions and stigmas attached to opiate dependence, the people who are addicted, those who treat them, and the settings in which services are provided") (attached as Exhibit B).

Contrary to the Department's stated position, detoxification is *not* "commonly accepted" among the scientific or medical community as being the best or most effective treatment for opioid addiction. In a study published in the Journal of the American Medical Association, researchers found, based on an extensive five-year investigation, that, as compared to detoxification, methadone maintenance therapy (MMT) resulted in greater treatment retention, lower heroin use, lower severity score for legal status and was equally effective with regard to employment and family functioning scores. Karen L. Sees, Kevin L. Delucchi, et al, *Methadone Maintenance vs. 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence. A randomized controlled trial,* 283 J. Am. Med. Ass'n. 1303-1310 (2000) (attached as Exhibit C). An overview of 5 meta-analyses summarizing 52 studies demonstrated that "methadone maintenance treatment was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. NIDA International Program

Methadone Research Web Gide, Part B, Question 1: Is methadone maintenance treatment effective for opioid addiction?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b. (attached as Exhibit D); see also M Connock, A Juarez-Garcia, et al, *Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation*, Health Tech. Assessment, March 2007 at 1 (attached as Exhibit E). Researchers confirm the effectiveness of long-term methadone maintenance:

> The benefits of long-term methadone maintenance are borne out by data. Two years of MMT appears to be the minimum duration before attempting withdrawal. Even patients receiving maintenance for long periods with substantial lifestyle changes often relapse after leaving treatment, and death rates are much higher than for individuals who remain in treatment. For many patients, therefore, years or even lifetime maintenance may be needed . . . . Ultimately, the problem of interminable maintenance vs. relapse may require learning how to reverse the brain changes associated with addiction. Until then, long-term agonist treatment remains a reasonable alternative.

Vincent P. Dole & Marie Nyswander, *Methadone Maintenance 4 Decades Later: Thousands of Lives Saved But Still Controversial*. 300 J. Am. Med. Ass'n. 2303-2305 (2008) (attached as Exhibit F). The National Center for Substance Abuse and Treatment has noted in its guidelines that "[s]tudies suggest that the duration of retention in treatment is directly related to success in outcome. For patients who drop out of treatment, the outcome is usually negative, whereas patients who remain in treatment, despite continued excessive use of alcohol or illicit drugs, tend to benefit from the treatment experience." CSAT Guidelines for the Accreditation of Opioid Treatment Programs, http://www.dpt.samhsa.gov/pdf/draft_accred_uidelines.pdf, Note 8 at 40 (attached as Exhibit G).

The Centers for Disease Control and Prevention (CDC) reports that the benefits of methadone include:

- Reduced or stopped use of injection drugs;
- Reduced risk of overdose and of acquiring or transmitting diseases such as HIV, hepatitis B or C, bacterial infections, endocarditis, soft tissue infections, thrombophlebitis, tuberculosis, and STDs;
- Reduced mortality – the median death rate of opiate-dependent individuals in MMT is 30 percent of the rate of those not in MMT;
- Possible reduction in sexual risk behaviors, although evidence on this point is conflicting;
- Reduced criminal activity;
- Improved family stability and employment potential; and
- Improved pregnancy outcomes.

Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (attached as Exhibit H). See also NIDA International Program Methadone Research Web Guide, Part B, Question 4: Does methadone maintenance treatment reduce criminal activity?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit I). Several studies confirm increased employment rates among patients on methadone maintenance programs. NIDA International Program Methadone Research Web Guide, Part B, Question 5: Does methadone maintenance treatment improve the likelihood of obtaining and retaining employment?, available http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit J). Others show reduction in suicide rates and lethal overdoses, and improved health and productivity. NIDA International Program Methadone Research Web Guide, Part, Question 1: Is methadone maintenance treatment effective for opioid addiction?, available at http://international.drubabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide-part-b (attached as Exhibit D). The benefits of methadone maintenance therapy are so clear and compelling that a panel of experts convened by the National Institutes of Health concluded as follows:

> Opiate dependence is a brain-related medical disorder that can be effectively treated with significant benefits for the patient and society, and society must make a commitment to offer effective treatment for opiate dependence to all who need it. All opiate-dependent persons under legal supervision should have access to methadone maintenance therapy, and the U.S. Office of National Drug Control Policy and the U.S. Department of Justice should take the necessary steps to implement this recommendation . . . . The unnecessary regulations of methadone maintenance therapy and other long-acting opiate agonist treatment programs should be reduced, and coverage for these programs should be a required benefit in public and private insurance programs.

Effective Medical Treatment of Opiate Addiction, NIH Consensus Statement, Nov. 17-19, 1997 at 2 (attached as Exhibit B).

Thus, to the extent that the Department is equating methadone maintenance therapy with continued illegal drug use, it fundamentally misunderstands the effects of methadone at clinical levels. Researchers have observed that "[f]rom the beginning of MMT, the program has been stigmatized by the belief that methadone treatment merely substitutes one drug for another. This belief blurs the crucial differences between an active heroin addiction and the use of methadone in a maintenance program." Herman Joseph, Sharon Stancliff, & John Langrod, *Methadone Maintenance Treatment (MMT): A Review of Historical and clinical Issues,* 67 Mt. Sinai J. Med. 347-364 at 358 (2000) (attached as Exhibit K). At proper levels, methadone not only does not cause intoxication itself but significantly reduces the rate of other drug use by relieving the craving for and blocking the "high" caused by other opiates. The CDC has stated that methadone:

- blocks the euphoric and sedating effects of opiates;
- relieves the craving for opiates that is a major factor in relapse;
- relieves symptoms associated with withdrawal from opiates;
- does not cause euphoria or intoxication itself (with stable dosing), thus allowing a person to work and participate normally in society;
- is excreted slowly so it can be taken only once a day.

Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available* at http://www.cdc.gov/idu/facts/methadonefin.pdf (attached as Exhibit H).

The Department's obvious and inexplicable opposition to maintenance therapy notwithstanding, science supports the use of long-term maintenance therapy for opioid addiction:

> Studies have shown that good outcomes from substance abuse treatment are unequivocally contingent on adequate length of treatment. A research-based guide on the principles of substance abuse treatment, released in 1999 by the National Institute on Drug Abuse (NIDA), notes that "For methadone maintenance, 12 months of treatment is the minimum, and some opiate-addicted individuals will continue to benefit from methadone maintenance treatment over a period of years." . . . Most of those who discontinue MMT later relapse. . .

Id. Further, there is no scientific distinction between addiction to heroin and addiction to prescription painkillers or in the effectiveness of MMT to treat such addictions.

Moreover, this treatment for Tennesseans currently costs the State nothing, as OTPs in Tennessee receive no state funding or reimbursement whatsoever. Patients in Tennessee pay for treatment with their own funds or, in rare cases, through private insurance. Additionally, the treatment is extremely cost-effective compared to alternatives. As Dr. Rachel Farmer, owner and medical director of the Dyersburg OTP, testified at the rulemaking hearing, an OTP patient receives an entire year of comprehensive treatment, including physical examination, counseling, medication and referrals, for the cost of 4 days of treatment in an inpatient setting. As a practical matter, OTP treatment is the *only* treatment available to the overwhelming majority of patients receiving

it in Tennessee, as there are no other accessible, affordable programs offered. The State of Tennessee, of course, offers no financial assistance or in-patient programs.

To the benefit of taxpayers, OTP programs actually provide cost-savings to state and local governments. In 1997 the National Institutes of Health estimated the financial costs of untreated opiate addiction to be $20 billion per year. *Id.* As the Centers for Disease Control has stated, "[t]hese costs, combined with the social costs of destroyed families, destabilized communities, increased crime, increased disease transmission, and increased health care costs, mean that opiate addiction is a major problem for affected individuals and society." *Id.* Methadone maintenance treatment reduces those costs in many ways. It decreases funds spent on law enforcement and incarceration by drastically reducing criminal activity among addicts receiving treatment. One study has shown a 70% reduction in crime days per year among narcotics addicts on methadone maintenance. Vincent P. Dole & Marie Nyswander, *Methadone Maintenance 4 Decades Later: Thousands of Lives Saved But Still Controversial.* 300 J. Am. Med. Ass'n 2303-2305 (2008) (attached as Exhibit F). The public savings from reduced criminal activity alone amounts to $4 for every $1 spent on methadone treatment. Harwood HJ, Hubbard RL, Collins JJ, Rachal, JV. The Costs of Crime and the Benefits of Drug Abuse Treatment: A Cost-Benefit Analysis Using TOPS Data, NIDA Research Monograph, Number 86, 1988, *available at* http://archives.drugabuse.gov/pdf/monographs/86.pdf (attached as Exhibit L); see also NIDA International Program Methadone Research Web Guide, Part B, Question 15: Are there cost benefits to methadone maintenance treatment?, *available at* http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit M). Effective addiction treatment also results in lower unemployment and lower healthcare costs for the medical problems associated with active illegal drug use. The National Institute on Drug Abuse (NIDA) states unequivocally that "when all costs to society are considered, methadone maintenance treatment is extremely cost-effective and beneficial to society." *Id.* Accordingly, an expert panel convened by the National Institutes of Health has "strongly recommended expanding access to methadone treatment by eliminating excessive Federal and State regulations and increasing funding for methadone treatment." Mathias, R. NIH Panel Calls for Expanded Methadone Treatment for Heroin Addiction. NIDA Notes 1997; 12 (6), *available at* http://archives.drugabuse.gov/NIDA_Notes/NNVol12N6/NIHPanel.html (attached at Exhibit N); See also Herman Joseph, Sharon Stancliff, & John Langrod, *Methadone Maintenance Treatment (MMT: A Review of Historical and Clinical Issues,* 67 Mt. Sinai J.Med. 347-364 (2000) (noting reduction in property crime, drug arrests, hepatitis and addiction-related deaths and going on to state that "[a]vailability of MMT should be increased and made more affordable") (Exhibit K).

To the extent that the Department believes its rules are necessitated by a concern about the risk of mortality associated with methadone, that concern manifestly does *not* warrant tighter restrictions on OTPs or their patients. "[M]ethadone is among the most thoroughly studied drugs in modern medicine" and has been proven to be safe when used as indicated. U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 10-11 (2004); see also NIDA International Program Methadone Research Web Guide, Part B, Question 12: Is the long-term use of methadone medically safe, and is it well tolerated by patients?, available at http://international.drugabuse.gov/educational-opportunities/certificate-programs/methadone-research-web-guide/part-b (attached as Exhibit O). As SAMHSA has noted, "[m]ethadone is a medication valued for its effectiveness *in reducing the mortality associated with opioid addiction* as well as the various medical and behavioral morbidities associated with addictive disorders." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 3 (2004) (emphasis added) (Exhibit A). Specifically, SAMHSA reported that "[m]ortality from all causes is many-fold lower in methadone-treated patients than in untreated opioid addicts." *Id.* at 11.

The federal Drug Enforcement Administration's Office of Diversion Control noted in April 2007 that a recent increase in methadone distribution "is primarily associated with increased use for pain management not narcotic treatment," and that "[c]urrent data suggest that medication from pain management is likely the source of methadone for illicit use." Methadone: Methadone Mortality Working Group, Drug Enforcement Administration, Office of Diversion Control, April 2007, *available at* http://www.deadiversion.usdoj.gov/drugs_concern/methadone/methadone_presentation_0407_revised.pdf at 8 and 41 (attached as Exhibit P). (Note: Page numbers were added to the presentation for citation purposes and did not appear in the original document.) The increase in the amount of methadone distributed by pharmacies has far outpaced that of OTPs, to the point that by 2002, "pharmacies accounted for 88 percent of all purchases of methadone tablets." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment 21 (2004) (Exhibit A). While it is true that methadone-related deaths have been reported, SAMHSA has conducted an expert national assessment of all available relevant data and announced that "[e]xamination of the data available to the National Assessment

participants indicates that OTP's and the 2001 regulatory changes {permitting more take home doses of methadone in OTP treatment] *did not* have a significant effect on rates of methadone-associated mortality." *Id.* at 22 (emphasis in original). "In the cases in which the sources of methadone associated with deaths could be traced, OTPs did not appear to be involved." *Id.* Rather, "participants concurred that methadone tablets and/or diskettes that have become available through channels *other than OTPs* are most likely the central factor in recent increases in methadone-associated mortality." *Id.* (emphasis in original). Accordingly, cases of methadone-related mortality do not justify tighter regulations targeted at limiting access to OTPs.

Given the demonstrated safety, effectiveness and cost-savings to the State associated with the treatment provided by OTPs, there is no scientific or even logical basis for the Department to treat OTPs or their patients more harshly than any other treatment setting. As discussed above, OTPs are not the only sources of methadone, and the federal Drug Enforcement Administration data show that, by 2006, pharmacies, hospitals and other practitioners accounted for approximately the same about of methadone distribution as OTPs (Methadone: Methadone Mortality Working Group, Drug Enforcement Administration, Office of Diversion Control, April 2007, available at http://www.deadiversion.usdoj.gov/drugs_concern/methadone/methadone_presentation0407_revised.pdf at 13, Exhibit P), and yet the Department's rules target only OTPs for restriction.

In this regard, the Tennessee Attorney General has opined, the "state may not invidiously discriminate, and may not rely upon a classification whose relationship to an asserted goal is so attenuated as to render the distinction arbitrary or irrational." Op. Tenn. Atty. Gen. No. 99-221, at * 4 (Nov. 4, 1999) attached as Exhibit Q). Accordingly, the Attorney General has repeatedly cautioned that prohibitions and limitations targeted at OTPs are "constitutionally suspect" as a violation of the right to equal protection and "also raise substantial legal concerns" about violations of the Americans with Disabilities Act and § 504 of the Rehabilitation Act. *See id.* (evaluating proposed legislation that would prohibit OTPs); Op. Tenn. Atty. Gen. No. 98-087 (Apr. 15, 1998) (finding proposed legislation requiring local government support for an OTP as prerequisite to a certificate of need to be "constitutionally suspect") (attached as Exhibit R); Op. Tenn. Atty. Gen. No. 97-099 (July 1, 1997) (finding proposed state agency rule preventing an OTP from locating within 100 miles of another OTP to be "constitutionally suspect") (attached as Exhibit S). There is, quite simply, no justification for the perception of OTPs embodied in these misinformed, illogical, illegal and arbitrary proposed rules.

CONTINUUM HEALTH PARTNERS (CONTINUUM)

The Regulations seem directed only at "programs" that provide methadone and/or buprenorphine. However, they address concerns that presumably apply to office-based opioid treatment (OBOT) providers as well: the risk of diversion, the need for monitoring patients, dosage issues, verification of medication prescribed by other providers, etc. Furthermore, many of the specific provisions that are proposed would be applicable all addiction treatment service providers, regardless of setting and whether medication is or is not utilized. Thus, the requirement that applicants for and recipients of "opioid treatment programs" be given "explanation of treatment options . . ." (page 9) is one I applaud, but it is equally imperative that applicants for drug-free care and for community-based buprenorphine treatment be informed of all options, including medication-assisted treatment and "programs," and that referral be facilitated upon request.

Comprehensive assessment" (page 10) would seem relevant to all care providers, and not just to medication-assisted treatment programs. (I note in passing that the "assessment," as described, includes many elements that would prove both time-consuming and expensive, and for which there is no evidence that they are essential.)

To the extent the requirements for "screening" applicants (pages 13 – 14) might be considered justified, why would they be less relevant to applicants seeking treatment other than in an OTP setting?

The proposed regulations would assign responsibility to state officials for decisions that should be entirely within the purview of the clinical care provider: determination of need for and appropriateness of a particular treatment modality; dosages; type and frequency of laboratory tests; response to less than optimal therapeutic results; justification for take-home medication; etc. It is not clear if the SOTA staff to whom these medical-clinical decisions are to be left are physicians – let alone whether they meet the various qualifications demanded of "program" medical directors (e.g., board eligibility in psychiatry and two years documented experience in the treatment of persons who are addicted" page 37), and other program physicians. Regardless of the academic and clinical qualifications of the authority staff, however, they presumably will be totally unfamiliar with the patients and may well never have had any contact with their healthcare providers other than through submission of

documents. In sum, this would seem to be a totally inappropriate system for reaching decisions with potentially life-and-death consequence.

* * *

Informed consent: this is –appropriately – required prior to beginning treatment and for release of confidential patient information under almost any circumstances. it is most strongly urged that informed consent, in writing, *also* be obligatory prior to initiation of voluntary *discharge*. The provider should be obligated to inform the patient of the consistent evidence that following detoxification (for any reason) relapse to illicit drug use is the rule rather than the exception, and that such relapse is associated with a very marked increase in likelihood of fatal overdose. Indeed, providing this information to applicants and patients should be mandatory *at the time of admission* to treatment as well, and mentioned explicitly in the "consent to treatment."

There are a great many additional criticisms that I believe the proposed rules merit, but I have limited myself to what I consider to be the most important. I urge that each and every provision be assessed from the standpoint of likely consequences – good and bad – for applicants and patients, providers, and the community as a whole. it is my conviction that with respect to every aspect of the proposal the question should be asked: would this be appropriate if applied to any other chronic, notoriously relapsing, incurable – but treatable – medical condition? From that perspective I am confident the right answers will be forthcoming and benefit all concerned.

SOLUTIONS OF SAVANNAH & RECOVERY OF COLUMBIA (SOS)

My business partner, Beverly Jones, and I own and operate two Opioid Treatment Programs in Tennessee. Solutions of Savannah and Recovery of Columbia are both small programs, and Solutions of Savannah is located in a rural area. We both live in Savannah and work in the clinics daily. We operate very clinical and ethical programs. We are able to see the difference medication-assisted treatment makes in the lives of individuals, families, and our community.

Many of the proposed new regulations are standards that we have always adhered to, and will continue to do so regardless. We understand that there have been changes in the field of medication-assisted treatment in the past few years, and that the regulations need to be updated. However, we feel that many of the proposed regulations are heavy-handed and punitive to the programs and clients.

Some of the proposed regulations will have a significant financial impact on programs, especially smaller ones, like ours. If the proposed regulations are approved, as written, they have the potential to force small clinics out of business. This will force people out of work and out of treatment. We are concerned about this impact as business owners, members of the community, and taxpayers.

We would like explanations as to the reasoning behind the changes in many of the regulations. The research that we follow recommends, in many instances, the opposite of what is being proposed here. We would like to see the Department's research behind the proposed changes.

Methadone Maintenance Treatment is one the most researched forms of treatment available. Please consider this research, when making your decision.

VOLUNTEER TREATMENT CENTER (VOLUNTEER)

First, the rules, as proposed by the Commissioner of the Department of Mental Health (Commissioner), exceed the Commissioner's authority by undermining the fundamental purpose of the legislature in enacting legislation to establish a statutory framework for regulating OTPs. It is well established that an administrative agency does not have the power to thwart the purpose of a statute enacted by the legislature. Deweese v. Board of Funeral Directors and Embalmers, 1994 WL 137873. The Tennessee legislature has authorized the establishment and licensure of OTP Facilities for the purpose of addressing the state's opiate abuse crisis. The cost of many of the requirements set forth in the Proposed Rules will make it almost impossible for OTP Facilities to continue to operate and provide much needed services for their patients. By making it unreasonably costly for OTP Facilities to operate, the Commissioner has promulgated rules that conflict with the intent and purpose of the statute.

Second, many of the Proposed Rules are unsupported by any clinical evidence that they will improve the efficiency or effectiveness of treatment, and are simply arbitrary and capricious. The actions of any administrative agency must not be arbitrary and should be supported by substantial and material evidence. Jackson Mobile

Phone Company, Inc. vs. Tennessee Public Service Commission, 876 S.W. 2d 106 (1994). The Proposed Rules as drafted do not meet this standard. Instead, they require actions and processes that are inconsistent with well-established standards of care in the industry which will not only limit access to treatment but will often eliminate the effectiveness of that treatment.

Further, the Proposed Rules are vague and in many instances will be impossible to implement. In order to meet the standards of both the Tennessee and United States Constitution, the Proposed rules must be in a form so that it is possible for a facility to know whether or not it in compliance. Williams v. State Department of Health and Environment, 880 SW2d 995 (Tenn. App. 1994). The Proposed Rules do not meet this standard. Often the requirements of the Proposed rules are so vague that reasonable men could easily differ in interpretation of the Proposed rules. In many instances, OTP Facilities will not know what steps they will be required to take in order to meet the requirements of the Proposed Rules and in other instances will not be able to take the actions that are mandated.

TDMHSAS Response: The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or Department) believes that Non-residential Opioid Treatment Program Facilities (OTPs) are an integral component in Tennessee's mission to curb and eliminate drug abuse of all kinds in this state and the Department recognizes that some of the practices of these facilities are indispensable for that purpose. However, in light of the prescription drug epidemic confronting our state and the vulnerable nature of the individuals served by OTPs, the Department believes that OTPs are in need of clearer operational guidelines and better reporting mechanisms in order to ensure the safety and health of their service recipients and to track the nature and scope of the medications the OTPs dispense. It is in the spirit of ensuring the safety and sobriety of our Tennessee citizens that the changes to 09040-05-42 have been promulgated.

The new rules have benefited from the extensive research done by TDMHSAS' Policy and Planning Division, particularly as it relates to the administrative procedures relative to OTPs in other states, especially those of nearby states with issues similar to Tennessee's relative to opioid addiction. Additionally, TDMHSAS considered other information gathered regarding the regulation and operation of OTPs, including: 1.) Information gathered during site visits by the State Opioid Treatment Authority (SOTA) and Licensure staff to OTPs in Illinois, New York, Maryland, Kentucky, and Texas; 2.) Meetings and telephone conferences with DEA personnel; 3.) Consultation with OTP regulators in other states; 4.) an overview of federal OTP regulations and various publications; 5.) Tennessee statutes and operating procedures; 5.) Federal regulations, particularly those regarding guidelines for the accreditation of OTPs; and 6.) Research regarding Tennessee's increasing opioid-addicted population and its unique characteristics. Furthermore, TDMHSAS has considered the concerns and comments presented by stakeholders (OTP service recipients, owners, operators, and employees) at the rulemaking hearing for these rules held on January 5th, 2012, the concerns and comments submitted by the stakeholders during the extended written comment period granted by TDMHSAS from January 5th to January 19th, 2012, and the arguments offered by the stakeholders during a meeting with TDMHSAS Commissioner Varney held pursuant to T.C.A. § 4-5-204(c)(1) on February 13, 2012. Based on those stakeholders' concerns and comments, TDMHSAS made appropriate changes to the rule.

All in all, TDMHSAS has been diligent in researching these rules and responsive in reacting to stakeholders' concerns and comments. As a result, it is TDMHSAS' belief that these new rules capture the best practices in the area of opioid treatment and represent a positive step forward in the area of OTP regulation which will allow Tennessee citizens to continue to access this important treatment option while benefitting from increased safety and public health accountability measures.

SPECIFIC COMMENTS

**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 November 15, 2011.*

(A) 0940-05-42-.01(2)(e)

VOLUNTEER: This proposed definition of "no less than thirty (30) minutes" is arbitrary. It assumes, with no medical basis, that therapy delivered for a short duration, such as in unscheduled crisis situations, is ineffective.

BHG: This provision defines a counseling session as a "face-to-face, therapeutic discussion between service recipient(s) and a facility counselor in a private location for a period of no less than 30 minutes . . ." The effect of this definition is to limit documentation credit for therapy provided via a crisis phone call or for face-to-face

conversations lasting less than 30 minutes. This essentially negates the opportunity to provide those forms of therapy, and may have the effect of causing patients to abandon treatment if they are required to submit to lengthy face-to-face conversations for every counseling session. We would ask that the definition be modified to include counseling via telephone and for shorter periods of time as appropriate to the patient's needs.

TDMHSAS Response: We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. SAMHSA TIP 43, pages 124-125, provides: "Studies have found that OTPs providing regular, structured, substance abuse-focused counseling had better outcomes than OTPs providing little or no counseling (Kidorf et al. 1999; Magura et al. 1999)." SAMHSA TIP 43, page 125, lists the elements of a "typical individual counseling session" at an OTP. In order for the OTP to effectively address each elements of a typical individual counseling session, it is TDMHSAS' belief that a minimum of 30 minutes per counseling session is needed.

(B) 0940-05-42-.01(2)(n)

BHG: This subsection defines a maintenance dose as one that 'suppress[es] signs and symptoms of withdrawal and drug cravings for individuals with opioid addiction.' This definition is technically incorrect as methadone does not reduce cravings for *all* drugs. That sentence should be modified to read 'signs and symptoms of withdrawal from opioid drugs and opioid drug cravings.'

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholder.

(C) 0940-05-42-.01(2)(q)

BHG: This subsection defines methadone as an "opioid agonist with actions similar to those of morphine and heroin." This is scientifically inaccurate. Among other critical distinctions, in contrast to morphine and heroin, methadone is long-acting and non-tolerance forming. The definition should be modified to provide that "Methadone is in a class of medications called opiate (narcotic) analgesics. Methadone works as a therapeutic replacement agent for drugs of abuse by preventing withdrawal symptoms in people who have stopped using these drugs."

VOLUNTEER: The comparison of methadone to heroin is arbitrary and inappropriate. VTC suggests using a definition similar as that for Buprenorphine. Any definition for methadone should not include a comparison to an illicit drug.

SOS: This definition seems to set the tone for the following proposed regulations. Treatment providers and clients are in a constant battle to fight the stigma of substance dependence and methadone treatment. We work in the community to improve relations and increase understanding and acceptance of medication-assisted treatment. This definition, with the Department comparing methadone to heroin, is a slap in the face to every treatment provider and client in the State of Tennessee.

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholders and returned to the earlier definition of methadone found in the current version of these rules.

(D) 0940-05-42-.01(2)(y)

VOLUNTEER: This definition should not include medical director, another defined term. Including the term medical director as part of a separate defined term creates confusion.

TDMHSAS Response: We disagree. No change has been made from the existing rule. Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(E) 0940-05-42-.01(2)(ee)

VOLUNTEER: The Board of Pharmacy regulates pharmacists, and has no jurisdiction to regulate OTPs. This definition is not needed and should be deleted. OTPs do not employ pharmacists. Only two (2) drugs are used at OTPs, and those drugs are properly dispensed through an automated dispensing system. Including this definition in these rules creates confusion and a perception that the Board of Pharmacy has some authority over OTPs.

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholder.

(F) 0940-05-42-.03

BHG: This subsection imposes new requirements on OTPs "when making application for a license." This language should be modified in order to make clear that these requirements apply only to those "making application for a *new* license," as opposed to those simply seeking renewals of existing licenses. More importantly, the proposed rule will require applicants for an opioid treatment program ("OTP") license to submit, in addition to the Certificate of Need ("CON") issued by the Tennessee Health Services Development Agency ("HSDA"), "a copy of the letter of support from the local governing body of the county or city in which the facility is proposed to be located." This requirement exceeds, and directly conflicts with State law, governing community input into the licensing of healthcare facilities. When any such proposed facility applies for a CON, any interested party may require the HSDA to conduct "a fact-finding public hearing on the application" in the community in which it is to be located. Tenn. Code Ann. § 68-11-1608(b). Additionally, within ten days of filing an application for a CON, OTPs must "send a notice to the county mayor of the county in which the facility is proposed to be located, the member of the house of representatives and the senator of the general assembly representing the district in which the facility is proposed to be located, and to the mayor of the municipality, if the facility is proposed to be located within the corporate boundaries of a municipality, by certified mail, return receipt requested, informing such officials that an application for a nonresidential methadone treatment facility has been filed with the agency by the applicant." Tenn. Code Ann. § 68-11-1607(c)(3). Any person may appear before the HSDA and express opposition to an application, Tenn. Code Ann. § 68-11-1609(g)(2), and any person who so objects to an application may petition the HSDA to hold a contested case hearing on the matter if the application is approved. Tenn. Code Ann. § 68-11-1610(a). Finally, any person who is aggrieved by the outcome of a contested case hearing may seek judicial review of that decision in the Davidson County Chancery Court. Tenn. Code Ann. § 4-5-322. Thus, there is ample opportunity for communities and government officials to have their opinions about a proposed OTP heard by both the agency and the courts responsible for reviewing CON proceedings. This proposed rule, however, goes much further. By requiring a letter of local government support as part of an application for an OTP license, this rule would essentially give local governments veto power over the establishment of an OTP within their jurisdictions. That power is expressly prohibited by State law, which provides that while local government input is to be heard, local government support is not required for the establishment of OTPs:

> At a hearing conducted by the HSDA for a nonresidential substitution-based treatment center for opiate addiction, if a local governing body requests to participate in such hearing, the officials of such governing body shall have the opportunity to appear before the agency and express support or opposition to the granting of a certificate of need to the applicant. The testimony of such officials shall be informational and advisory to the agency, and **the support of the local governing body shall not be a requirement** for the granting of a certificate of need by the agency. Tenn. Code Ann. § 68-11-1624 (emphasis added).

In 1998 the Tennessee Attorney General opined that proposed legislation designed to give local governments a veto over OTPS would be "unconstitutional as a violation of equal protection of the laws," and noted that it would likely also violate the Americans with Disabilities Act and the Rehabilitation Act. *See* Op Tenn. Atty. Gen. No. 98-087 at *14 (attached as Exhibit R). Specifically the Attorney General cited case law to the effect that "irrational prejudice" and fears of property owners and residents are insufficient support for a legislative classification between various types of facilities or populations, *Id.* at *10-11, and concluded that the disparate treatment of nonresidential methadone treatment facilities were 'insufficiently and concluded that the disparate treatment of nonresidential methadone treatment facilities was "insufficiently narrow in scope and insufficiently grounded in fact" to be rationally related to any legitimate state interest. *Id.* at *14. Accordingly the proposed requirement of a letter of support from local government is unlawful.

Rather than giving credence and power to local misconceptions about OTPs, the Department should be acting in its role as a public health agency to educate the public about many societal and individual benefits provided by methadone maintenance treatment. As SAMHSA has announced, "public misperceptions about methadone must be addressed," and "[t]here is an immediate need for professional organizations and regulatory agencies to present scientific evidence and credible data to counter misinformation about methadone and 'methadone clinics' (OTPs) presented in the mass media." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin, Methadone-Associated Mortality: Report of a National Assessment 26 (2004).

VOLUNTEER: This rule should be deleted because it is confusing and exceeds the authority of the Commissioner to impose such a requirement. First, "as of the effective date of these rules" is not specific and will not give adequate notice to those who seek to comply. Second, the requirement of a "letter of support from the local governing body" is vague and confusing. Finally, such a requirement is an inappropriate delegation of authority to a separate government body not contemplated by the statute.

TAADAS: TAADAS recommends the deletion of the language "along with a copy of the letter of support from the local governing body of the county or city in which the facility is proposed to be located," and substituting instead the language, "The application shall include a resolution adopted by the city governing body and the county legislative body where the facility is proposed to be located stating that the facility's proposed land use is appropriate under the local government's land use regulations." The explanation for this revision is that a local governing body acts by its resolutions and ordinances. Procedurally, a governing body does not draft letters, unless of course the rule may have intended for the letter of support and statement of compliance with land use regulations to be drafted by the city mayor and the county mayor.

SOS: The Tennessee Health Services Development Agency does not require a letter of support from the local governing body of the county or city in which the facility is proposed to be located. How can one State agency re-write the requirements of another State agency?

TDMHSAS Response: TDMHSAS has removed the licensure provision requiring OTPs to submit a letter of support from the local governing body of the county or city in which the facility is proposed to be located.

(G) 0940-05-42-.05

BHG: This section requires in part that "[e]ach facility shall clearly identify the governing body, as defined in Rule 0940-05-01-.01, in its policies and procedures manual including the name and contact information of the governing body." The effect of this rule will be to require BHG facilities to provide personal contact information of their board members, a requirement that addresses no legitimate state interest and impinges on the privacy rights of the members of the board. This rule should be modified to allow for the provision of corporate office/CEO contact information only or to require that the documents containing personal contact information for board members or other individuals are to be accessible only by the proper regulatory authorities. This same objection applies to 0940-05-42.27(7), which is additionally objectionable as redundant.

VOLUNTEER: It is appropriate to require each OTP to identify its governing body and to submit such information to the Department of Mental Health. It is beyond the scope of the Commissioner's authority to dictate the terms of an OTP's policy and procedure manual and to require information about the governing body be contained therein. Further, name and address information is not a policy or procedure.

TDMHSAS Response: TDMHSAS clarified the citation as suggested by the stakeholders. TDMHSAS disagrees with regard to the remainder of the comments. The governing body is the licensee and the name and contact information for the governing body shall be provided. TDMHSAS will make no further change to the rule as proposed in its November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. See also TDMHSAS' Response to Comment regarding 0940-05-42-.27(7).

(H) 0940-05-42-.06

BHG: Subsection (1) of this rule provides a list of treatment options for new patients. The language should be modified to include "long-term detoxification" among those options, in order to be consistent with other provisions of the rules (i.e., Rule 0940-05-42-.19(1)) and to ensure that patients are apprised of and screened for all potentially appropriate treatment options.

VOLUNTEER: This rule arbitrarily limits the medical judgment of the physician to three (3) treatment options, "opioid substitution, short-term detoxification or drug-free treatment." These limitations should be deleted and the physician should be allowed to determine the appropriate treatment plan for the patient. The statute does not confer on the Commissioner or the State Opioid Treatment Authority (SOTA) authority to make treatment decisions. No such limitations are imposed in other care settings. In fact, to impose such authority on the Commissioner or SOTA would be an unauthorized and illegal practice of medicine.

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholders and deleted the term "short-term" from 0940-05-42-.06(1). TDMHSAS clarified that certain evaluations need to be

completed prior to admission.

(I) 0940-05-42-.06(3)

BHG: This subsection (.06(3)) provides that "[n]o standardized routines or schedules of increases or decreases of medications may be established or used." BHG supports and follows an individualized approach to treatment for patients suffering from addiction. However, as it is currently written, this rule would prohibit best practice protocols such as starting all patients at an initial 20 mg dose (in the absence of any factors indicating the need for a higher initial dose). Just as general practitioners and over-the-counter drug labels prescribe standard doses of medications based on a person's size, OTP providers must be able to rely on that same approach when appropriate to care for their patients.

TDMHSAS Response: We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(J) 0940-05-42-.06(5)

BHG: As written, this subsection (.06(5)) provides that an OTP may only admit and retain patients "whose known needs can be met by the facility." Construed strictly, this would prevent an OTP from treating a patient who suffers from *any* known ailment in addition to his drug dependency, which is impractical in any patient population but especially not possible or practical among those suffering from addiction. In fact, the likelihood of addicted patients presenting health problems in addition to their addiction is implicitly acknowledged by subsection (8) of this same rule. This language should be modified to provide for admission of patients "whose known needs can be met by the facility directly or indirectly through coordination of care."

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholder and amended the proposed rule to include the suggested language.

(K) 0940-05-42-.06(8)(a)

SOS: What is an initial plan of care?

TDMHSAS Response: TDMHSAS concurs that the rule was unclear as to the reference to "initial plan of care". Therefore, TDMHSAS amended the proposed rule by deleting the term "initial plan of care".

(L) 0940-05-42-.06(8)(a)7

BHG: This subsection 0940-05-42-.06(8)(a)(7) requires a "toxicology screen to determine *immediate* use of opioids" as part of the initial assessment to determine a patient's eligibility and need for treatment. Because "immediate" use of opioids is not necessary in order for a patient to be addicted, and many patients present in full withdrawal, this provision should be modified to make clear that evidence of "immediate" use is not a pre-requisite to eligibility for treatment. The Department's use of the term "immediate" is ambiguous and should be clarified or replaced with "recent" or some other more definite modifier.

TDMHSAS Response: TDMHSAS concurs that the rule was unclear with regard to toxicology screening. Therefore, TDMHSAS amended the proposed rule by deleting subsection (7).

(M) 0940-05-42-.06(8)(a)8

BHG: As part of the same initial assessment, this subsection (.06(8)(a)(8) requires an "initial drug test to determine whether an individual is either opioid addicted or presently receiving methadone for an opioid addiction from another opioid treatment program." This provision is quite simply nonsensical. Drug tests indicate the presence of drugs in the body; they do not establish whether or not a person is *addicted* to those drugs. Additionally, while a drug test can reveal a patient's use of methadone within a particular time frame, it obviously cannot determine the source of that methadone, whether "from another opioid treatment program" or elsewhere. Because the toxicology screen required by subsection (8)(a)(9) will already reveal the presence of opioids and/or methadone in a patient's body, this subsection service no purpose and should be eliminated entirely as redundant, or it should be re-written to clarify what feasible additional requirement is being imposed.

SOS: How does a drug test determine if a person is receiving methadone for an opioid addiction from another opioid treatment program?

TDMHSAS Response: TDMHSAS concurs that the rule was unclear with regard to initial drug test. Therefore, TDMHSAS amended the proposed rule by deleting subsection (8).

(N) 0940-05-42-.06(8)(a)9

BHG: This subsection requires a "full toxicology screen" as part of the initial assessment. We ask that the subsection be modified to clarify that it is satisfied by a CLIA waived on-site (instant) drug test.

TDMHSAS Response: The rule requires a full toxicology screen but does not specify the need for specific lab certification. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(O) 0940-05-42-.06(9)a

BHG: This subsection requires that "[w]henever possible and with the service recipient permission, the intake process shall include a non-addicted family member or significant other to assist in provision of accurate information and a full understanding and retention of instructions given to the service recipient." In order to mirror HIPAA and other applicable regulatory language, the word 'permission' in this provision should be changed to 'consent.' Furthermore, because whether or not a family member or significant other is 'non-addicted' is not immediately apparent in the absence of a thorough evaluation, the term 'non-addicted' is unenforceable and should be eliminated from this requirement.

TDMHSAS Response: We concur. The term "non-addicted" was removed from the proposed rules.

(P) 0940-05-42-.06(9)(c)1-4

SOS: Is this supposed to be referring to the SNAP (Strengths, Needs, Abilities, Preferences)?

TDMHSAS Response: Regardless of the specific instrument used for the psychosocial evaluation (SNAP, etc.), the provisions stated in the rule must be achieved by the psychosocial evaluation.

(Q) 0940-05-42-.06(11)

BHG: This subsection requires an inquiry with the Central Registry in connection with a patient's admission to an OTP, but as written it is unclear whether such inquiry must be made prior to admission or within 72 hours after admission. It should be modified or stricken entirely as redundant, as the requirement at issue is already adequately and more clearly covered by Rule 0940-05-42-.21(3).

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholder's comment and clarified that the OTP must notify the SOTA within 72 hours of the admittance of a new patient.

(R) 0940-05-42-.06(13)(b)

BHG: This provision requires that a discharge and aftercare plan for patients who complete their course of treatment 'shall include documented discussion between the service recipient and facility counseling and/or medical staff about an individualized detoxification program appropriate to the service recipient as required in section 0940-05-42-.19 herein.' The reference to a long-term detoxification option offered as an alternative to admission is confusing in the context of documentation related to discharge of a patient who has already completed a course of treatment. This provision should be modified to clarify what, if any, additional discussion of long-term detoxification is required by this subsection, and to correct the apparent typographical error in the first word of the subsection.

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholder's comment.

(S) 0940-05-42-.07(2)(a)9

AMERICAN ASSOCIATION FOR THE TREATMENT OF OPIOID DEPENDENCE, INC. (AATOD): The regulations require that all patients be screened through a Central Registry System before the first dose of methadone can be dispensed and the patient is formally admitted to treatment. What protections will be guaranteed as OTPs are registering patients with such systems? States that have such systems in place have gone to considerable effort to ensure that patient confidentiality is not compromise in any way that the Central Registry Services are completely compliant with Federal Confidentiality Regulations 42 CFR 2.

BHG: This rule requires that, prior to development of an Individualized Program Plan, a provider must verify that a prospective adult patient has been dependent on opioids for at least two years. The effect of this rule is to require OTPs to deny treatment to patient who cannot prove that they have been addicted for two years or more. This requirement exceeds the applicable federal guideline, which requires only one year of addiction prior to admission, which can be waived in some circumstances. 42 CFR Section 8.12(e); CSAT Guidelines for the Accreditation of Opioid Treatment Programs (draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pef 2(f)(4) at 12 (attached as Exhibit G). It creates an artificial barrier to treatment for individuals who are without doubt in need of it, which is all the more arbitrary in light of the Department's recognition of the 'drug epidemic co9nfronting our state.' This rule will force OTPs to turn away people who are suffering from addiction and have taken the step of voluntarily seeking treatment for which they are willing to pay with no assistance from the State. Preventing people from receiving medically necessary treatment for their illness serves only to prolong the negative consequences of drug addiction that the state seeks to address. This proposal is clearly against the best interests of the patient, is arbitrary and irrational, and should be eliminated from the rule. Nor does this proposed rule serve the public interest and, in fact, perpetuates activities that increase both economic and non-economic costs to society.

Perhaps this is best illustrated by the following description of a patient from one of BHG's managers:

"After working in OMT for over 11 years, I have witnessed many patient who took several years to finally achieve a negative urine screen. I remember one male patient in particular who became very discouraged because he was consistently positive for opiates – heroin in his case. He insisted that he was 'cutting down' but unfortunately his urine screens did not indicate that. His counselor recommended that he keep a 'using journal.' At his highest use, he reported using heroin every couple of hours. As he began documenting his use, he saw that he decrease to a couple of times a day, to once a day to a couple of days a week. Even that amount of use would result in a positive urine screen monthly, but he was able to see his own progress. He was finally able to go for longer and longer periods without using and began getting negative urine screens and finally earned take home privileges. It took several years for this patient to get that first negative urine screen; yet after he did, he remained drug free until a successful discharge from the program."

CONTINUUM: Neither evidence nor logic supports such a criterion for "eligibility." To demand prior treatment "failure" before admission to what is widely acknowledged to be the "gold standard" care for opioid dependence is no more justified than insisting that a deeply depressed patient demonstrate two prior unsuccessful attempts at suicide before permitting the prescription of anti-depressant medication.

NATIONAL ALLIANCE FOR MEDICATION ASSISTED RECOVERY, INC. (NAMA): Requiring admissions to have two documented treatment failures. It can take time and in the meantime an individual needing treatment is made to wait. It has been our experience that when individuals seeking services are denied or delayed services, they do not return. Some will go to another state if they do not have the required documentation and have the funds. Those without the funds will continue their addiction because they have been denied the most effective treatment for their opiate addiction. Neither of these options is positive for the state.

MIDSOUTH: Requires 2 Years addiction – formerly 1 year. DSM criteria specify 1 year, does not conform to standards of care, will limit access to care for those with the disease of addiction.

VOLUNTEER: The requirement to verify the patient's addiction for a period of two (2) years is arbitrary, not based on medical standards or protocol and should be deleted.

TDMHSAS Response: After consideration, TDMHSAS made a change to this section as suggested by the stakeholders. The rule now requires either two years of addiction or one year of addiction and one unsuccessful documented attempt at clinical treatment.

(T) 0940-05-42-.07(2)(a)10

SOS: The Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) states the criteria for dependency "must occur at any time in the same 12-month period". The DSM-IV-TR is the manual recognized and used universally for diagnosing individuals with mental health and substance disorders. It is considered standard of care to use DSM criteria for diagnoses.
The Federal Regulations 42 CFR Part 8. *8.12 Federal opioid treatment standards*
(e) Patient admission criteria. – (1) Maintenance treatment. An OTP shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment by qualified personnel who have determined, using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), that the person is currently addicted to an opioid drug, and that the person became addicted at least 1 year before admission for treatment. Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005. Refers to the Federal regulations and states "opioid pharmacotherapy is appropriate for persons who currently are addicted to an opioid drug and became addicted at least 1 year before admission".

We are required to be accredited. Our accreditation body is the Commission of Accreditation of Rehabilitation Facilities (CARF). In the CARF Standards Manual 2010, it states
Page 114 B. Screening and Access to Services
5. The opioid treatment program has admission criteria that are consistent with those outlined in the definition of opioid dependence in *Diagnostic and Statistical Manual of Mental Disorders.*

Our concern is if we refuse admission to someone, that person then overdoses and dies, or hurts someone else; we could be sued for not following standard of care. We feel that this regulation will open our facilities to more liability.

TDMHSAS Response: After consideration, TDMHSAS revised the language originally proposed in 0940-05-42-.07(2)(a)(10) and deleted and combined some, but not all, of those requirements with that proposed in 0940-05-42-.07(2)(a)(9). As amended, 0940-05-42-.07(2)(a)(9) states: "If a prospective service recipient is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years or verification of one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. If clinically appropriate, the program physician may waive these dependency and detoxification requirements for service recipients released from penal institutions (within 6 months after release), for pregnant service recipients with a verified pregnancy and for previously treated service recipients."

(U) 0940-05-42-.07(2)(a)11

BHG: The proposed rule as published and as distributed at the January 5 hearing reads: "Verification shall be obtained that the service recipient has had two documented unsuccessful attempts at detoxification or drug-free treatment within a 24-hour period." There was discussion at the hearing about the apparent typographical error in this provision, in that two attempts at detoxification in a 24-hour period is a factual impossibility. However even assuming the language is corrected to specify some other period of time, the effect of this rule is to deny treatment to patients who cannot demonstrate repeated failures at other forms of treatment that have scientifically proven to be less effective. One major problem with this requirement is that the State does not provide an facilities or support for those attempts at detoxification that the Department is mandating, which is fundamentally unfair to the patient. But perhaps even more significant is the fact that there is absolutely no logical, medical, scientific or other sound rationale for requiring patients to fail at other treatments before allowing them access to the most effective treatment ever utilized for their illness. The State should not dictate the use of a treatment known to be relatively ineffective for an illness before permitting the use of the most effective treatment, and it does not do so in any other circumstance. This 'fail-first' requirement increases the likelihood of harm to patients and should be eliminated.

MIDSOUTH: "Verification shall be obtained that the service recipient has had two documented unsuccessful attempts at detoxification or drug-free treatment within a 24-hour period. "The speed of getting responses from other treatment centers, if we can obtain correct contact information, and if they still exist, is not under OTP's control. Many patients do not have insurance, cannot afford the money or the time away from their job and family to attend other treatment programs. Many areas of the state do not have other appropriate treatment facilities

available, and many low or no cost facilities such as Grace House or Serenity House do not have openings for patients. For these and other reasons, this will deny access to care.

SOS: Again this is not a standard requirement in the field. There are no such requirements in the Federal Regulations. Ethics and morality dictate that treatment providers refer a person to another treatment provider, if the person is not eligible or appropriate for services. With the limited resources in Tennessee for persons with no insurance, which describes the majority of our clients/perspective clients, referrals for these individuals will be difficult at best. Again if we refuse admission based on the proposed regulation, which is not standard of care, and something happens to the perspective client. Would we not, as well as the State, be held liable for not adhering to standard of care?
"Treatment needs to be readily available. Because drug-addicted individuals may be uncertain about entering treatment, taking advantage of available services the moment people are ready for treatment is critical. Potential patients can be lost if treatment is not immediately available or readily accessible. As with other chronic diseases, the earlier treatment is offered in the disease process, the greater the likelihood of positive outcomes". National Institute on Drug Abuse (NIDA)
Requiring two previous unsuccessful attempts in a 24-month period is going to limit greatly the access to treatment for many people. Research has shown that once a person relapses, after a treatment episode, the time period to seek treatment again is greater than two years. This is even truer for a person, who has relapsed twice, after treatment. This regulation will deny treatment to many people, who are in desperate need.

VOLUNTEER: The required verification of prior unsuccessful attempts at detoxification or drug-free treatment is arbitrary and should be deleted. Such requirement, by rule, imposes a medical judgment regarding appropriate treatment options which is beyond the scope of the Commissioner's authority.

TDMHSAS Response: TDMHSAS has deleted 0940-05-42-.07(2)(a)(11). See TDMHSAS's Response to Comment regarding 0940-05-42-.07(2)(a)(9) and (10) above. TDMHSAS feels that the comment for (T) was handled in the changes made to 0940-05-42-07(2)(a)(9).

(V) 0940-05-42-.07(3)

Continuum: This is – appropriately – required prior to beginning treatment and for release of confidential patient information under almost any circumstances. It is most strongly urged that informed consent, in writing, *also* be obligatory prior to initiation of voluntary *discharge*. The provider should be obligated to inform the patient of the consistent evidence that following detoxification (for any reason) relapse to illicit drug use is the rule rather than the exception, and that such relapse is associated with a very marked increase in likelihood of fatal overdose. Indeed, providing this information to applicants and patients should be mandatory *at the time of admission* to treatment as well, and mentioned explicitly in the "consent to treatment."

TDMHSAS Response: We disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(W) 0940-05-42-.07(10)

SOS: We have policies and procedures that are in place (and in writing) that covers all of these situations. Is this "written report" something else? If so, why?

TDMHSAS Response: After consideration, TDMHSAS deleted the language "[a] written report" and inserted the language "[d]ocumentation that the service recipient was informed about".

(X) 0940-05-42-.08(3)

VOLUNTEER: The requirement to verify that the service recipient is not receiving similar services from another OTP within a one hundred and twenty-five (125) mile radius is arbitrary and overly burdensome, and should this be deleted. The cost of compliance with this single requirement would be significant and would add no real value to patient care.

TDMHSAS Response: We agree. TDMHSAS changed the radius from 125 miles to 75 miles.

(Y) 0940-05-42-.10(2)

VOLUNTEER: Requiring service recipients to be treated as new patients when they transfer to a new OTP, or re-enroll is an arbitrary burden of unnecessary paperwork. This requirement should be deleted or revised into a more reasonable requirement based on a valid regulatory purpose.

TDMHSAS Response: TDMHSAS disagrees that requiring service recipients to be treated as new patients when transferring to a new OTP or re-enrolled is a burden of unnecessary paperwork. TDMHSAS feels that such a service recipient should be treated as a new service recipient so that the new facility can gain the requisite knowledge about the terminated service recipient. A terminated service recipient should not be instantly eligible for take-home doses when they move to a new facility. Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(Z) Rule 0940-05-42-.12(3)b

MIDSOUTH: "Drug use is not necessarily a reason for discharge", conflicts with .18(9)(d), which requires discharge after a 4th positive UDS. Patients must be treated on an individualized basis, and treatment planning should be the purview of the medical provider and treatment team.

TDMHSAS Response: After consideration, TDMHSAS made a revision to reflect the need to treat service recipients on an individualized basis. As amended, "[t]he treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective.

(AA) 0940-05-42-.14(3)(a-d)

MIDSOUTH: 2 times per week counseling for 90 days is a significant increase, and may pose a hardship for patients who are employed, or have family responsibilities. Counseling is already conducted according to the current regulations, and is conducted more frequently on an individualized basis.

SOS: Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005. Page 88 "Ideally, service intensity should depend on the level of care required to help patients achieve and maintain successful treatment outcomes".
Page 125 "Usually, individual sessions during the acute phase are more intensive than those that follow, although individual needs should dictate the frequency and duration of counseling".
Comment also referred reader to pages 88 and 125 of TIP 43.

TDMHSAS Response: TDMHSAS recognized that this rule needed clarification. Therefore, TDMHSAS revised the rule to state as follows:

(a) During the first 30 days of treatment, counseling sessions shall take place twice a week.
(b) During the next 90 days of treatment (day 31-120), counseling sessions shall take place at least once a week.
(c) During the following 90 days of treatment (day 121-210), counseling sessions shall take place at least two times per month.
(d) For subsequent 90 day periods of treatment (day 211 forward), counseling sessions shall take place as needed or indicated in the service recipient's IPP, but not less frequently than monthly as long as the service recipient is compliant.

(BB) 0940-05-42-.16(1)(a)(1)

MIDSOUTH: "Pharmacy". OTP's do not have pharmacies; they have dispensaries for 1-2 medicines. See comments on section .30(3)9.

TDMHSAS Response: TDMHSAS has removed the "pharmacy" provision.

(CC) 0940-05-42-.16(1)(a)(3)

VOLUNTEER: The Commissioner has authority to regulate mental health facilities. He/she does not have authority to direct the activities of physicians and pharmacists. Thus, the Commissioner may not specify how physicians and pharmacists transmit and respond to verbal orders. This provision is void and should be deleted.

TDMHSAS Response: TDMHSAS has removed the language regarding the pharmacy requirements. Additionally, the subject of this comment was already contemplated in existing OTP rule (0940-05-42-.06).

(DD) 0940-05-42-.16(1)(a)(5)

BHG: The first proposed rule (0940-05-42-.16(1)(a)5) refers to a dosage's being "dispensed by the pharmacist," and the second (0940-05-42-.30(3)(g)) provides than an "OTP shall provide on-site pharmacist services for the dispensing of opioid drugs." this rule violates applicable State law governing the practices of both physicians and pharmacists and would unlawfully discriminate against physicians operating in OTPs. Rules governing the practice of pharmacy are promulgated by the Tennessee Board of Pharmacy and are beyond the scope of this Department. *See* Tenn. Code Ann. § 63-10-304. The Board of Pharmacy's rules provides provide that "[a] pharmacist may compound and dispense prescription drugs and devices and related materials *only in a pharmacy practice site which is duly licensed by the board [of pharmacy]* and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy." Tenn. Comp. R. & Regs. 1140-03-.02 (emphasis added). Because OTPs are not licensed pharmacies, it would constitute a violation of State law for a pharmacist to be employed to dispense medication on-site. Rather, OTPs are able to deliver medication to patients under the legal authority of all physicians to dispense medication as part of their practice, either personally or through a "licensed supervisee pursuant to appropriate protocols or medical orders." *See* Tenn. Comp. R & Regs. 0880-02-.14. The Department's proposal to carve out an exception to that legal authority for physicians practicing in OTPs is arbitrary, exceeds its authority and violates the constitutional right to equal protection of the law.

SOS: This regulation is unclear. If additional milligrams are ordered by the physician on the first day, nurses can legally administer the medication. All medications are administered in the clinic on the first day, there is no take home medication given.

VOLUNTEER: The Commissioner does not have authority to dictate treatment instructions to a pharmacist. This provision is arbitrary and should be deleted.

TDMHSAS Response: TDMHSAS recognized the need for clarity in this rule. Therefore, TDMHSAS made revisions (changed the word "dispense" to "administer" to clarify that medication does not leave with the patient on the first day of treatment, and took out the provision requiring a pharmacist). However, TDMHSAS respectfully disagrees that these provisions violate state law.

(EE) Rules No. 0940-05-42-.16(1)(a)8, (1)(a)9, (1)(a)10 and (1)(i)1

AATOD: How will the SOTA make determinations with regard to the prescribing of dosages of 100 mgs or greater? What are the special medical qualifications of the SOTA in order to make the appropriate dosage evaluations in view of the fact that the Tennessee regulations are so specific with regard to the expertise of physicians or other licensed service providers? One would assume that the SOTA has equal or greater medical knowledge in making such an assessment. If not, AATOD suggested that this requirement be removed from the regulatory proposal.

BHG: Each of these provisions, both old and new, interjects the State Opioid Treatment Authority ("SOTA") into individual medical treatment decisions that are the province of patients and their healthcare providers, and exceed the scope of the SOTA's authority and expertise. The rules define the SOTA simply as "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." Rule 0940-05-42-.01. There is no requirement that the SOTA be a licensed healthcare provider in Tennessee. Accordingly, having the SOTA in a position to make decisions with respect to the dosage or quantity of medication ordered by a lawful prescriber for a patient would not only unreasonably intrude upon the provider-patient relationship and unnecessarily delay care, but could constitute the unlicensed practice of medicine or professional nursing. *See* Tenn. Code Ann. § 63-6-204(a)(1) (defining the practice of medicine to include treating or prescribing for any physical ailment of another); 63-7-123 (authorizing certified nurse practitioners to prescribe, order and issue medication). Another problem with this proposal is that it embodies a presumption that higher dosage levels of methadone are somehow suspect and inherently to be avoided or limited. Such a presumption is arbitrary and is contradicted by the available data. The CIDE has addressed this issue:

Most patients require a dose of 60-120 mg/day to achieve optimum therapeutic effects of methadone. Compared to those on lower doses, patients on higher doses are shown to stay in treatment longer, use less heroin and other drugs, and have lower incidence of HIV infection. Some patients need even higher doses for fully effective treatment. Studies of methadone, effectiveness have shown a dose-response relationship, with higher doses more effective in reducing heroin use, helping patients stay in treatment, and reducing criminal activity.

Centers for Disease Control and Prevention – IDU HIV Prevention, Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (Exhibit H); see also Eric C. Donny, Susan M. Brasser, et al, *Methadone doses of 100 mg or greater are more effective than lower doses at suppressing heroin self-administration in opioid –dependent volunteers*, 100 Addiction 1496-1509 (2005) (attached as Exhibit T). Accordingly, national guidelines expressly provide that "[t]here are no limits on the duration or the dosage level of medication, unless clinically indicated." CSAT Guidelines for the Accreditation of Opioid Treatment Programs (Draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf (2)(m)(2)(d) at 18 (Exhibit G). Moreover these rules unfairly target prescribers practicing in OTPs for additional and unwarranted state oversight of their orders, to which prescribers –even prescribers of methadone – and their patients in other settings are not subjected. This requirement is arbitrary and illegal.

CONTINUUM: See comments above regarding shifting the responsibility for critical medical decisions, including those that determine dosage, from the treating physician to government appointees whose credentials and experience are unspecified, and who have never seen the patient (and who will probably refuse to acknowledge liability if their decisions have serious adverse consequences). In addition, there appears to be a misunderstanding regarding the significance of "peak and trough" blood concentrations of methadone; such measurements are not utilized to justify need for higher doses, but rather to identify the possibility that *divided* dosages might be more efficacious (though even if split-dosing were found to be indicated, it would probably be precluded by regulatory restrictions on dispensing of "take-home" doses).

NAMA: Reporting dose to the state. The federal government had a similar requirement and found that it was counterproductive to quality treatment. This regulation raises a number of issues:
(1) it sends a message to clinicians that doses over 100 mgs are not good;
(2) most clinicians will not want to report doses over 100 mgs to the state and therefore patients needing a dose over 100 mgs will be left with three decisions:
(a) remain in withdrawal half the day resulting in reduced health;
(b) purchase methadone illegally; or
(c) purchase other narcotics illegally;
(3) quality clinicians begin to leave the state treatment system because they are being forced to practice bad medicine; and
(4) patients will leave the state for treatment elsewhere because they cannot get an adequate dose.

Over time, reporting of dose results in poor quality treatment and low dose clinics. Pain patients are prescribed doses three times the amount of opiate treatment programs and yet only opiate treatment clinicians are required to report doses.

SOS: The current State Opioid Treatment Authority (SOTA) is a pharmacist. This regulation allows the SOTA to practice medicine without a medical license. The SOTA is going to approve a dose of medication for a person that he/she has not ever laid eyes on, has not examined, and has no license to do so. Does this not open the State up for liability? If a person's dose is approved by the SOTA, and the person overdoses and dies, what is the responsibility of the SOTA?
The Federal Regulations puts no cap on the dosage of methadone. We are not opposed to there being a cap and guidelines, but the program physician should have final approval.

VOLUNTEER: The statute does not confer on the Commissioner or the SOTA authority to make treatment decisions. Dictating medication dosage is tantamount to dictating treatment decisions and medical judgment by rule. This exercise of such administrative authority is void and should be deleted. The Commissioner does not have authority to confer upon the SOTA authority to make medical judgments. Treatment decisions should be made by physicians. This rule is arbitrary, not authorized by law and should be completely rewritten or deleted.

TDMHSAS Response: With regard to (1)(a)(8), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. This requirement is in the existing OTP rule (0940-05-42-.11) - written notification to the SOTA is required for dose

increases greater than 100 mgs.

TDMHSAS Response: With regard to (1)(a)(9), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. This requirement is in the existing OTP rule (0940-05-42-.11) - no dose of methadone in excess of 120 mgs may be ordered or administered without the prior approval of the SOTA.

TDMHSAS Response: With regard to (1)(a)(10), we agree. TDMHSAS has deleted this section.

TDMHSAS Response: With regard to (1)(i)(1), we disagree. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State. The 14 day provision prevents abuse by a patient guest dosing for an extended period of time without receiving the required non-medication treatment (i.e.-counseling or drug screens).

(FF) 0940-05-42-.16(1)(c)

BHG: This subsection requires that "[a]ll medications shall be stored in a locked safe when not being administered or self- administered." This provision should be modified to account for the fact that OTP staff must be able to unlock and access the medication supply for other purposes besides administering medications, including stocking, counting and otherwise physically managing the medication supply.

TDMHSAS Response: We disagree in part. The strictness of this provision is designed to prevent diversion of these medications. However, TDMHSAS recognized the need for clarification: TDMHSAS modified the rule so that the supply of medication could be managed without staff violation of the rule.

(GG) 0940-05-42-.16(1)(g)(1)

BHG: This requirement includes terminology, such as "refill instructions" and "prescription order data" that is not appropriate for OTPs and appears geared toward regulation of pharmacies. For the reasons explained above in connection with Rules 0940-05-42-.16(1)(a)5 and 0940-05-42-.30(3)(g), this type of regulation is not appropriate for OTPs. Additionally, this subsection requires prescribers using a computerized system for medication or dosing orders to certify that such information is correct *daily* by either printing and signing each day's medical or prescription data or by maintaining a log attesting that each day's dosing information is correct. This rule as written is both unclear and unduly burdensome. Printing all daily data for signature would defeat the cost and space-saving purpose of electronic record-keeping. Moreover, even the proposed rules do not require prescribers to be on-site daily, so this rule would add a burden that even the Department does not believe is necessary to provide optimal care for OTP patients. This rule is unnecessary and arbitrary. At a minimum, the rule should be modified to clarify that the prescriber is only required to attest to the accuracy of his or her own orders as recorded, and not to the actual dosing that is carried out and recorded by another staff according to those orders. In fact, OTPs are required by 21 CFR Section 1304.24 to maintain a dispensing log detailing all medication activity conducted (dispensed and administered) that indicates which specific licensed practitioner actually dispensed or administered the medication – either by signature or by electronic record that can be reproduced if requested.

VOLUNTEER: The Commissioner has authority to regulate mental health facilities. He/she has no authority over prescribers or the prescribing of medication. Thus, these provisions are overly broad and exceed the authority of the Commissioner and are, therefore, void and should be deleted.

TDMHSAS Response: After consideration, TDMHSAS agrees with the stakeholders' comments and has removed section (g)(1) from the proposed rules.

(HH) 0940-05-42-.16(1)(h)

MIDSOUTH: Checking PMP at random, about 1-2 times per year is reasonable, requiring more often is not. Over the past 3 years or so, I have been checking it on a random basis, and it can very occasionally be a therapeutic tool.

TDMHSAS Response: We concur. TDMHSAS has revised this section of the proposed rules to require the Facility to check the PMP database upon admission of the service recipient, at least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient, and

thereafter as clinically indicated. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred.

(II) 0940-05-42-.16(1)(i)1-3

BHG: This rule (.16(1)(i)(2)) provides that patients are ineligible for guest doses treatment for the first thirty days of treatment. The effect of this rule is that newly enrolled patients will be prohibited from traveling away from their home facilities for more than a day. In essence, the rule penalizes patients for beginning treatment for their addiction, which is a decision that both the State and healthcare providers should, instead, be supporting and encouraging. While likely intended to ensure safety, this requirement is not supported by any factual or medical rationale and should be modified to provide OTP Medical Directors with the ability to approve guest dosing privileges to newly enrolled patients with a documented justification for doing so.

VOLUNTEER: The administration of medication to a patient is a medical decision requiring medical expertise and judgment. The statute does not confer upon the Commissioner or the SOT authority to make medical judgments for patients through the regulatory process. Thus, this rule is void and should be deleted.

TDMHSAS Response: We disagree. TDMHSAS feels that the proposed rule, as written, will help ensure that service recipients are clinically stable before participation in guest dosing. OTPs can request that the SOTA approve guest dosing for service recipients enrolled at the home clinic for less than thirty days. No change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(JJ) 0940-05-42-.17

BHG: Subsection (2) of this rule may be read to require that OTPs revoke a patient's take-home privileges any time a patient fails to report information about prescriptions from outside physicians. This type of punitive measure is often not warranted by the circumstances and should be considered on an individualized basis rather than dictated without exception by the Department. National guidelines recognize that take-home privileges are a key component of OTP treatment plans and should be left within sound professional judgment of the patient's physician and treatment team staff in accordance with the criteria set forth in the applicable federal regulation, 42 CFR 8.12(h):

Providing medication for unsupervised use is a reflection of the physician's judgment and staff's assessment of a patient's behavior while in treatment. Time in treatment is also an important factor. Take-home medication is a valuable therapeutic tool and is part of an individualized treatment plan. Program policies that do not permit take-homes for any patients are unacceptable as these policies would preclude individualized patient care. Take-home medication often becomes a critical issue with patients who are deciding whether to enter and remain in treatment. CSAT Guidelines for the Accreditation of Opioid Treatment Programs, http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf 2(v)(1)(a) at 32 (Exhibit G). This rule should be modified to clarify that loss of take-home privileges is one option to be included in the OTP's guidelines, but that it is not mandatory in every instance of failure to report.

TDMHSAS Response: We disagree. TDMHSAS would like to clarify that that the section concerning the failure to report prescriptions from outside physicians only requires that the loss of take-home privileges be included in the program's procedures for dealing with the failure to report. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(KK) 0940-05-42-.18(2)(a) and (b)

BHG: This subsection provides that "[d]rug screen procedures shall be individualized", then proceeds to mandate a schedule of drug screens, while the remainder of section .18 dictates both the substance and the OTP responses to the screens. National guidelines provide that after admission, "the frequency of toxicological testing is determined by the clinical appropriateness for each individual patient and related to the stage of treatment." *Id.* 1(s)(8) at 26. This subsection should be amended to clarify what is meant by "individualized" drug screening procedures, as the proposed rules are internally inconsistent on this point.

SOS: (2)(a) Requires **weekly** random drug screens for new recipients during the first 30 days of treatment. (2)(b) Requires new recipients be tested upon admission and at approximately **14 days** of treatment. What is the requirement here, weekly or at 14 days? This needs clarification.

VOLUNTEER: The language in (a) and (b) are in conflict. VTC recommends retaining the language in (b) and deleting the language in (a).

TDMHSAS Response: We concur. TDMHSAS has revised this section of the proposed rules to state as follows: "Drug screening procedures shall be individualized and shall include at least weekly random drug screens for newly admitted service recipients during the first 30 days of treatment and at least monthly thereafter."

(LL) 0940-05-42-.18(6)

BHG: Subsection (c) specifically requires that the screen for benzodiazepines include detection of diazepam, clonazepam, alprazolam and lorazepam. A test for clonazepam is not included in the typical benzodiazepine panel, and its addition would be both costly and unnecessary in the vast majority of cases. Clonazepam is used far less frequently in our patient population than other drugs for which we routinely screen, and OTP practitioners are in the better position to determine when screening for this drug is necessary in light of a patient's drug abuse history and other indicators than is the Department National guidelines provide that "Drug testing should be determined by community drug use patterns and individual medical indications." *Id.* 2(s)(4) at 26. This requirement should be eliminated in favor of the individualized approach to care that underlies the provider-patient relationship and the majority of the proposed rules at issue.

VOLUNTEER: This list of drug screens that shall be performed is overly broad and arbitrary. Discretion should be left to the treatment professional working with the service recipient. Further, the added expense for the costly new screens may not yield any benefit to the patient. This language should be deleted.

TDMHSAS Response: After reviewing the comments to this section, TDMHSAS made a revision to provide that each sample collected shall be screened to include, but not be limited to, opioids including synthetics and the broad category of benzodiazepines.

(MM) 0940-05-42-.18(7)

BHG: This subsection requires that "[c]ollection and testing shall be done in a manner that assures a method of confirmation for positive results and documents the chain of custody of the collection." This provision should be modified to clarify exactly what is required. Given the volume of drug screens required by OTPs, it is impracticable to maintain a urine sample for every on-site (instant) test conducted, and the expense associated with attempting to do so would increase operating costs and patient fees.

TDMHSAS Response: We agree. TDMHSAS has revised this section of the proposed rules to follow the existing OTP rule (0940-05-42-.06). As amended, this section of the proposed rules states: "Collection and testing shall be done in a manner that assures that urine collected from service recipients is unadulterated. Such collection and testing may include random direct observation conducted professionally, ethically and in a manner which respects service recipients' privacy."

(NN) 0940-05-42-.18(9)

AATOD: According to AATOD, the provisions in this section are generally reasonable until you get to the section of responding to positive drug test results. The regulations set forth the idea that the fourth positive drug test results within a six month period of time would require the patient to be immediately discharged. This recommendation runs counter to federal Treatment Improvement Protocols on this topic as published by SAMHSA in 2005 (TIP #43), Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs. AATOD goes on to quote the following from Chapter 9 within the TIP, Drug Testing as a Tool: "For patients who continue to abuse drugs or test negative for treatment medication, the consensus panel recommends that OTPs institute more frequent, random tests. Increased testing provides greater protection to patients vulnerable to relapse because only short periods pass before a therapeutic intervention can be initiated. However, as emphasized throughout this chapter, programs should avoid making treatment decisions affecting patients' lives that are based solely on drug test reports." The chapter goes on to state that "OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result." Basically, the federal recommended guidelines underscore the fact that OTPs should use the drug testing results clinically and not punitively. Such drug tests results should be used as a guidance to intervene more frequently with the patient and to make appropriate therapeutic dosage determinations. According to AATOD, in

view of the long-term literature with regard to patient relapse once treatment has ended (greater than 80% of this patient population), this requirement should be eliminated.

BHG: This subsection requires that patients with positive drug test results participate in weekly counseling meetings "with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules." This provision should be amended to conform to the qualifications for counselors provided in Rule 0940-05-42-.30(4)(g). But far more importantly, this subsection goes on to mandate increasingly proscriptive treatment for patients suffering from relapse of their illness, including mandatory discharge upon a fourth positive drug screen. this punitive approach to a patient's illness is contrary to the standard of care and evidences a fundamental misunderstanding of addiction and its treatment. National guidelines provide that "clinical decisions about take home or discharge are not based on toxicology test reports solely." *Id.* 2(s)(9) at 26. In its Treatment Improvement Protocols, the National Center for Substance Abuse Treatment counsels that numerous studies indicate that involuntary discharge leads to serious negative consequences for patients:

[P]atients who were discharge from medical maintenance or long-term detoxification treatment had consistently worse outcomes than patients who remained in treatment. Zanis and Woody (1998) found substantial increases in death rates among those involuntarily discharged for continued drug use. The consensus panel strongly recommends that involuntary discharge be avoided if possible, especially when patients would like to remain in and might benefit from [methadone-assisted treatment]. Center for Substance Abuse treatment, TIP 43 Chapter 8, Approaches to Providing Comprehensive Care and Maximizing patient Retention. SAMHSA/CSAT Treatment Improvement Protocols. Rockville (MD): Substance Abuse and Mental Health Services Administration (US): 1993, *available at* http://www.ncbi.nlm.nih.gov/books/nbk25994/ (attached as Exhibit U). The panel particularly cautions against discharge for continued substance abuse:

The consensus panel recommends that patients receive every chance to continue treatment and that treatment last as long as it is effective. Program effectiveness may be determined by comparing a patient's substance use and overall adjustment at admission with his or her current status. . . . Studies have shown significant improvement in patients even when complete abstinence was not achieved (e.g., Strain et al. 1999); therefore, caution should be used in judging patients' progress in MAT based solely on drug tests.

Id. Similarly, the CDC has advised that "[r]ealistic expectations of treatment reflect the understanding that recovery is a day-to-day process with occasional relapses." Centers for Disease Control and Prevention – IDU HIV Prevention. Methadone Maintenance Treatment, February 2002, *available at* http://www.cdc.gov/idu/facts/methadonefin.pdf (Exhibit H). National guidelines, therefore, provide that "It is not uncommon for a patient to relapse. there is both an individual and public health advantage to maintaining a patient on medication, even when psycho-social treatment may not be yielding optimum results," and that "A major goal for programs is to retain patients for as long as they can benefit from treatment and express a desire to continue it." CSAT Guidelines for the Accreditation of Opioid Treatment Programs (Draft), http://www.dpt.samhsa.gov/pdf/draft_accred_guidelines.pdf 2(m)(1) at 18 and 2(n) at 19 (Exhibit G). Contrary to the advice of these experts and voluminous scientific studies underlying their guidance, the Department would have OTPs arbitrarily discharge upon a fourth positive drug testing six months a patient whose pre-treatment drug use may have been chronic and debilitating. And significantly, the Department would do so with the full knowledge that the patient as *no other alternative* for treatment in this State.

Drug addiction, by its very nature, is a "chronic, relapsing disease of the brain," and "[r]elapses are more the norm." Alan I. Leshner, *Addiction Is a Brain Disease, and It Matters*, 1 Focus 190-193 (2003) (reprinted with permissionfrom278 Science 45-47 (1997) (attached as Exhibit V). Accordingly, as with other chronic illnesses such as diabetes and chronic hypertension, "a reasonable standard for treatment success [is] the management of the illness, not a cure." *Id.* OTPs help patients suffering from addiction manage their illness by addressing the causes and appropriate treatments for relapse on an individualized case-by-case basis, just as an endocrinologist would treat a diabetic patient with blood sugar spikes despite insulin therapy or a cardiologist would treat a hypertensive patient with blood pressure spikes despite antihypertensive medication therapy. Requiring OTPs effectively to punish their patients and even discontinue treatment based on their exhibiting a symptom of their disease is the equivalent of requiring a physician to discontinue insulin treatment to a diabetic patient. The results can be deadly. SAMHSA reports that "research shows that patients in whom methadone therapy is discontinued have mortality rates three to four times higher than patients in whom methadone therapy is continued." U.S. Dep't of Health & Human Services, Substance Abuse & Mental Health Services Admin., Methadone-Associated Mortality: Report of a National Assessment (2004)(Exhibit A). The State does not enforce this "cure or give up" approach to any other illness or healthcare provider in the State. Requiring these proscriptive responses

regardless of individual needs and circumstances would be disastrous to patients, arbitrary and a violation of the rights of both patients and providers.

CONTINUUM: This provision is inappropriate and counter-intuitive, and another example of seeking to impose by *fiat* clinical decisions that should be left to healthcare providers. Patients whose laboratory and/or clinical findings confirm the diagnosis (and the severity!) of the condition being treated are those who obviously most *need* the treatment being provided. This provision would be analogous to requiring discontinuation of anti-tuberculosis treatment for patients who suffer persistent hemoptysis, or refusing further insulin to diabetics whose blood sugar for whatever reason(s) – including patient non-compliance with a prescribed diet regimen – repeatedly exceeds a stipulated threshold.

NAMA: Requiring patients to lose their home privileges for a single positive urine. Drug screens are not perfect and false positives do exist and in numbers enough for the federal government to require a warning at the first positive drug screen with no loss of privilege. It was also decided that this would be using the medication as a behavioral tool without first taking some sort of intervention in case of a relapse. A working patient that has a false positive drug screen could be placed in a stressful position having to go daily. We believe that guidelines can be made but not regulated for such decisions.

MIDSOUTH: In total [this section] is an example of a possible method of "upping the ante" or increasing consequences for patients who relapse repeatedly. If it were a law they were breaking, like speeding, having a predetermined sequence of penalties might be fair. However, we are dealing with persons who have a disease that cannot always be controlled by rules or willpower. Addiction treatment professionals will agree that relapse is part of the natural history of addiction. We agree that guidelines for helping motivate addicts to not use their substance of choice are helpful. We also agree that sometimes discharge of a patient is helpful or necessary. We do not agree, however, that mandated discharge of those we are trying to serve is always therapeutic. We must remember that the treatment philosophy of opiate replacement therapy is reduction of harm, and "ongoing multi-drug use is not necessarily a reason for discharge."

SOS: A positive drug test result after the first six months in an opioid treatment program shall result in the following:

(a) Upon the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program; and

2. Immediately revoke the take-home privilege for a minimum of 30 days;

(b) Upon a second positive drug test result within six months of a previous positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling which shall include weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

2. Immediately revoke the take-home privilege for a minimum of 60 days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within a period of six months the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is licensed, certified, or enrolled in the process of obtaining licensure or certification in compliance with the rules on staff at the opioid treatment program;

2. Immediately revoke the take-home privilege for a minimum of 120 days; and

3. Provide mandatory and documented treatment team meetings with the service recipient which shall include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and

documentation that the service recipient has been advised that s/he shall be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test within a six month period, the service recipient shall be immediately discharged from the opioid treatment program, or, at the option of the service recipient, shall immediately be provided the opportunity to participate in a medically-supervised detoxification plan, followed by immediate discharge from the opioid treatment program.

Tennessee is not recognizing Dependency as a chronic, recurring disease. This regulation goes against what years of research recommend for the treatment of Opioid Dependency. The State is redefining what Substance Dependency is, and treatment.

Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005.

On page 154, "programs should avoid making treatment decisions affecting patients' lives that are based solely on drug test reports".

Page 155, "OTP directors should ensure that results are not used to force patients out of treatment and that no treatment decisions are based on a single test result". "OTPs should use drug test results clinically – not punitively – for guidance, treatment planning, and dosage determination".

Page 156, "Again, the consensus panel emphasizes that results should be used to explore different treatment interventions and treatment plans that will reduce and eliminate substance use and improve treatment compliance".

Page 122 "Studies of patients who left MAT prematurely have determined that length of retention was the most important indicator of treatment outcomes. Patients who stayed in treatment a year or longer abused substances less and were more likely to engage in constructive activities and avoid criminal involvement than those who left treatment earlier".

Page 139 "In their review of numerous studies, Magura and Rosenblum (2001) concluded that patients who were discharged from medical maintenance or long-term detoxification treatment had consistently worse outcomes than patients who remained in treatment.

"Zanis and Woody (1998) found substantial increases in death rates among those involuntarily discharged for continued drug use".

"The consensus panel recommends that patients receive every chance to continue treatment and that treatment last as long as it is effective".

"Studies have shown significant improvement in patients even when complete abstinence was not achieved; therefore, caution should be used in judging patients' progress in MAT based solely on drug tests".

Page 186 "Some have argued for early treatment discharge if patients continue using multiple substances. In addition, some State regulations set specific timetables for compliance, although the requirement is unsupported by research".

"Policies favoring treatment termination for patients who use substances negate a fundamental principal- that longer retention in treatment is correlated highly with increased treatment success".

"Consensus panel members have found that, if patients with secondary substance use problems remain in MAT and staff members address overall substance abuse patterns for these patients, many patients stop using nonopioid and nonprescribed substances".

"Without treatment, a person with these problems may continue criminal activity; remain obsessed with substance use; experience severe financial, vocational, and personal problems; and be at increased risk of overdose death".

"Given the importance of retention in MAT for positive outcomes, the consensus panel agrees that a policy of discharge for other substance use is seldom appropriate".

CARF Standards Manual:

Page 109-110.

23. b. Drug screening procedures, including:

(4) Procedures to ensure that drug screening results are not used:
(a) As the sole basis for treatment decisions
(b) As the sole basis for termination from treatment.

23. d. That ongoing drug abuse is not, in and of itself, a reason for discharge unless the person served refuses recommended levels of intensive treatment.

National Institution on Drug Abuse (NIDA): Unfortunately, when relapse occurs many deem treatment a failure. This is not the case: successful treatment for addiction typically requires continual evaluation and modification as appropriate, similar to the approach taken for other chronic diseases. For example, when a patient is receiving active treatment for hypertension and symptoms decrease, treatment is deemed successful, even though symptoms may recur when treatment is discontinued. For the addicted patient, lapses to drug abuse do not indicate failure—rather, they signify that treatment needs to be reinstated or adjusted, or that alternate treatment is needed.

Ethics and morality dictate that a treatment provider refers a person to another treatment provider, if the person is discharged from the facility. We are being forced to discharge a client, who is obviously in a relapse, and we have very limited (if any) place to refer. Again, if this client overdoses and dies, we could be found liable for not adhering to the standard of care. We are being asked by the State to go against Federal regulations and our Accrediting body's recommendations and standards.

VOLUNTEER: Setting forth specific procedures for the result of a positive drug test is overly broad, arbitrary and should be revised or deleted. Treatment decisions should be based on the needs of the individual patient. This one-size fits all approach will negatively impact patient care. Clinical staff should make treatment decisions for each patient.

TDMHSAS Response: We concur. Upon review, TDMHSAS has revised this section of the proposed rules by removing the mandatory detoxification and discharge at the 4th positive drug test; stating that for each positive drug test, the opioid treatment program shall immediately revoke the take-home privilege for a minimum of 30 consecutive days; and modifying the qualifications required for a counselor. As amended, this section of the proposed rules states:

(a) Upon the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision; and

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days;

(b) Upon a second positive drug test result within six months of the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within six months of the second positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory and documented treatment team meetings with the service recipient which shall include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and documentation that the service recipient has been advised that the service recipient may be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test result within six months of the third positive drug test result, opioid treatment program shall:

1. Through an assessment of the service recipient's IPP, address the on-going multi-drug use through increased group and individual counseling, intensive outpatient and residential clinical treatment. The treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. If the service recipient refuses recommended, more intensive levels of care, the service recipient shall be immediately enrolled in an individualized, medically supervised detoxification plan for up to two weeks, followed by immediate discharge from the opioid treatment program.

(OO) 0940-05-42-.18(9)a

MIDSOUTH: [This section] requires licensed, certified, or in process counselors. [Section] .30(4) g recommends that counselors shall be qualified by training, education and/or experience, and is more reasonable. Finding counselors at all, much less licensed, certified, or in process trainees in some parts of Tennessee is difficult to impossible. Some clinics already employ counselors qualified under .30(4)g, but not .18(9)a(1). This would force unemployment for some who have been working with patients in a competent manner, when unemployment and staffing are pervasive issues.

TDMHSAS Response: We agree. TDMHSAS has modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(PP) 0940-05-42-.18(17)(a) thru (d)

BHG: For clarity, this subsection (.18(17)(a)) should be revised to read "Before the *initial* administration of methadone . . .These provisions (.18(17)(b) – (d)) require an OTP to query the Prescription Drug Monitoring Program (PMP) after any positive drug test, at every 90-day treatment review, and every six months for each patient. This volume of PMP query is unduly burdensome, particularly in light of the limited personnel access to the PMP, the frequency of drug screening required by OTPs and the fact that the PMP itself is only updated by the State on a monthly basis. This requirement will be unproductive and costly and result in no benefit to patients. It should be eliminated or modified to require PMP query "when clinically indicated" or on some far less frequent basis than the current proposed rule would require.

VOLUNTEER: This provision is confusing, unnecessary, and overly broad. The "Prescription Monitoring Program" is defined in the Proposed Rule 0940-05-42-.01 as a program that is part of the Department of Commerce and Insurance. It is unclear if this reference is to the same or if a similar program exists at the

Tennessee Board of Pharmacy. Notwithstanding clarification on that point, the Commissioner does not have authority to force mental health facilities to comply with programs administered by other departments without specific authority from the legislature.

TDMHSAS Response: We agree. TDMHSAS accepted the change suggested by the stakeholders.

(QQ) 0940-05-42-.19(1)

SOS: Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs.* Treatment Improvement Protocol (TIP 43). U.S. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration, 2005.

Page 64 "Control of withdrawal symptoms often is insufficient treatment to prevent a relapse to opioid abuse, and detoxification alone may yield only short-term benefits. Research has shown that retention in treatment over an extended period is key to successful outcomes for opioid addiction in many patients, just as it is for other chronic diseases like hypertension, diabetes, and asthma" (McLellan et al. 2000).

"Comprehensive, long-term opioid agonist maintenance remains the treatment with the best track record of controlling opioid use and saving lives".

TDMHSAS Response: We disagree. Although TIP 43 (p. 64) states that long-term detoxification gives service recipients the best chance at not relapsing, service recipients should still have the option of participating in a short-term detoxification program. This provision is not in conflict with TIP 43 (pg. 102), which states: "Although the phases of treatment model is structured for patients admitted for comprehensive maintenance treatment, some patients may be admitted specifically for detoxification from opioids." This provision simply allows a facility the option of providing short-term detoxification services as well as long-term detoxification services. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(RR) 0940-05-42-.19(3)

BHG: This subsection provides that the "program physician shall provide onsite medical supervision and oversight of the detoxification program." OTP Physicians control detoxification by ordering medically appropriate dose changes during their onsite hours. This provision should be modified to clarify that the physician need not be onsite for every clinic visit by a patient undergoing detoxification.

TDMHSAS Response: We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholder.

(SS) 0940-05-42-.19(4)

VOLUNTEER: Standards for detoxification and medically supervised withdrawal should be the same as those for maintenance programs. Less counseling for patients in a detoxification program than they receive in a maintenance program does not promote patient recovery.

TDMHSAS Response: We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholder.

(TT) 0940-05-42-.19(10)(b)

BHG: The word "possible" in this subsection is awkward and not clearly related to medical necessity; it should be replaced with "if deemed medically necessary."

VOLUNTEER: The language contained in this section is so confusing it is impossible to know how to comply. Thus, this provision is void for vagueness.

TDMHSAS Response: We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(UU) 0940-05-42-.19(12)(a)(1)

AATOD: The proposed regulations recommend that OTPs provide an administrative withdrawal schedule that will not be less than a six month period of time for patients who have been maintained for a two year period. A detoxification schedule is considered at 90 days or less in a number of other state regulations. In this particular case, if the state does have an interest in establishing this six month period of time in order to maintain a long-term tapering schedule, there should be some consideration in developing a fund for patient care so that programs will be able to sustain such treatment, in addition to providing other counseling and medical services. Such regulations need to be balanced against the need to ensure that when a patient loses his or her ability to pay for treatment that the withdrawal schedule should not be precipitous and should be related to the length of time the patient has been in treatment in addition to the maintenance dosage and other medical conditions.

BHG: This subsection requires OTPs to provide detoxification treatment for a period of six months or more, free of charge, to a non-paying patient. As discussed above, the decision to discharge a patient involuntarily is extremely serious and is considered by an OTP only as a last resort. However, like all healthcare providers, OTPs must be paid for service rendered in order to keep their doors open and continue to provide care to their patients. Mandating six months of free treatment to nonpaying patients could severely impair the financial viability of OTPs. It is also subject to abuse by patients who may be nearing administrative discharge for other reasons and would stop paying in order to benefit from the continued treatment that is free and mandatory for the OTP under this provision, but no so if the patient is pursuing detoxification or being discharged for other reasons. Moreover, this blanket requirement is contrary to the goal of providing individualized healthcare decision based on each patient's circumstances. Finally and perhaps most importantly for the purposes of this proceeding, this rule if implemented would constitute a regulatory taking without just compensation in violation of the Fifth Amendment of the Constitution of the United States and Article 1, Section 21 of the Constitution of Tennessee.

MIDSOUTH: We agree with the possible underlying motivation of the Department. Rather than summarily discharging patients who do not pay for services and incur large balances, a variety of ways to discontinue MMT are used in our clinic. We work with them as they work with us. Methadone Maintenance clinics are private clinics, for profit. The significant financial losses that will be incurred will have to be offset by increased fees. Word of the policy will spread rapidly, and patients will begin to "game the system". These and other consequences of this requirement will increase the financial burden on patients in this sagging economy, and decrease access to care for other potential patients. As a private provider receiving no state or federal funding, OTP's should not be forced to provide free services.

SOS: The detoxification schedule is considered at 90 days or less in a number of other state regulations and Section 0940-05-42-.01(g) defines "Administrative withdrawal" as usually relatively brief.

We work with clients on an individual basis and take many things into consideration, not just time in treatment. As business owners, we must take into consideration the financial impact of certain decisions. As well intended as the department may be in this, this can and will put a financial hardship on clinics. Clients will quickly learn to manipulate the system and take advantage of this regulation.

Being a private, for-profit business, we are inquiring about the legality of this regulation.

VOLUNTEER: This requirement is excessive and inappropriate and should be withdrawn. Part of compliance with the patient's treatment plan is demonstration of financial responsibility. The proposed provision would create a situation where many patients would leave treatment with enormous bills that they could never pay back. This would result in the patient not being able to afford reentry into an OTP if relapse occurs. Such a broad overreach of authority is void and unconstitutional as it dictates the terms of an agreement between two private parties.

TDMHSAS Response: We agree. TDMHSAS modified this section of the proposed rules to reflect the change suggested by the stakeholders.

(VV) 0940-05-42-.20(1)(b)

VOLUNTEER: This rule creates an unnecessary burden on the patient. We agree with the current call back requirements of six (6) or more take-homes are sufficient.

TDMHSAS Response: We disagree. The more frequent the amount of take home doses distributed, the higher the possibility of diversion of those take home doses. This change was made to minimize the potential for diversion. With the rise of methadone related deaths in TN and the emphasis the state is focusing on prescription

drug abuse, TDMHSAS, through this provision, is attempting to clamp down on the amount of doses that could be potentially diverted. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(WW) 0940-05-42-.20(1)(c)

AATOD: AATOD recommends that the State work with the Drug enforcement Administration and SAMHSA in order to best understand current regulations/policies concerning diversion control plans and call back medication programs. There are recent developments at the federal level concerning the procedures in how such call back programs are used. More careful consideration is needed in developing this policy and certainly a longer time period than the proposed hearing schedule of January 5, 2012 allows.

BHG: This subsection mandates "uniform sanctions for violating take-home policies." This requirement is in direct conflict of the concept of individualized treatment inherent in the provider-patient relationship and underlying many of the Department's own rules. An OTP's response to apparent tampering should be based on the patient's individual circumstances, including the patient history and any explanation provided. The entire notion of "uniform sanctions" should be eliminated from the rules.

TDMHSAS Response: We disagree. The rule simply requires the OTPs to establish written procedures to impose sanctions for a service recipient tampering with take home doses. Accordingly, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(XX) 0940-05-42-.21(5) and (6)

BHG: These provisions require contact with every OTP in an adjoining state within 125 miles upon admission of a new patient in order to avoid dual enrollment. At a minimum, these provisions must be modified to provide that such contact is subject to the patient's written consent, pursuant to the requirements of HIPPA. Moreover, the mileage requirement should be reduced, as the current requirement would force some facilities to contact dozens of out of state OTPs for every patient admission, which is simply infeasible and unnecessary.

CONTINUUM: Federal regulations (CFR 42) clearly specify that central registries containing information about patients receiving methadone maintenance treatment are permitted – but *exclusively* for the purpose of preventing multiple simultaneous enrollment. Any proposed state regulation establishing such a registry should clearly acknowledge this strict and unqualified limitation and specify the key procedures that shall minimize the likelihood of violation. For example, there should be explicit reference to the fact that notification to the registry will be required within a matter of days *after discharge* (for any and all reasons), and that upon such notification all identifying information of the (former!) patient will be expunged. It should also be stated that applicants for treatment who are not actually enrolled will not be included in the registry.

TDMHSAS Response: TDMHSAS accepts the change suggested by the stakeholders and decreased the radius from 125 miles to 75 miles. The issue of written consent is already addressed in .19(2).

(YY) 0940-05-42-.21(7)

SOS: According to the proposed regulations, the IPP is a detailed document. IPP is required to contain both medical and psychological health information that is protected by law. This is too much information to be sent to the Department. How will the Department store this information to maintain confidentiality, and who will have access to it? What if a client refuses consent to release this information to the Department? What is the purpose of the Department having this information?

The following is a list of Code of Ethics regarding disclosure of information:

- American Psychiatric Association. *The Principals of Medial Ethics with Annotations Especially Applicable to Psychiatry 2010 Edition.*

Section 4
A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences and privacy within the constraints of the law.

Psychiatric records, including even the identification of a person as a patient, must be protected with extreme care. Confidentiality is essential to psychiatric treatment. This is based in part on the special nature of psychiatric therapy as well as on the traditional ethical relationship between physician and patient. Growing concern regarding the civil rights of patients and the possible adverse effects of computerization, duplication equipment, and data banks makes the dissemination of confidential information an increasing hazard. Because of the sensitive and private nature of the information with which the psychiatrist deals, he or she must be circumspect in the information that he or she chooses to disclose to others about a patient. The welfare of the patient must be a continuing consideration.

- American Medical Association. Code of Medical Ethics.

Opinion 5.05 – Confidentiality
When the disclosure of confidential information is required by law or court order, physicians generally should notify the patient. Physicians should disclose the minimal information required by law, advocate for the protection of confidential information and, if appropriate, seek a change in the law. (III, IV, VII, VIII)

- American Counseling Association. Code of Ethics.

Section B
Confidentiality, Privileged Communication, and Privacy
B.2.d. Minimal Disclosure

To the extent possible, clients are informed before confidential information is disclosed and are involved in the disclosure decision-making process. When circumstances require the disclosure of confidential information, only essential information is revealed.

- Code of Ethics *of the National Association of Social Workers*

1.07 Privacy and Confidentiality
(c) Social workers should protect the confidentiality of all information obtained in the course of professional service, except for compelling professional reasons. The general expectation that social workers will keep information confidential does not apply when disclosure is necessary to prevent serious, foreseeable, and imminent harm to a client or other identifiable person. In all instances, social workers should disclose the least amount of confidential information necessary to achieve the desired purpose; only information that is directly relevant to the purpose for which the disclosure is made should be revealed.

- American Psychological Association. Ethical Principles of Psychologists and Code of Conduct

2010 Amendments
4.04 Minimizing Intrusions on Privacy
(a) Psychologists include in written and oral reports and consultations, only information germane to the purpose for which the communication is made.
(b) Psychologists discuss confidential information obtained in their work only for appropriate scientific or professional purposes and only with persons clearly concerned with such matters.

TDMHSAS Response: In response to the stakeholder's comment, TDMHSAS revised the type of information required to be submitted by the stakeholders.

(ZZ) 0940-05-42-.22(3)(a)

BHG: This subsection requires a facility to report "[m]edication errors" to the Department and SOTA. This provision should be revised to clarify that the errors included in this requirement are limited to those that cause or had the potential to cause harm to a patient, such as medication dosing errors, and do not include immaterial medication errors such as patient spills or emesis, etc.

TDMHSAS Response: We agree. TDMHSAS accepts the change suggested by the stakeholder.

(AAA) 0940-05-42-.23(3)

BHG: Subsection (3) requires the facility's quality improvement plan to include an "assessment of the average cost of services per service recipient per week and the average charge per service recipient per week." Essentially, this provision requires a facility to include details about its profit margin as part of its plan for quality improvement. This information has absolutely no bearing on the quality of the care provided or how best to improve it, and its inclusion in the quality improvement plan is not supported by any rationale. The requirement would constitute an unwarranted intrusion by the State in the operations of a private entity.

VOLUNTEER: Assessment of the average cost of services is proprietary business information. The Commissioner does not have authority to require submission of such information. It serves no statutory or regulatory purpose to require submission of this information. Thus, the provision is void.

TDMHSAS Response: After review, TDMHSAS revised the language in this section of the proposed rule to reflect the suggestion by the stakeholders.

(BBB) 0940-05-42-.27

SOS: As business owners, who rely on client payments for revenue, it is in the best interest of the clinics to accommodate their clients' needs. We already offer a crisis number for clients 24 hours a day, seven day per week. We do not agree that the state should mandate hours of operation. Hours should be based on the size and needs of each clinic individually. We operate small clinics and can adequately provide the services needed in less time than larger clinics. We do not feel that mandating hours will enhance client care, only the opposite. Clinics will have to increase fees to pay additional salaries to employees to sit idle.
Sunday Dosing – I can only guess that the rationale behind this regulation would be diversion risk. We live and operate a clinic in a small town. We take diversion very seriously and are constantly working on ways to prevent it. However, we feel that requiring clients to come to the clinic on Sundays and holidays will not decrease diversion. Many studies have found that methadone diversion is mainly from prescriptions, not OTP's.

In a report published by the Government Accountability Office in March 2009, on methadone associated overdose deaths, the study concluded that the growing availability of methadone through its increased use for pain management is a contributing factor to the rise in methadone-associated overdose deaths and addiction treatment in OTP's was not related to increased deaths.

We feel this regulation will force more clients out of OTP's and into pain clinics. Pain clinics prescribing methadone is already a problem in Tennessee. This will be a financial burden on clients as many have to travel long distances to get treatment. This requirement takes away a person's ability to spend time with family and their ability to participate in religious activities. It will be much easier and affordable to obtain a 30 day prescription from a pain clinic than being required to be at an OTP seven days a week.

Section 0940-05-42-.27 states that "A facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care, and variable shift work." How does requiring additional days in the clinic accommodate any of these?

TDMHSAS Response: Service recipients who are new to OTP treatment and service recipients who have been found to be diverting medication need to be dosed daily so that the service recipient can be properly assessed and so that the OTP can ensure that the service recipient's medication is not being diverted. TDMHSAS continues to believe that services should be available to service recipients seven days a week; therefore, no change was made to this part.

(CCC) 0940-05-42-.27(1)

BHG: This section begins by requiring that a "facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work." It further requires OTPs to "make dosing and counseling available at least six hours per day from Monday through Friday" and "at least three hours on Saturday." It requires three hours of dosing on Sundays, and provides that "[c]ounseling may be provided on Sunday to accommodate a service recipient's schedule." Subsection (3) mandates that every facility offer comprehensive services including counseling and medical exams at least six days per week. these requirements are wholly arbitrary, as they bear no relationship to the needs of the population served by an individual facility. the proposal requires OTPs to be open 365 days a year, except for 4 nonconsecutive holidays an one training day. This is completely unnecessary and is *not required of any other non-emergent healthcare provider in this State.* In addition to the unwarranted burden placed on the OTPs by dictating this schedule, the effect of this rule

would have serious negative consequences for the patients being served. Bringing patients into the clinic on Sundays, for example, disrupts the patient's sense of freedom of movement and worship and the normal social structure that contributes to successful treatment. The Center for Substance Abuse Treatment has encouraged facilities to improve patient retention by "*[r]educ[ing]* the attendance burden":

Attendance requirements can exert powerful effects on retention.
Rhoades and colleagues (1998) found that patients who were
required to visit an OTP less frequently were less likely to drop out of treatment and no more likely to use other drugs than patients on
a daily attendance schedule.

Center for Substance Abuse Treatment, Chapter 8, Approaches to Providing Comprehensive Care and Maximizing Patient Retention. SAMHSA/CSAT Treatment Improvement Protocols. Rockville (MD): Substance Abuse and Mental Health Services Administration (US): 1993, *available at* http://www.ncbi.nlm.nih.gov/books/nbk25994/(Exhibit U). Increasing the patients' attendance burden where no medically indicated, as required by this and other proposed rules under consideration, would result in increased drop-out rates and more untreated drug addicts in this State. These requirements should be eliminated and left to the discretion of the program and treatment team based on the parameters of 42 CFR 8.

MIDSOUTH: Must be open 365 days per year and close only 4 nonconsecutive days. We oppose this new requirement. Being allowed to close the same amount of holidays as State facilities and other private outpatient treatment facilities is equitable. Limiting to 4 holidays is no safer, does not increase access to care or positive outcomes, and does not minimize diversion. Requiring patients to travel to the clinic on Sundays and holidays decreases important family time and poses a travel hardship for some. Public transportation is not available in northwest Tennessee.

VOLUNTEER: VTC vigorously opposes the requirement to operate seven (7) day per week. Mediation and clinical services are currently offered six (6) days per week. Opening Sundays will not increase admissions. There is no evidence that seven (7) day operation improves any aspect of treatment. Seven (7) day operation creates the need for the patient to travel an extra day to the clinic every week for the first nine (9) months in treatment compared to what they do now. This extra cost to the patient provides no benefit and will reduce access to care. No studies have been provided which demonstrate that seven (7) day operation improves treatment outcomes. If this is being done to prevent diversion, the DEA in multiple reports have declared that the vast majority of diverted methadone on the street is from prescriptions out of pain management and private practices.

TDMHSAS Response: Service recipients who are new to OTP treatment and service recipients who have been found to be diverting medication need to be dosed daily so that the service recipient can be properly assessed and so that the OTP can ensure that the service recipient's medication is not being diverted. TDMHSAS continues to believe that services should be available to service recipients seven days a week; therefore, no change was made to this part.

(DDD) 0940-05-42-.27(3)

SOS: (3) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least six day per week.

This regulation is excessive. There is no reason to offer medical exams on Saturdays. Clinics open very early to accommodate patient schedules. We begin appointments at 5:30 a.m. This should be based on size and need of each clinic. We currently have no need to offer medical exams on Saturdays. No other outpatient treatment providers, including mental health agencies, offer any type of medical services on Saturdays.

TDMHSAS Response: After consideration, TDMHSAS made revisions to this section of the proposed rules as suggested by the stakeholder: Medical exams shall be provided on days when new admissions to the clinic occur.

(EEE) 0940-05-42-.27(7)

VOLUNTEER: As previously stated, VTC objects to putting information about the governing body into the Policies and Procedures as contact information has nothing to do with policies and procedures.

TDMHSAS Response: After consideration, TDMHSAS deleted this section of the proposed rules. However, TDMHSAS disagrees with the stakeholder's characterization of the request for governing body information. The governing body is the licensee and the name and contact for the governing body is already required to be provided pursuant 0940-05-42-.05.

(FFF) 0940-05-42-.29

BHG: This section makes OTPs responsible for ensuring that its patients do not "act in a manner that would constitute disorderly conduct or harassment," and requires them to "assure responsiveness to community needs," including "soliciting . . . community ideas about medication assisted treatment." As discussed above, communities already have an opportunity to raise their concerns about OTPs and the treatment they provide during public CON proceedings. The issuance of a CON constitutes a determination by the State that the OTP is "necessary to provide needed health care in the are to be served, can be economically accomplished and maintained, and will contribute to the orderly development of adequate and effective health care facilities or services," despite any misgivings by members of the community. *See* Tenn. Code Ann. § 68-11-1609(b). Once that express determination has been made, to require OTPs – and no other CON-holders – to continually respond to community complaints about the nature of their operations is unfair, arbitrary and clearly designed to raise the burden to OTPs of providing a treatment that the Department has admitted it opposes on a philosophical basis. Beyond its legal invalidity, the Department's attempt to task OTPs with "***ensuring***" that their patients do not commit disorderly conduct or harassment raises an absolute impossibility. OTPs are no more able to control their patients' off-site behavior than any other health care provider or business establishment. Ironically, however, studies indicate that the most effective means of reducing the incidence of criminal activity in opioid addicts is to provide the very treatment that the Department seems intent on eliminating –methadone maintenance treatment.

Additionally, this entire section suffers from a grammatical awkwardness that makes it difficult to understand exactly what burdens are being imposed. For example, BHG is unable to decipher what is meant by "[i]nclude policies and procedures or resolve community problems" ((2)(b)) or "addressing community concerns and the Facility's presence in the community." ((2)(c)). For the reasons discussed above, the section should be stricken in its entirety. At the very least, it must be complete re-written in order to be decipherable.

TDMHSAS Response: After consideration, TDMHSAS revised this section of the proposed rules to require that OTPs are only responsible for the actions of service recipients while on the OTP's property.

(GGG) 0940-05-42-.30(3)(b)

BHG: This existing rule generally prohibits physicians from serving as medical director of more than one OTP. This prohibition does nothing to improve the quality of care provided to OTP patients, and serves only to make it more difficult for OTPs to find physicians who are qualified and willing to serve in this position. The rule is arbitrary.

VOLUNTEER: This requirement is overly burdensome, arbitrary and provides no benefit to patient care. As long as each facility has adequate physician coverage, the use of one (1) physician in multiple clinics should be allowed. An excellent Medical Director should be allowed to train and lead multiple clinics.

TDMHSAS Response: We disagree. The subject of this comment was already contemplated in existing OTP rule (0940-05-42-.04). Therefore, no change will be made to the rule as proposed in the November 15, 2011 Notice of Rulemaking Hearing filing with the Secretary of State.

(HHH) 0940-05-42-.30(3)(c) and (3)(c)(2)

AATOD: According to AATOD, there needs to be a better understanding of the basis for requiring the physician time and its relation to the use of approved physician extenders (physician assistants, nurse practitioners) or other clinical personnel, who are approved to provide services in OTPs under Tennessee law. Once again, staffing ratios need to be based on the reality of what patients will need as opposed to regulations that have arithmetic calculations without connection to patient outcome.

BHG: This rule requires OTPs to "provide on-site prescriber services of two hours per week for every 15 service recipients," at least 12.5% of which must be provided by a physician. Once again, this requirement evidences an underlying misunderstanding about the nature of OTP treatment. The fundamental nature and work-flows of

addiction treatment in OTPs are centered around counselors, not around physicians. Only on occasion do a small subset of OTP patients require a non-routine level of attention that can only be provided by a physician, and then only for short periods of time. As Dr. Farmer explained at the rulemaking hearing, this proposal is so excessive that it would require her to be present in her facility almost twice as many hours per week as there are actually patients in the facility. Requiring the proposed level of coverage by physicians has shown to be unnecessary to patient care, would not improve patient care, and would serve only to increase the costs of operating an OTP so dramatically that it would create an obstacle to treatment among patients who could not afford the increase and have nowhere else to turn. The proposed rule will ultimately increase the number of individuals not engaged in treatment and actually increase costs to the communities in the form of increased criminality, drug abuse, and acute hospital/ER visits. This requirement should be eliminated or greatly revised. For example, the Department's proposal dated March 31, 2010 reflected requirements that are more consistent with actual OTP medical coverage requirements.

MIDSOUTH: Requires 2 hrs/wk medical provider per every 15 pts. This appears arbitrary and not related to clinical needs. OTP's are more driven by counseling time than by medical provider time. Face to face time with a medical provider is several times per week right after admission, then yearly for annual exams. Some patients request a change in their dose, and this may necessitate a visit. Most patients who must come into the clinic are usually present the first 5 hours of operation. Many patients only come to the clinic every 1-3 weeks. There simply is no clinical need to have a medical provider present 40 hours per week for a 300 patient base. A clinic that size would be required to have a medical provider present 40 hours per week when patients are present in the clinic only 24 hours per week. We recommend that, as in any other medical office, each clinic be allowed to determine staffing hours needed.

VOLUNTEER: The requirements in this section are arbitrary and do not make sense. The level of medical coverage required by this provision is not medically necessary and is not required by any other state in the United States. The primary purpose of these facilities is to provide counseling centered treatment. The on-site physician requirement will not improve patient care and will be possible for only the largest facilities to meet. This will reduce services and access to care.

TDMHSAS Response: After consideration, TDMHSAS revised this section of the proposed rules: An on-site physician will now be required to provide services at the OTP a minimum of one hour per week for every 35 services recipients.

(III) 0940-05-42-.30(3)(g)

MIDSOUTH: Nurses are clinically trained to assess patients for signs of intoxication, withdrawal, and other medical conditions before dispensing medications and pharmacists are not. In clinics and hospitals, nurses dispense medications, and insure that counts of medications are correct. In some diet clinics, 5 to 10 controlled medications are dispensed, and they are not required to have a pharmacist on staff. In dental and surgical clinics, several medications, including controlled drugs may be dispensed without a pharmacist. Most OTP's dispense one medication, and are strictly monitored by the DEA for accountability. In the state of Tennessee, it is within the scope of practice of physicians to dispense. Medicines are dispensed legally and safely without a required pharmacist. Requiring the use of a pharmacist for something a physician is licensed in Tennessee to do is restricting the scope of practice for only selected physicians. This appears to be an arbitrary decision, and we question its legality.

SOS: We do not agree that the addition of a pharmacist to staffing requirements will enhance client care. Physicians and nurses can legally dispense medication in Tennessee. Nurses assess patients every time they dose. Pharmacists are not qualified to make medical assessments. We use automated Sci-Log dispensing pumps in our clinics. We have documentation to support the accuracy of these pumps. We are regulated and inspected by the DEA. We would like to see the department's research on how they feel this will improve patient care. We are not aware of any problems that would have prompted this change?
This proposed regulation adds operating cost with no obvious benefits.

VOLUNTEER: VTC vehemently objects to this arbitrary requirement. OTPs do not operate pharmacies and oversight by a pharmacist is not necessary. This requirement presents an additional, costly financial burden which will reduce access to treatment with no additional benefit to patient outcome or safely.

TDMHSAS Response: After consideration, TDMHSAS removed the pharmacist requirement from this section of the proposed rules.

(JJJ) 0940-05-42-.30(4), (4)(a) and (4)(h)

BHG: Both of these provisions set the credentials required for an OTP medical director and program director unreasonably high. Few physicians have two years of addiction experience, and even fewer have treated opioid addiction with a replacement medication. The American Society of Addiction Medicine does not require board eligibility in psychiatry in order to be certified as an addiction medicine specialist, so the Department's requirement of such eligibility in addition to ASAM certification is unreasonable and clearly unwarranted. The Department has not cited any evidence that patient outcomes have been negatively impacted by current credentialing standards or that the proposed standards would have any beneficial effect on patient care. Given the already limited pool of professionals willing and able to serve in these roles, the proposed requirements will have a significant negative impact on OTP's ability to hire qualified medical directors in order to stay in business. [See also comment re: Rule 0940-05-42-.16(1)(a)(5) herein.]

VOLUNTEER: Requiring one (1) year of supervisory or administrative experience for all program directors is arbitrary and will limit the field of potential candidates at a time when there is great need for the services provided by OTPs. VTC recommends replacing "behavioral healthcare" where "substance abuse" now appears.

TDMHSAS Response: After consideration, TDMHSAS reverted back to the requirements of the existing OTP rule (0940-05-42-.05). Additionally, TDMHSAS revised the medical director qualifications to include board certification as an addiction medicine specialist as an alternative, thereby expanding the pool from which OTPs can choose.

Regulatory Flexibility Addendum
Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

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.

Rules Chapter 0940-05-42 has been written to conform to federal guidelines and regulations for Opioid Treatment Programs (OTPs), incorporating best practices for the treatment of service recipients.

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

As indicated in the comments section, TDMHSAS made several changes suggested by stakeholders participating in the rulemaking hearing to improve rule clarity and conciseness.

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

The Department deleted requirements for financial reporting, reverting to its current requirements for reporting of serious incidents and other matters to the TDMHSAS Office of Licensure and the SOTA, including reporting findings by federal agencies such as the DEA and FDA and accrediting bodies, such as the Joint Commission.

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

Timeframes for laboratory testing were lengthened to conform to federal guidelines. Otherwise, no changes were made to current compliance and reporting requirements.

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

The proposed rules impose no new reporting requirements of costs for reporting on the OTPs. The OTPs will continue to report information impacting the health, safety and well-being of its service recipients to the SOTA and TDMHSAS Office of Licensure.

(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 provide the operational standards necessary to safeguard the health, safety and well-being of service recipients receiving opioid replacement treatment services.

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

Federal and state law requires entry requirements prior to obtaining a license for operation of an opioid treatment program (e.g., TCA §68-11-1607(a)(4)(requires a certificate of need prior to obtaining a Tennessee license)).

Economic Impact Statement

(1) The type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, or directly benefit from the proposed rule.

These rules apply to non-residential opioid treatment programs (OTPs) in Tennessee. One-half

of the twelve OTPs currently operating in Tennessee qualify as small businesses with fewer than 50 employees. All OTPs will bear the costs associated with the proposed rules.

(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 rules impose no new substantive reporting requirements or costs for reporting on the OTPs. The rules envision that the OTPs will continue with current electronic reporting to the SOTA and the TDMHSAS Office of Licensure. The rules further envision that the OTPs will follow current federal law that requires 1) that OTPs be approved by the FDA, DEA and SOTA before beginning operation; and 2) that they obtain and maintain accreditation by a nationally recognized accrediting body. See 42 CFR §8.4.

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

The new rules will have three primary impacts on small businesses. First, OTPs will be required to be open 7 days per week and 365 days per year. Second, OTPs will be required to test service recipients for HIV status (if the prospective service recipient consents to be tested), pregnancy, STDs, tuberculosis, and Hepatitis C. And, third, the OTP will be required to provide on-site prescriber services of 1 hour per week for every 35 service recipients. At least 12.5% of the required prescriber services per week must be provided by a physician.

All of these changes were made to safeguard the health and safety of service recipients. Service recipients currently taking methadone have a higher incidence of infection from TB, HIV, Hepatitis B and C, thereby requiring additional monitoring by a qualified prescriber. Because the half-life of methadone is extremely variable, the effects of methadone accumulate over time and adverse effects can be delayed one to two weeks. These safety concerns resulted in the development of rules allowing for daily monitoring when clinically indicated. The requirement that there be on-site prescriber services of 1 hour per week for every 35 service recipients will allow prescriber (e.g., physician, physician assistant, nurse practitioner) monitoring of service recipients with complex and multiple medical disorders in addition to physical and emotional issues. The proposed rules will increase the quality of care provided to service recipients. The Department developed these rules through extensive research, recognizing the need to protect the health, safety and well-being of the service recipients.

(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.

Because of the safety issues associated with methadone replacement treatment, the Department finds that increased prescriber time is necessary to ensure the safety and well-being of service recipients. In response to cost concerns, the Department allowed up to 87.5% of physician services to be provided by physician assistants or advanced practice nurses with a certificate of fitness for prescribing legend drugs.

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

The proposed rules conform to federal guidelines and regulations governing non-residential opioid treatment programs.

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

The effect of exempting small businesses from all or any part of the requirements contained in the new OTP rule would be inequitable, considering one-half of the total number of OTPs currently operating in Tennessee qualify as small businesses (six of twelve OTPs). More importantly, an exemption would create an environment in which the safety and public health accountability measures contemplated by the new OTP rule would be unevenly applied to the already small number of OTPs currently providing services in Tennessee.

Department of State
Division of Publications
312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 09-07-12
Rule ID(s): 5309
File Date: 9/20/12
Effective Date: 12/19/12

Rulemaking Hearing Rule(s) Filing Form

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

Agency/Board/Commission:	Tennessee Department of Mental Health and Substance Abuse Services
Division:	Office of Licensure
Contact Person:	Kurt Hippel
Address:	710 James Robertson Parkway 11th Floor, Andrew Johnson Tower
Zip:	37243
Phone:	615-532-9439
Email:	Kurt.Hippel@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
X Repeal

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

Chapter Number	**Chapter Title**
0940-05-42	Minimum Program Requirements for Non-Residential Opioid Treatment Program Facilities
Rule Number	**Rule Title**
0940-05-42-.01	Definitions
0940-05-42-.02	Application of Rules
0940-05-42-.03	Licensing Procedures
0940-05-42-.04	Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of SOTA
0940-05-42-.05	Policies and Procedures
0940-05-42-.06	Intake, Admissions, and Discharges
0940-05-42-.07	Service Recipient Record Requirements
0940-05-42-.08	Multiple Enrollments
0940-05-42-.09	Orientation
0940-05-42-.10	Service Recipient Transfers
0940-05-42-.11	Individualized Program Plan
0940-05-42-.12	Special Populations
0940-05-42-.13	Professional Services
0940-05-42-.14	Counseling
0940-05-42-.15	Medication Management
0940-05-42-.16	Pharmacotherapy Guidelines
0940-05-42-.17	Drug Screens
0940-05-42-.18	Detoxification and Medically Supervised Withdrawal
0940-05-42-.19	Diversion Control Plan
0940-05-42-.20	Central Registry
0940-05-42-.21	Reporting Requirements
0940-05-42-.22	Quality of Care
0940-05-42-.23	Infectious Hazardous Waste

0940-05-42-.24	Infection Control
0940-05-42-.25	Managing Disruptive Behavior
0940-05-42-.26	Hours of Operation
0940-05-42-.27	Service Recipients' Rights
0940-05-42-.28	Community Relations
0940-05-42-.29	Personnel and Staffing Requirements

RULES
OF
THE TENNESSEE DEPARTMENT OF MENTAL HEALTH
AND DEVELOPMENTAL DISABILITIES

CHAPTER 0940-5-42
MINIMUM PROGRAM REQUIREMENTS FOR ALCOHOL AND DRUG ABUSE
NON-RESIDENTIAL OPIATE TREATMENT FACILITIES

TABLE OF CONTENTS

0940-5-42-.01	Definitions	0940-5-42-.08	Building Standards
0940-5-42-.02	Licensing Procedures	0940-5-42-.09	Life Safety
0940-5-42-.03	Disciplinary Procedures	0940-5-42-.10	Infectious and Hazardous Waste
0940-5-42-.04	Administration	0940-5-42-.11	Records and Reports
0940-5-42-.05	Admissions, Discharges and Transfers	0940-5-42-.12	Clients Rights
0940-5-42-.06	Basic Services	0940-5-42-.13	Repealed
0940-5-42-.07	Reserved	0940-5-42-.14	Disaster Preparedness

0940-5-42-.01 DEFINITIONS.

(1) Abuse. The infliction of physical pain, injury, or mental anguish on a client by a caretaker. Abuse includes "exploitation" as defined by these rules.

(2) A.D.A. The Americans with Disabilities Act.

(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) Aftercare Plan. A plan which specifies, as appropriate, referral for further counseling and/or treatment services at another level of care, the type of contact, planned frequency of contact and the staff responsible for referrals. The focus of the aftercare phase is to ensure the maintenance of gains made and the ongoing achievement of long term goals.

(5) Alcohol and Other Drugs of Abuse Services:

(a) Treatment Services. Formal, organized services for persons who have abused alcohol and/or other drugs. These services are designed to alter specific physical, mental or social functions of persons under treatment by reducing client disability or discomfort, and ameliorate the signs or symptoms caused by alcohol and/or other drug abuse.

(b) Rehabilitation or Habilitation Services. A range of services for persons who have abused alcohol and/or other drugs. These services may include an array of counseling, vocational, social and/or educational services aimed at restoring overall well being, health and ability to engage in rewarding and/or productive activities.

(6) Assessment. A documented evaluation of a client for the purpose of determining treatment and/or rehabilitation or habilitation needs. An assessment may, but does not necessarily, include examination and tests determined to be necessary by the treatment staff, based on the presenting problems and symptoms of the individual client.

(7) Board. The Board for Licensing Health Care Facilities.

(8) Business Occupancies. Those facilities used for the transaction of business (other than that covered under mercantile), for the keeping of accounts and records, and similar purposes.

(Rule 0940-5-42-.01, continued)

(9) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a resident, 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 resident where cardiac or respiratory arrest has occurred or is believed to be imminent.

(10) Case Management. A series of actions based on the relationship between a person and a case manager, which assist the person and his/her family to access clinical treatment, housing, education, employment, financial, medical, and other support services that the person and the case manager deem necessary for his/her successful community living.

(11) Central Registry. An electronic system used to register clients currently receiving opioid replacement treatment at a NRNTF. The Department or SNA may require NRNTFs to initiate a clearance inquiry and client registration into an approved central registry for the purpose of gathering program information, performance data and to prevent simultaneous enrollment in other NRNTFs.

(12) Chief Executive Officer or Director. The person appointed, designated, or hired by the governing body to be responsible for the day to day operation of the facility or facilities operated by the licensee.

(13) Civil Rights. The rights of personal liberty guaranteed to citizens by the Constitutions of the United States and the State of Tennessee, and by federal and state statutes.

(14) Client. The individual who is the direct recipient of the services provided by the facility subject to the licensure jurisdiction of the Tennessee Department of Health.

(15) Commissioner. The Commissioner of Health or his/her designee.

(16) Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.

(17) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(18) DEA. The United States Drug Enforcement Agency.

(19) Department. The Tennessee Department of Health.

(20) Detoxification. Medical and non-medical procedures resulting in the systematic reduction of the amount of a toxic agent in the body or the elimination of a toxic agent from the body.

(21) Do Not Resuscitate (DNR) Order. An order entered by the client's treating physician in the client's medical records which states that in the event the client suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain

(Rule 0940-5-42-.01, continued)

limiting ~~language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.~~

~~(22) Drug Abuse. A condition characterized by the continuous or episodic use of a drug or drugs resulting in impairment of the user's physical, mental, emotional, or social well being, vocational impairment, psychological dependence or pathological patterns of use as defined in currently accepted diagnostic nomenclature.~~

~~(23) DSM. Diagnostic and Statistical Manual of Mental Disorders (DSM IV is the fourth edition of the manual).~~

~~(24) Exploitation. The improper use by a caretaker of funds which have been paid by a governmental agency to a patient or client or to the caretaker for the use or care of the patient or client; the "borrowing" or improper solicitation, use or conversion of any monies or property paid by a person or entity to a patient or client or to the caretaker for the use of or care of the client; engaging in sexual contact or sexual penetration with a patient or client by the caretaker; coercion, conspiring with or aiding a patient or client to engage in any criminal activity by the caretaker.~~

~~(25) Facility. A treatment resource, counseling center, or other entity providing alcohol and drug abuse services.~~

~~(26) FDA. The United States Food and Drug Administration.~~

~~(27) Governing Body. The person or persons with primary legal authority and responsibility for the overall operation of the facility 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, etc. The Governing Body maintains and controls the program and is legally responsible for the operation.~~

~~(28) Inspection. Any examination by the Department or its representatives of a provider, 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 a provider 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.~~

~~(29) LAAM. The acronym for levo alpha acetyl methadol or levomethadyl acetate hydrochloride (trade name ORLAAM). LAAM is a synthetic opioid agonist which has been approved by the FDA for the maintenance treatment of opiate addiction.~~

~~(30) Licensee. The proprietorship, partnership, association, governmental agency or corporation which operates a facility under the licensure jurisdiction of the Department.~~

~~(31) Licensure. The process by which an agency of government grants permission, to persons or health care facilities meeting qualifications, to engage in a given occupation and/or use a particular title.~~

~~(32) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.~~

~~(33) Maintenance Treatment. The dispensing of a narcotic drug, at relatively stable dosage levels, for a continuous, open ended period deemed medically necessary by a program~~

(Rule 0940-5-42-.01, continued)

~~physician or medical director, in the treatment of an individual for dependence on heroin or other opiate like drugs.~~

~~(34) Medical Director. A physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has been designated by the governing body of the NTF to be responsible for the administration of all medical services performed by the NTF, including compliance with all federal, state, and local laws and rules regarding medical treatment of narcotic addiction. The medical director shall have the experience and credentials specified in subparagraph 0940-5-42-.04 (5) (a) of these rules.~~

~~(35) Medically Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the resident or to achieve the expressed goals of the informed resident. In the case of the incompetent resident, the resident's representative expresses the goals of the resident.~~

~~(36) Medical Record. 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 confinement or services rendered to residents, patients or clients.~~

~~(37) Methadone. A synthetic narcotic agonist which has been approved by the FDA for detoxification and maintenance treatment of narcotic addiction (trade name Dolophine).~~

~~(38) Multidisciplinary Treatment Team (Treatment Team). Professionals which may include a physician, nurse, alcohol and drug abuse counselor and mental health professionals who assess client progress.~~

~~(39) Narcotic Dependent. An individual who physiologically needs heroin or other opiate like drugs to prevent the onset of signs of withdrawal.~~

~~(40) Narcotic Treatment Facilities (NTF). Any program for chronic heroin or other opiate like drug users that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a rehabilitative context; the term facility includes any program or clinic licensed by the Department to operate as a Non-Residential Narcotic Treatment Facility (NRNTF).~~

~~(41) Non-Residential Narcotic Treatment Facility (NRNTF). A non-residential narcotic treatment facility which provides a combination of medical, mental health, and social services for treating the opiate dependent client with the goal of the individual becoming free from any drug which is not medically indicated. Non-residential narcotic treatment services in Tennessee consist of three (3) treatment modalities as follows: Thirty (30) Day Detoxification Treatment, Long-Term Detoxification Program (180 day program), and Narcotic Replacement Maintenance Treatment Program. Clients are admitted to the various modalities based upon client requests and admission criteria defined in the state and federal rules, as medically appropriate. Each modality is further defined as follows:~~

~~(a) Thirty (30) Day Detoxification Treatment. A period of continuous detoxification treatment with narcotic replacement therapy not to exceed thirty (30) days in length for the purpose of assisting the opiate dependent client in reaching a drug free state. There must be at least thirty (30) days between thirty (30) day treatment episodes. An episode of thirty (30) day detoxification is any length of time in which the client receives narcotic replacement therapy for three (3) or more days.~~

(Rule 0940-5-42-.01, continued)

~~(b) Long-Term Detoxification Program. A period of narcotic replacement therapy services or programs in Tennessee not to exceed 180 days. Clients who have completed the 180-day detoxification must wait seven (7) days between Long-Term Detoxification Program episodes.~~

~~(c) Narcotic Replacement Maintenance Treatment Program. That period of continuous open-ended narcotic replacement treatment services as deemed necessary by the program physician/medical director. Clients will be admitted or re-admitted to this modality only after careful clinical evaluation by a multidisciplinary team.~~

~~(42) Narcotic Replacement Treatment. The substitution of a prescription drug which has been approved by the FDA for the treatment of opiate addiction to heroin or other opiate-like drugs.~~

~~(43) Neglect. The deprivation of services, including adequate and nutritious food and drink, by a caretaker, which are necessary to maintain the health and welfare of the client. Neglect includes "exploitation" as defined by these rules.~~

~~(44) Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.~~

~~(45) On Duty/On Site. A staff person who is on the facility's premises and has the obligation to carry out any job responsibilities designated in his/her job description.~~

~~(46) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; 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 such living will shall not be deemed "patient abuse" for purposes of these rules.~~

~~(47) Philosophy of Opiate Dependence and Treatment. A narrative overview as to why persons become opiate dependent which addresses the social, emotional, physiological, and spiritual aspects of dependency. The overview must further address how narcotic treatment and its ancillary services help the opiate dependent person in their recovery.~~

~~(48) Physical Holding. The use of body contact by staff to prevent the client's behavior from becoming dangerous to self, others, or property.~~

~~(49) Physician. A physician is a person who is duly licensed in Tennessee to practice medicine by the Tennessee Board of Medical Examiners or by the Tennessee Board of Osteopathic Examination.~~

~~(50) Policies and Procedures Manual. A document that describes the philosophy, services, organization, policies, and procedures for implementing services to the clients of a facility.~~

~~(51) Program Director (or "Sponsor"). The person designated by the program's governing body who is responsible for the operation of the program, for overall compliance with federal, state and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program.~~

~~(52) Program Physician. Any physician, including the medical director, who is employed by a NTF to provide medical services to clients. Any program physician who is not a medical director must work under the supervision of the program's medical director.~~

(Rule 0940-5-42-.01, continued)

~~(53) Psychiatrist. A physician who specializes in the assessment and treatment of individuals having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has the documented equivalent in education and training, and who is fully licensed to practice medicine in the State of Tennessee.~~

~~(54) Qualified Alcohol and Other Drugs of Abuse Personnel. Persons who meet the criteria described in items (a), (b) and (c) as follows:~~

~~(a) Currently meet one (1) of the following conditions:~~

~~1. Licensed or certified by the State of Tennessee as a physician, registered nurse, practical nurse, clinical or counseling psychologist, psychological examiner, social worker, alcohol and other drugs of abuse counselor, teacher, professional counselor, or marital and family therapist, or, if there is no applicable licensure or certification by the state, has a bachelor's degree or above in a behavioral science or human development related area; or~~

~~2. Actively engaged in a recognized course of study or other formal process for meeting the criteria of part (1) of subparagraph (a) above, and directly supervised by a staff person who meets the criteria in part (1) of subparagraph (a) above, who is trained and qualified as described in subparagraphs (b) and (c) below, and who has a minimum of two (2) years experience in his/her area of practice; and~~

~~(b) Are qualified by education and/or experience for the specific duties of their position; and~~

~~(c) Are trained in alcohol or other drug specific information or skills. (Examples of types of training include, but are not limited to, alcohol or other drug specific services, workshops, substance abuse schools, academic coursework and internships, field placement, or residencies).~~

~~(55) Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.~~

~~(56) Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.~~

~~(57) Reputable and Responsible Character. Possession of a personal, professional and/or business history and practice that recommends the licensed owner or operator or applicant be entrusted with the responsibility for persons with mental illness and those particularly susceptible to participation in illegal, medically dangerous, unhealthy practices and financial and sexual and other forms of exploitation. Personal, professional and/or business histories and practices containing evidence of the operation of substandard facilities, violation of the professional and business licensing laws and regulations of the State of Tennessee and the United States of America are presumed inconsistent with a "reputable and responsible character".~~

~~(58) State Board of Pharmacy. The Board created to regulate the practice of pharmacy pursuant to T.C.A. §63-10-501.~~

~~(59) State Narcotic Authority (SNA). The Tennessee Department of Health or any agency that has been designated in Tennessee to exercise the responsibility and authority for governing~~

(Rule 0940-5-42-.01, continued)

~~the treatment of narcotic addiction with a narcotic drug in accordance with all applicable state and federal regulations.~~

~~(60) Treatment. A broad range of services including outreach, identification, assessment, diagnosis, detoxification, therapy, medical services, lectures/seminars, group process, social services, and follow up or aftercare for individuals with alcohol and other drug problems. The overall goal is to eliminate the alcohol and drug use as a contributing factor to physical, psychological and social dysfunction and to arrest or reverse the progress of any associated problems.~~

~~(61) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.~~

~~(62) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.~~

~~(63) Volunteer. A person who is not paid by the licensee and whose varied skills are used by the licensee to support and supplement the efforts of the paid facility staff.~~

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~0940-5-42-.02 LICENSING PROCEDURES.~~

~~(1) No person, partnership, association, corporation, or state, county or local government unit, or division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the State of Tennessee any NRNTF, as defined, 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 annually on June 30th. The license shall be conspicuously posted in the NRNTF.~~

~~(2) In order to make application for a license:~~

~~(a) The applicant shall submit an application on a form provided by the Department along with a copy of the Certificate of Need (CON), if necessary, issued by the Tennessee Health Facilities Commission or any other applicable state agency. Any condition placed on the CON will also be placed on the license. The written application for operation of a NRNTF must be filed simultaneously with the Substance Abuse and Mental Health Services Administration and the DEA, and/or any other applicable federal agencies.~~

~~(b) Each initial and renewal application for licensure shall be submitted with the appropriate fee or fees. All fees submitted are nonrefundable. The fee rate is based on the number of distinct facility categories to be operated at each non residential site. Any applicant who files 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 under the following schedule:~~

~~1. The Annual License Fee for each NRNTF is $600.00~~

(Rule 0940-5-42-.02, continued)

2. An additional fee of $150.00 is required for each additional distinct facility category to be licensed in conjunction with the above.

(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. Clients shall not be admitted to the NRNTF until a license has been issued. Providing narcotic replacement treatment services without a license is unlawful and will result in civil and/or criminal sanctions pursuant to T.C.A. §68-11-213. A license shall not be issued until the facility is in substantial compliance with these rules and regulations.

(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 the review process.

(e) The applicant must prove the ability to meet the financial needs of the facility.

(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 NRNTF 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 NRNTF's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the NRNTF 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:

(Rule 0940-5-42-.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.

(4) To be eligible for a license or renewal of a license, each NRNTF shall be periodically inspected for compliance with these rules. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.

(5) Every facility owner or operator shall designate a distinctive name for the facility which shall be on the application for a license. The name of a facility shall not be changed without first notifying the Department in writing. The change will be made when renewal of license is due.

(6) A separate license shall be required for each facility when more than one facility is operated under the same management or ownership.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-213, and 68-11-216 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-5-42-.03 DISCIPLINARY PROCEDURES.

(1) The board may suspend or revoke a license for:

(a) Violation of federal statutes or rules.

(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 NRNTF.

(d) Conduct or practice found by the board to be detrimental to the health, safety, or welfare of the clients of the NRNTF.

(e) Failure to renew the license.

(Rule 0940-5-42-.03, continued)

~~(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 clients of 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 a NRNTF 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 NRNTF's license to possible disciplinary action.~~

~~(5) Any licensee or applicant for a license, aggrieved by a decision or action of the Department or board, pursuant to this chapter, may request a hearing before the board. The proceedings and judicial review of the board's decision shall be in accordance with the Uniform Administrative Procedures Act, T.C.A. §4-5-101, et seq.~~

~~(6) Reconsideration and Stays. The Board authorizes the member who chaired the Board for a contested case to be the agency member to make the decisions authorized pursuant to rule 1360-4-1-.18 regarding petitions for reconsiderations and stays in that case.~~

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 4-5-219, 4-5-312, 4-5-316, 4-5-317, 68-11-202, 68-11-204, 68-11-206 through 68-11-209, and 68-11-213 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed March 1, 2007; effective May 15, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.04 ADMINISTRATION.**~~

~~(1) The governing body shall ensure the following:~~

~~(a) The facility complies with all applicable federal, state and local laws, ordinances, rules, regulations and accreditation requirements.~~

(Rule 0940-5-42-.04, continued)

~~(b) The facility is administered and operated in accordance with written policies and procedures.~~

~~(c) There is general direction over the facility and policies established governing the operation of the facility and the welfare of the individuals served.~~

~~(d) A responsible individual is designated for operation of the facility.~~

~~(e) The licensed facility serves only persons whose placement will not cause the facility to violate its licensed status and capacity based on the facility's distinct licensure category, the facility's life safety occupancy classification, and the required staffing ratios.~~

~~(f) A written policies and procedures manual is maintained. The manual shall include the following elements:~~

~~1. A description of each facility service provided by the licensee. The description must include the hours of operation, and admission and discharge criteria.~~

~~2. An organizational chart or a statement which clearly shows or describes the lines of authority between the governing body, the chief executive officer, and the staff.~~

~~3. Policy and procedures which ensure that someone is delegated the authority to act in the absence of the individual responsible for the operation of the facility.~~

~~4. A schedule of fees, if any, currently charged to the client for all services provided by the licensee. The schedule must identify all fees which are chargeable to clients and a copy of the schedule shall be provided to the client, or to a parent, guardian or responsible party during the admission process.~~

~~5. A statement of client rights and a policy which establishes a definite procedure by which grievances presented by the client, his/her physician, relative (friends in some instances), staff or administrator may be handled.~~

~~6. Policy and procedures which ensure the confidentiality of client information and which include the following provisions:~~

~~(i) The facility staff shall comply with applicable confidentiality laws and regulations;~~

~~(ii) The client shall not be required to make public statements which acknowledge gratitude to the licensee or for the licensee's facility services;~~

~~(iii) The client shall not be required to perform in public gatherings;~~

~~(iv) Identifiable photographs of the client shall not be used without the written and signed consent of the client or the client's guardian; and~~

~~(v) A medication administration policy and control procedures for facilities involved in the administration of medication to clients.~~

~~This policy and procedures must include a written notice of rights and responsibilities provided to each client at orientation.~~

(Rule 0940-5-42-.04, continued)

7. The plans and procedures to be followed in the event of fire evacuation, bomb threat and natural disaster emergencies evidenced by a record that the clients and staff have been informed of the procedures.

8. The plans and procedures to be followed in the event of an emergency involving client care which will provide for emergency CPR and initial care at the facility, emergency transportation of clients, emergency medical care, and staff coverage in such events.

9. A policy which prohibits clients from having any of the following responsibilities:

   (i) Responsibility for the care of other clients;

   (ii) Responsibility for the supervision of other clients unless on duty/on site staff are present; and

   (iii) Responsibilities requiring access to confidential information.

10. Policy and procedures to be followed in the reporting and investigation of suspected or alleged abuse or neglect of clients, or other critical incidents. The procedures must include provisions for corrective action to be taken as a result of such reporting and investigation.

11. Policy and procedures which ensure that volunteers, if used by the facility, are in a supportive capacity, are under the supervision of appropriate designated staff members, and understand confidentiality and privacy of the client.

12. Policy and procedures for the purpose of admitting and assessing deaf and hard of hearing individuals which shall include a mechanism for providing sign language interpreters for all clients whose primary means of communication is through manual communication. Interpreters shall be qualified.

13. A policy regarding the use of human subjects in research, if the facility is involved or planning to be involved in such research, which includes procedures for the following:

   (i) Identification of subjects, projects, and staff;

   (ii) Provisions to protect the personal and civil rights of the subjects;

   (iii) Obtaining informed consent of the subjects prior to research;

   (iv) Assurance that all research projects are conducted under the direction and supervision of professional staff qualified by education and experience to conduct research;

   (v) Emergency guidelines for problems that may develop during research activities;

   (vi) Appointment of a facility representative to act as coordinator of the research activities; and

   (vii) An identified individual and phone number for a client/guardian to call if there are any problems that develop during research activities.

(Rule 0940-5-42-.04, continued)

14. Monitoring procedures for multiple enrollment and cumulative time in all prior narcotic replacement treatment episodes with other narcotic treatment programs in Tennessee and participation in the central registries of adjoining states, if the programs are within 125 miles of the adjoining states' boundaries.

15. Pharmacotherapy guidelines for narcotic replacement treatment clients covering the program's own prescribing and review of prescriptions from other physicians which shall minimally include assurance that clients' prescriptions from outside physicians will be reported to the medical staff and reviewed by the program physician.

16. Evaluation criteria, clinical justification process, and ongoing review procedures will be in the form of an annual justification form and a six month update form, completed by the primary counselor, included in the client's chart detailing why a client is to remain in treatment as determined by multidisciplinary team evaluation and signed by the program physician or medical director of the program.

17. Procedures for providing non-narcotic replacement treatment detoxification services to opiate dependent clients who are no longer eligible for further narcotic replacement treatment services. Such services may be provided directly by the agency or indirectly through referrals based on written agreements with other service providers.

18. Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment, including an appropriate time frame over which the procedure would take place.

19. Policy and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures must govern their use and must minimally address the following:

    (i) Any restrictive procedure shall be used by the facility only after all less restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective;

    (ii) The client shall have given prior written consent to any restrictive measures taken with him/her by the staff;

    (iii) The restrictive procedure(s) shall be documented in the Individual Treatment Plan, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;

    (iv) Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and

    (v) The adaptive or desirable behavior shall be taught to the client in conjunction with the implementation of the restrictive procedures.

20. A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the client and may only be used when the client poses an immediate threat under the following conditions:

(Rule 0940-5-42-.04, continued)

(i) The client poses an immediate danger to self or others; and/or

(ii) To prevent the client from causing substantial property damage.

21. Hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work. Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical exams and referral services, at least five days per week. Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days. Facilities shall provide the SNA with at least two weeks notice prior to any change in program hours.

22. A facility that intends to voluntarily close shall notify the SNA no later than thirty days prior to closure. In order to assure continuity of care, any facility which closes, either voluntarily or involuntarily, will comply with all directions received from the SNA regarding the orderly transfer of clients and their records.

23. Each licensee shall clearly identify the governing body in its policies and procedures manual.

24. A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:

(i) The Diversion Control Plan shall apply to all clients receiving more than five (5) take-home medications.

(ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.

(iii) Each client receiving take-home medications must be called back at a minimum of once per three (3) months.

(iv) Upon call back a client must report to the clinic within twenty four (24) hours of notification, with all take-home medications. The quantity and integrity of packaging shall be verified. If take-home medications are liquid or any take-home dose shows evidence of tampering, one dose must be replaced and sent for analysis to verify strength and contents.

(v) The facility shall maintain individual callback results in the client record.

(vi) The facility must maintain a current log of all callbacks with the results of compliance.

(2) Financial Management.

(a) The licensee holding or receiving funds or property for the client as trustee or representative payee will adhere to all laws, state and federal, that govern his/her position and relationship to the client.

(b) The licensee must prohibit staff and proprietors from borrowing money from clients.

(c) The licensee must not take funds or property of the client for the facility's own use or gain.

(Rule 0940-5-42-.04, continued)

(d) The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records must be available upon request by the Department for examination and review by the Department.

(3) Personnel.

(a) 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 and each individual file shall include:

1. Identifying information including name, current address, current telephone number, emergency contact person(s);

2. A ten year employment history or a complete employment history if the person has not worked ten years;

3. Records of educational qualifications if applicable;

4. Date of employment;

5. The person's job description or statements of the person's duties and responsibilities;

6. Documentation of training and orientation required by these rules;

7. Any records relevant to the employee's performance; and

8. Evidence that any professional license required as a condition of employment is current and in good standing.

(b) Wage and salary information, time records, and authorization and record of leave, shall be maintained but may be kept in a separate location.

(c) A job description shall be maintained which includes the employment requirements and the job responsibilities for each facility staff position.

(d) A personnel record shall be maintained which verifies that each employee meets the respective employment requirements for the staff position held, including annual verification of basic skills and annual evaluation of personnel performance. This evaluation shall be in writing. There shall be documentation to verify that the employee has reviewed the evaluation and has had an opportunity to comment on it.

(e) Training and development activities which are appropriate in assisting the staff in meeting the needs of the clients being served shall be provided for each staff member including STD/HIV education. The provision of such activities shall be evidenced by documentation in the facility's records.

(f) Training and development activities which are appropriate in assisting volunteers (if volunteers are used by the facility) in implementing their assigned duties shall be provided for each volunteer. The provision of such activities shall be evidenced by documentation in the facility's records.

(Rule 0940-5-42-.04, continued)

(g) Direct services staff members shall be competent persons aged eighteen (18) years of age or older.

(h) All new employees, including volunteers, who have routine contact with clients shall have a current tuberculosis test prior to employment.

(i) Employees shall have a tuberculin skin test annually and at the time of exposure to active TB and three months after exposure.

(j) Employee records shall include date and type of tuberculin skin test used and date of tuberculin skin test results, date and results of chest x ray, and any drug treatment for tuberculosis.

(4) Staffing.

(a) Program Director. The governing body of each facility shall designate in writing a program 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 narcotic treatment programs, and for all employees including practitioners, agents, or other persons providing services at the facility. Facilities must notify the Department in writing within ten (10) calendar days whenever there is a change in program director.

(b) Medical Director. The governing body of each facility shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state and local laws and regulations regarding the medical treatment of narcotic addiction. No physician may serve as medical director of more than one NTF without the prior written approval of the SNA. Facilities must notify the Department in writing within ten (10) calendar days whenever there is a change in medical director.

(c) Program Physician. Facilities are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve client needs. A program physician's responsibilities include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current DSM criteria, determination of narcotic dependence, reviewing treatment plans, determining dosage and all changes in dosage, ordering take home privileges, discussing cases with the treatment team and issuing any emergency or verbal orders relating to client care. At all times a facility is open and a physician is not present, a program physician must be available for consultation and emergency orders. Facilities must be able to document a referral agreement with a local hospital or health care facility.

(d) Physician's Assistants and Nurse Practitioners. Licensed physician's assistants and certified nurse practitioners may be employed by facilities and perform any functions permitted under Tennessee law.

(e) Nurses. Facilities shall insure that adequate nursing care is provided at all times the facility is in operation and that a nurse is present at all times medication is administered at the facility. Facilities that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols and are properly supervised.

(f) Counselors. There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:

(Rule 0940-5-42-.04, continued)

1. During the first ninety (90) days of treatment, counseling session(s) shall take place at least one time a week;

2. During the second ninety (90) days of treatment, counseling session(s) shall take place at least three (3) times per month;

3. During the third ninety (90) days of treatment, counseling session(s) shall take place at least two (2) times per month;

4. For subsequent ninety (90) day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;

5. If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

(5) Staff Qualifications.

(a) Medical Director. All medical directors shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain their licenses in good standing and shall have the following experience and/or credentials:

1. Three (3) years documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least one (1) year of experience in the treatment of narcotic addiction with a narcotic drug; or

2. Board eligibility in psychiatry and two (2) years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or

3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM).

(b) Variance From Medical Director Qualifications. Facilities that are unable to secure the services of a medical director who meets the requirements of subparagraph (a) above may apply to the SNA for a variance. The SNA has the discretion to grant such a variance when there is a showing that:

1. The facility has made good faith efforts to secure a qualified medical director, but has failed;

2. The facility can secure the services of a licensed physician who is willing to serve as medical director and participate in the training plan;

3. A training plan has been developed which is acceptable to the SNA and which consists of a combination of continuing education in addiction medicine and in-service training by a medical consultant who meets the qualifications specified in subparagraph (a) above; and,

4. A medical consultant who meets the requirements of subparagraph (a) above will be available to oversee the training of the medical director and the delivery of medical services at the program requesting the variance.

(Rule 0940-5-42-.04, continued)

~~(c) Program Physician. All program physicians must be licensed to practice medicine in Tennessee, must maintain their licenses in good standing and must have at least one (1) year of documented experience in the treatment of persons addicted to alcohol or other drugs.~~

~~(d) Variance From Program Physician Qualifications. Facilities seeking to employ a program physician, in addition to the medical director, but are unable to secure the services of a program physician who meets the requirements of subparagraph (c) above may apply to the SNA for a variance. The SNA has the discretion to grant such a variance when there is a showing that:~~

~~1. The facility has made good faith efforts to secure a qualified program physician, but has failed;~~

~~2. The facility can secure the services of a licensed physician who is willing to serve as program physician and participate in the training plan;~~

~~3. A training plan has been developed which is acceptable to the SNA and which consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director; and~~

~~4. The facility employs a qualified medical director who has the experience and credentials specified in subparagraph (a) above, has completed the training program specified in subparagraph (b) above or has completed the continuing education specified in subparagraph (e) below.~~

~~(e) Current Medical Directors and Program Physicians. All physicians serving as medical director or program physician as of the effective date of these rules who do not meet the criteria specified above will be deemed qualified provided that they obtain 50 hours of continuing education in addiction medicine approved by the SNA within two years from the effective date of these rules. At least 25 hours of this continuing education must be obtained within one year from the effective date of these rules.~~

~~(f) Nurses. All registered nurses and licensed practical nurses must be licensed to practice in Tennessee and must maintain their licenses in good standing.~~

~~(g) Counselors. All counselors must be qualified by training, education and experience to provide addiction counseling services as required by these rules.~~

~~(h) Program Directors. All program directors must have at least one year of supervisory or administrative experience in the field of substance abuse treatment.~~

~~(i) Professional Practice. All professional staff, including but not limited to, physicians, pharmacists, physicians' assistants, nurses, and counselors may perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.~~

~~(j) Staff Training and Orientation. Prior to working with clients, all staff who provide treatment and services must be oriented in accordance with these rules and must thereafter receive additional training in accordance with these rules. Orientation must include instruction in:~~

~~1. The facility's written policies and procedures regarding its purpose and description; client rights, responsibilities, and complaints; confidentiality; and~~

(Rule 0940-5-42-.04, continued)

other policies and procedures that are relevant to the employee's range of duties and responsibilities;

2. The employee's assigned duties and responsibilities; and

3. Reporting client progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.

(k) Additional training consisting of a minimum of eight (8) clock hours of training or instruction must be provided annually for each staff member who provides treatment or services to clients. Such training must be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for narcotic treatment such as dosage, based on physician's clinical decision-making and individual client needs; drug screens; take home medication practices; phases of treatment; treating abusers of multiple substances; narcotic treatment during pregnancy; HIV and other infectious diseases; co-morbid psychiatric conditions; and referring clients for primary care or other specialized services. Facilities shall maintain records documenting that each staff member has received the required annual training.

(l) Employee Drug Screening. Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug screening of all facility employees. Each sample collected must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SNA.

(m) Staff Ratios and Responsibilities. The facility shall have sufficient types and numbers of staff to provide the treatment and services required by all applicable state and federal laws and regulations and as outlined in its program description and these rules.

(n) A minimum of one (1) on duty staff member trained in CPR, Heimlich Maneuver, and First Aid shall be maintained.

(6) All health care facilities licensed pursuant to T.C.A. §§ 68-11-201, et seq. shall post the following in the main public entrance:

(a) Contact information including statewide toll free number of the division of adult protective services, and the number for the local district attorney's office;

(b) A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the division concerning abuse, neglect and exploitation; and

(c) A statement that any person, regardless of age, who may be the victim of domestic violence may call the nationwide domestic violence hotline, with that number printed in boldface type, for immediate assistance and posted on a sign no smaller than eight and one half inches (8½") in width and eleven inches (11") in height.

Postings of (a) and (b) shall be on a sign no smaller than eleven inches (11") in width and seventeen inches (17") in height.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-201, 68-11-202, 68-11-204, 68-11-206, 68-11-209, 68-11-210, 68-11-222, and 71-6-121 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18,*

(Rule 0940-5-42-.04, continued)
~~*2003; effective May 4, 2003. Amendment filed April 30, 2003; effective July 14, 2003. Amendment filed April 20, 2006; effective July 4, 2006. Amendment filed July 18, 2007; effective October 1, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.05 ADMISSIONS, DISCHARGES AND TRANSFERS.**~~

~~(1) The facility shall maintain written policies and procedures governing the intake and assessment process and specify the following:~~

~~(a) The information to be obtained on all applicants or referrals for admission;~~

~~(b) The procedures for accepting referrals from outside agencies or organizations;~~

~~(c) The records to be kept on all applicants;~~

~~(d) Any prospective client data to be recorded during the intake process; and~~

~~(e) The procedures to be followed when an applicant or a referral is found ineligible or admission.~~

~~(2) Screening, Admission, and Orientation of Clients.~~

~~(a) A facility may only admit and retain clients whose known needs can be met by the facility in accordance with its program purpose and description and applicable federal and state laws and regulations. Written policies and procedures for client referral, intake, assessment, and admission must be established and implemented and must include the following provisions or requirements:~~

~~1. Screening. All applicants for admission must be initially screened by facility staff to determine eligibility for admission. No applicant may be processed for admission until it has been verified that he or she meets all applicable criteria, and that the sources and methods of verification have been recorded in the applicant's case folder. The screening process must include:~~

~~(i) Verification, to the extent possible, of an applicant's identity, including name, address, date of birth and other identifying data;~~

~~(ii) Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence, determination by medical examination performed by a program physician of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group, and determination of current DSM diagnosis;~~

~~(iii) Medical history, including HIV status, pregnancy, current medications (prescription and nonprescription), and active medical problems;~~

~~(iv) Psychiatric history and current mental status exam;~~

~~(v) Physical assessment and laboratory tests, including drug screens and HIV status (if the applicant consents to be tested), pregnancy, STD, and Mantoux TB tests;~~

~~(vi) If an applicant has previously been discharged from treatment at another methadone clinic or program, the admitting facility must initiate an~~

(Rule 0940-5-42-.05, continued)

~~investigation into the applicant's prior treatment history, inquiring of the last program attended the reasons for discharge from treatment;~~

~~(vii) Determination if the applicant needs special services, such as treatment for alcoholism or psychiatric services, and determination that the facility is capable of addressing these needs either directly or through referral;~~

~~(viii) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the applicant;~~

~~(ix) If an applicant is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of one year; and~~

~~(x) If an applicant is under 18 years of age, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years.~~

~~2. Assessment. Each client admitted to the facility must be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether narcotic substitution, short term detoxification, long term detoxification, or drug free treatment will be the most appropriate treatment modality for the client. The evaluation must include an assessment of the client's needs for other services including treatment, educational and vocational.~~

~~3. Admission.~~

~~(i) Consent. Except as otherwise authorized by law, no person may be admitted for treatment without written authorization from the client and, if applicable, parent, guardian or responsible party. The following information must be explained by a trained staff person to the client and other consenters, and documented in the client file:~~

~~(I) The program's services and treatment;~~

~~(II) The specific condition that will be treated;~~

~~(III) The expected charges for services including any charges that might be billed separately to the client or other parties; and,~~

~~(IV) The facility's rules regarding client conduct and responsibilities.~~

~~(ii) Admission Clearance. No person may be admitted unless the facility conducts an inquiry with the Central Registry in accordance with rule 0940-5-42-.05 (4).~~

~~(iii) Orientation. The facility shall provide orientation to clients within 24 hours of admission for treatment. Orientation must be done by a staff person who has been determined to be qualified by education, training, and experience to perform the task. Facilities shall ensure that each client signs a statement confirming that the following information has been explained to the client:~~

(Rule 0940-5-42-.05, continued)

(I) The expected benefits of the treatment that the client is expected to receive;

(II) The client's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

(III) An explanation of individualized treatment planning;

(IV) The identification of the staff person who is expected to provide treatment or coordinate the treatment;

(V) Facility rules including requirements for conduct and the consequences of infractions;

(VI) Client's rights, responsibilities, and complaint procedures;

(VII) Drug screening policies and procedures; and

(VIII) HIV information.

(b) Drug dependent pregnant females must be given priority for admission and services when a facility has a waiting list for admissions and it is determined that the health of the mother and/or unborn child is more endangered than is the health of other clients waiting services. Pregnancy tests for females must be conducted at admission and at least annually thereafter, unless otherwise indicated.

(c) No facility may provide a bounty, free services, medication or other reward for referral of potential clients to the clinic.

(d) Non-Admissions. The facility shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs must identify the reasons why the persons were not admitted and what referrals were made for them by the facility.

(3) Discharge and Aftercare Plans. A facility must complete an individualized discharge and aftercare plan for clients who complete their course of treatment. This plan must be developed prior to discharge and must be completed within seven days of discharge by the person who has primary responsibility for coordinating or providing for the care of the client. It must include a final assessment of the client's status at the time of discharge and a description of aftercare plans for the client. The client must participate in discharge and aftercare planning and, if applicable, parents or guardian, or responsible persons should participate.

(4) Central Registry.

(a) To prevent simultaneous enrollment of a client in more than one facility, all facilities shall participate in a central registry approved by the Department. Clients must be informed of the facility's participation in the central registry and prior to initiating a central registry inquiry, the facility must obtain the client's signed consent. Within seventy-two (72) hours of admission, the facility shall initiate a clearance inquiry by submitting to the approved central registry the name, date of birth, anticipated date of admission or discharge and any other relevant information required for the clearance procedure. No person shall be admitted to a facility who is reported by the central registry to be participating in another such facility, or in the event a dual enrollment is found, the client must be discharged from one facility in order to continue enrollment at

(Rule 0940-5-42-.05, continued)

another facility. Reports received by the central registry shall be treated as confidential and shall not be released except to a licensed facility, or as required by law. Information made available by the central registry to facilities shall also be treated as confidential.

(b) To prevent simultaneous enrollment of persons in different facilities located in different states, if a facility operates within 125 miles of any adjoining state and that state also has a central registry, the facility shall, at the direction of the SNA, also participate in the central registry of the adjoining state.

(5) The facility shall provide services, as available, to clients to address their needs as indicated on the assessment/ history in the areas of social/ family/ peer, employment/ education/ financial, emotional/ psychological health, physical health, legal, and community living skills/housing. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers must be documented. The provision of such services to individual clients must be documented in the client record. The facility shall ensure that clients are instructed in the proper storage and security of take home medications after they leave the facility.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 1, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-5-42-.06 BASIC SERVICES.

(1) Quality of Care. The Narcotic Treatment facility will develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

(a) Structured assessment of the program which addresses program management, staffing, policies and procedures and general operations.

(b) A service delivery assessment which at a minimum shall evaluate appropriateness of the treatment plan and services delivered, completeness of documentation in clients' records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out of program services, and availability of services and medications for other conditions (e.g. prenatal, T.B., HIV).

(c) An assessment of utilization and cost effectiveness of the services delivered which shall examine treatment slot utilization and cost per slot, staff to client ratio and cost per counseling session and other support services.

(d) An assessment of medication related issues including take home procedure, security, inventory and dosage issues.

(e) Such process shall serve to continuously monitor the program's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement process must be delegated to a staff person who has been determined to be qualified by education, training, and experience to perform such tasks. The medical director shall be actively involved in the process.

(f) Programs shall participate in additional quality improvement outcome studies as directed by the Department or SNA.

(Rule 0940-5-42-.06, continued)

~~(2) Performance Outcome. The Narcotic Treatment Facility shall monitor performance outcome. The following performance indicators may be used to evaluate the impact of the program on clients and the community:~~

~~(a) Client receipt of needed program or out-of-program services.~~

~~(b) Client satisfaction.~~

~~(c) Client employment status.~~

~~(d) Improvement in medical conditions.~~

~~(e) Drop-out rates.~~

~~(f) Recidivism rates.~~

~~(g) Alcohol use.~~

~~(h) Criminal arrests.~~

~~(i) Illicit drug use, as indicated by drug screens.~~

~~(j) Improvement in social and living standards.~~

~~(3) Staff Training. The Narcotic Treatment Facility shall promote, utilize and provide staff training on current clinical practice guidelines for narcotic replacement treatment. The following areas shall receive emphasis during training:~~

~~(a) Dosage.~~

~~(b) Counseling.~~

~~(c) Urinalysis.~~

~~(d) Phases of treatment.~~

~~(e) Treating multiple substance abuse.~~

~~(f) Narcotic treatment during diseases.~~

~~(g) HIV and other infectious diseases.~~

~~(h) Co-morbid psychiatric conditions.~~

~~(i) FDA approved drugs for the treatment of opiate addiction, including methadone and LAAM.~~

~~(4) Community Relations. The Narcotic Treatment Facility shall develop procedures for community relations to include the following:~~

~~(a) Identify community leaders (representatives within the area in which the clinic is situated as well as in the districts served) and establish interpersonal contact, liaison, education or proactive association in an advisory group with elected officials, health,~~

(Rule 0940-5-42-.06, continued)

~~substance and human service directors, business leaders, law enforcement, religious and spiritual leaders and community grass roots organizations.~~

~~(b) Develop a community relations plan specific to the configuration and needs of the facility within the community to include the following:~~

~~1. Liaison with community representatives.~~

~~2. Define the goals and procedures of the community relations plan.~~

~~3. Provide a mechanism to hear community concerns about the narcotic treatment facility's presence and operations in the community.~~

~~4. Develop policies and procedures to resolve community issues and problems to insure that program operations do not adversely affect community life.~~

~~5. Document all community relations efforts, community contacts and resolutions, and evaluate these efforts and contacts over time.~~

~~(c) A facility shall be responsible for assuring that its clients do not cause unnecessary disruption to the community by loitering in the vicinity or acting in a manner that would constitute disorderly conduct or harassment. Clients who consistently cause disruption to the community or to the facility should be discharged from the program.~~

~~(d) Each facility shall provide the Department, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its clients and the actions it will take to assure responsiveness to community needs. The Department may require that such plan include the formation of a committee to consist of representative members of the community. Such committee shall meet on a regular basis.~~

~~(5) Individual Treatment Planning. A facility must develop an individual treatment plan for each client within thirty (30) days of admission. Clients must be involved in the development of their treatment plans. Treatment plans must document a consistent pattern of substance abuse treatment services and medical care appropriate to individual client needs.~~

~~(a) Medical care, including referral for necessary medical service, and evaluation and follow up of client complaints must be compatible with current and accepted standards of medical practice. All clients must receive a medical examination at least annually. All other medical procedures performed at the time of admission must be reviewed by the medical staff on an annual basis, and all clinically indicated tests and procedures must be repeated. The medical director or program physician shall record the results of this annual medical examination and review of client medical records in each client's record.~~

~~(b) In recognition of the varied medical needs of clients, the case history and treatment plan must be reviewed at least every 90 days for clients in treatment less than a year and at least annually for clients in treatment more than a year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review must also include an assessment of the current dosage and schedule and the rehabilitative progress of the individual, as part of a determination of whether additional medical services are indicated. If this review results~~

(Rule 0940-5-42-.06, continued)

~~in a determination that additional or different medical services are indicated, the facility must ensure that such services are made available to the client.~~

~~(c) When the program physician prescribes other controlled substances to clients in the facility, the facility shall ensure that such prescription is in accord with all applicable statutes and regulations and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any client unless the physician first sees the client and assesses the client's potential for abuse of such medications.~~

~~(d) As part of the rehabilitative services provided by the facility, each client must be provided with individual and group counseling appropriate to his/her needs. The frequency and duration of counseling provided to clients must be determined by appropriate program staff and be consistent with the treatment plan. Treatment plans must indicate a specific level of counseling services needed by the client as part of the rehabilitative process.~~

~~(e) All clients shall receive HIV risk reduction education appropriate to their needs.~~

~~(f) When appropriate, each client must be enrolled in an education program, or be engaged in a vocational activity (vocational evaluation, education or skill training) or make documented efforts to seek gainful employment. Deviations from compliance with these requirements must be explained in the client's record. 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 clients who demonstrate a need for such services. The facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support services recommended and utilized must be documented in the client record.~~

~~(g) All facilities will develop and implement policies for matching client needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling and rehabilitative services provided to a client varies depending upon the client's phase of treatment. Phases of treatment may include intensive stabilization for new clients and those in need of acute care, graduated rehabilitation phases, and for long term stable clients, a medical maintenance or methadone tapering phase.~~

~~(h) Each client's individualized treatment plan must include the counseling needs, including both group and individualized counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.~~

~~(6) Infection Control. A facility must develop policies and procedures to be followed for infection control, including:~~

~~(a) Reporting all suspected or diagnosed cases of infectious disease including tuberculosis, AIDS, and sexually transmitted disease (STD) promptly to the regional health department in accordance with 42 C.F.R., Part 2 and T.C.A. §§68-10-101, 68-9-201 and 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health;~~

~~(b) Management of clients who are infected with Hepatitis B or C Virus, HIV/AIDS or other STD;~~

~~(c) Nondiscrimination of employees and clients regarding their HIV/AIDS status;~~

(d) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens;

(e) Infectious disease testing will be made on a voluntary basis for any client who requests it, and be documented in appropriate records;

(f) Assurance that a client's HIV, other STD, and tuberculosis status will be kept confidential in accordance with "Confidentiality of Alcohol and Drug Abuse Patient Records" (42 C.F.R., Part 2);

(g) Documentation on the establishment of linkages between the facility and the local health department to ensure clients receive appropriate medical care relative to their infection and/or exposure to TB, Hepatitis B or C, and STD (including HIV), i.e., establish contact between the health department and the facility to communicate appropriate information to assure that the client receives appropriate care;

(h) Informed consent of clients before screening and treatment; and

(i) Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus and other sexually transmitted diseases, and tuberculosis.

(7) Client Records.

(a) Facilities must organize and coordinate client records in a manner which demonstrates that all pertinent client information is accessible to all appropriate staff and to the Department. The client Central Registry I.D. number must be shown on each page of the client's record. Each client record must contain, at a minimum, the following:

1. The name of the client.

2. The address of the client.

3. The current telephone number of the client.

4. The sex of the client.

5. The date of the client's birth.

6. The date of the client's admission to the program.

7. The source of the client's referral to the facility.

8. The name, address, and telephone number of an emergency contact person.

9. If the facility charges fees for its services, a written fee agreement dated and signed by the client (or the client's legal representative) prior to provision of any services. This agreement shall include at least the following information:

(i) The fee or fees to be paid by the client;

(ii) The services covered by such fees;

(Rule 0940-5-42-.06, continued)

(iii) Any additional charges for services not covered by the basic service fee; and

(iv) Procedures for medically supervised withdrawal in the event the patient becomes unable to pay for treatment.

10. Appropriate signed and dated informed consent and authorization forms for the release or obtainment of information about the client.

11. Documentation that the client or someone acting on behalf of the client has been informed of the client's rights and responsibilities and of the facility's general rules affecting the client.

12. Documentation of Central Registry clearance as required in paragraph 0940-5-42-.05 (4) of these rules.

(b) Records shall be retained for a minimum of five (5) years even if a facility discontinues operations.

(c) The Department must be notified in advance of a facility's closing.

(d) Upon the closing of any facility, a person of authority representing the facility may request final storage or disposition of the facility's records by the Department.

(8) Drug Screens. The facility shall develop and implement written policies and procedures for random drug screens. These policies and procedures will be for the purposes of assessing the client's abuse of drugs and making decisions about the client's treatment. These policies and procedures must include the following provisions:

(a) Urine drug screens must be conducted on a random basis weekly for new clients during the first thirty days of treatment and at least monthly thereafter. However, clients on a monthly schedule whose drug screen reports indicate drug abuse will be returned to a weekly schedule for at least two weeks, or longer if clinically indicated.

(b) Each sample collected must be screened for opiates, methadone, amphetamines, cocaine, benzodiazepines, THC and other drugs as indicated by individual client use patterns or that are heavily used in the locale of the client or as directed by the SNA.

(c) Facilities shall develop policies to ensure that urine collected from clients is unadulterated. Such policies may include random direct observation which shall be conducted professionally, ethically, and in a manner which respects clients' privacy.

(9) Narcotic Drugs. Facilities shall develop and implement written policies and procedures for prescription and administration of narcotic drugs and their security. These policies and procedures must include the following:

(a) Administration.

1. A program physician shall determine the client's initial and subsequent dose and schedule. If the physician did not perform the medical assessment required in these rules, the physician must consult with the person who performed the assessment before determining the client's initial dose and schedule. The physician shall communicate the initial and subsequent dose and schedule to the pharmacy or the person supervising medication. The physician may assign such

(Rule 0940-5-42-.06, continued)

dose and schedule by verbal order, however, all such orders must be confirmed in writing by the physician within 72 hours.

2. Proper dose should be based on the clinical judgment of the program physician who has examined the client and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, client interview, and specific circumstances pertaining to the individual client.

3. The initial dose of methadone may not exceed 30 milligrams. Additional dosage may be given in the first day where the physician documents that 30 milligrams does not suppress withdrawal symptoms. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring client may receive an initial dosage of no more than the last daily dosage authorized at the former facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the record which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.

4. Clients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the client comfortable for at least 24 hours with no need to resort to illicit opiates to satisfy opiate cravings.

5. The dose must be administered by a professional authorized by law to do so. No methadone may be administered unless the applicant has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures must be completed on the next working day. No take-home medication may be given in such an emergency.

6. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SNA.

(b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is filed with the individual treatment plan. The record must include:

1. Name of medication;

2. Date prescribed;

3. Dosage;

4. Frequency of administration;

5. Route of administration;

6. Date and time administered; and

7. Documentation of staff administering medication or supervising self-administration.

(c) Take-home doses of methadone and LAAM shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other

(Rule 0940-5-42-.06, continued)

applicable federal agency. All requests for take home exceptions must be reviewed and approved by the SNA and any other applicable federal agency.

(d) Adverse drug reactions and errors must be reported to a program physician immediately and corrective action initiated. The adverse reaction or error must be recorded in the drug administration record, the nurse progress notes and the individual treatment plan, and all persons who are authorized to administer medication or supervise self medication must be alerted.

(e) All medications must be stored in a locked safe when not being administered or self-administered.

(f) Medication orders and dosage changes must be written or printed on a form which clearly displays the physician's signature. Dosage dispensed, prepared or received must be recorded and accounted for by written or printed notation in a manner which achieves a perpetual and accurate inventory at all times. Every dose must be recorded in the client's individual medication record at the time the dose is dispensed or administered. If initials are used, the full signature and credentials of the qualified person administering or dispensing must appear at the end of each page of the medication sheet. The perpetual inventory must be totaled and recorded in milligrams daily. Where computer based recording is utilized, the facility shall show that hard copy records are maintained for inspection.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-222, 68-11-305, and 68-11-308 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed February 18, 2003; effective May 4, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-5-42-.07 RESERVED.

0940-5-42-.08 BUILDING STANDARDS.

(1) The non-residential narcotic treatment facility must be constructed, arranged, and maintained to ensure the safety of the clients.

(2) The condition of the physical plant and the overall non-residential narcotic treatment facility environment must be developed and maintained in such a manner that the safety and well-being of clients are assured.

(3) When construction is planned by any facility for any building, additions to an existing building or substantial alterations to an existing building, two (2) sets of plans and specifications shall be submitted to the department to be approved. For the purpose of life safety, non-residential narcotic treatment facilities are required to meet business occupancies and all new facilities shall conform to the current addition of the Standard Building Code, the National Fire Protection Code (NFPA), and the National Electrical Code, as adopted by the Board for Licensing Health Care Facilities. All new and existing facilities are subject to the requirements of the Americans with Disabilities Act (A.D.A.).

(4) Flammable and combustible liquids such as gasoline, cleaning fluids, kerosene, turpentine etc., shall be stored in safety containers and stored at least 16 feet from the building or stored in a U.L. approved/listed cabinet and ventilated as prescribed by code requirement or manufacturers' recommendation.

(5) Mechanical

(Rule 0940-5-42-.08, continued)

(a) All units having a total of 2,000 cubic feet per minute (CFM) or greater in a zone shall shut down when the fire alarm panel is activated.

(6) Electrical

(a) The electrical system, components, equipment and appliances shall be kept in good repair at all times.

(b) Knob and Tube wiring is prohibited.

(c) Electrical cords shall not have splices.

(d) Electric circuit breaker panel boxes shall not have open slots exposing wiring.

(e) Circuit breakers shall be properly labeled.

(f) In all new facilities or renovations to existing electrical systems, the installation must be approved by an inspector or agency authorized by the State Fire Marshall.

(g) The electrical system shall not be overloaded.

(h) Ground Fault Circuit Interrupters (GFCI) are required in all wet areas, such as kitchens, laundries, janitor closets, bath and toilet rooms, etc. and within six (6) feet of any laboratory.

(7) Fire Alarm

(a) Manual pull stations shall be installed in paths of travel to exits and by each required exit.

(b) All alarm devices shall be connected to the fire alarm panel.

(c) The fire alarm panel shall have auxiliary power such as batteries or generators.

(d) All sprinkler systems are to be electrically supervised.

(e) Structures with atriums, vertical openings or monumental stairs open to another floor must have their fire alarm system automatically transmit an alarm to the municipal fire department or to an agency acceptable to this department with equipment which meets NFPA signaling and standard building codes. Fire protection systems and smoke evacuation systems must be on emergency power.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-5-42-.09 LIFE SAFETY.

(1) Any non-residential narcotic treatment facility which complies with the required applicable building and fire safety regulations at the time the board adopts new codes or regulations will, so long as such compliance is maintained (either with or without waivers of specific provisions), be considered to be in compliance with the requirements of the new codes or regulations.

(Rule 0940-5-42-.09, continued)

(2) The non-residential narcotic treatment facility shall provide fire protection by the elimination of fire hazards, by the installation of necessary fire fighting equipment and by the adoption of a written fire control plan. All fires which result in a response by the local fire department shall be reported to the department within seven (7) days. The report shall contain sufficient information to ascertain the nature and location of the fire, its probable cause and any injuries incurred by any person or persons as a result of the fire. Records which document and evaluate these incidents must be maintained for at least three (3) years.

(3) The non-residential narcotic treatment facility shall have a written emergency plan to document instructions to staff, upon employment, and clients, upon enrollment, in fire evacuation procedures. The plan shall include actions to be taken in inclement weather and internal and external emergencies. Evacuation plans shall be posted in prominent areas such as reception areas, near door in class rooms, etc. and shall designate meeting places outside the building in event of emergencies.

(4) Corridor doors shall not have louvers.

(5) Battery powered emergency lighting shall be installed in corridors, common areas and in stair ways.

(6) Corridors shall be lighted at all times, to a minimum of one foot candle.

(7) Corridors and exit doors shall be kept clear of equipment, furniture and other obstacles at all times. There shall be a clear passage at all times from the exit doors to a safe area.

(8) Corridors in multi storied buildings shall have two exits remote from each other. At least one exit shall be directly to the outside.

(9) Storage beneath any stair is prohibited.

(10) Combustible finishes and furnishings shall not be used.

(11) Open flame and portable space heaters shall not be permitted in the facility. Cooking appliances other than microwave ovens shall not be allowed in the facility.

(12) All heaters shall be guarded and spaced to prevent ignition of combustible material and accidental burns. The guard shall not have a surface temperature greater than 120°F.

(13) Fireplaces and/or fireplace inserts may be used only if provided with guards or screens which are secured in place. Fireplaces and chimneys shall be inspected and cleaned annually and verified documentation shall be maintained.

(14) All electrical equipment shall be maintained in good repair and in safe operating condition.

(15) Electrical cords shall not be run under rugs or carpets.

(16) The electrical systems shall not be overloaded. Power strips must be equipped with circuit breakers. Extension cords shall not be used.

(17) Fire extinguishers, complying with NFPA 10, shall be provided and mounted to comply with NFPA 10. An extinguisher in the kitchen area shall be a minimum of 2-A:10-B:C and an extinguisher with a rating of 20-A shall be adjacent to every hazardous area. The minimum travel distance shall not exceed fifty (50) feet between the extinguishers.

(Rule 0940-5-42-.09, continued)

~~(18) Smoking and smoking materials shall be permitted only in designated areas. Ashtrays must be provided wherever smoking is permitted. The facility shall have written policies and procedures for smoking within the facility which shall designate a room or rooms to be used exclusively for clients who smoke. The designated smoking room or rooms shall not be the dining room or activity room.~~

~~(19) Trash and other combustible waste shall not be allowed to accumulate within and around the facility and shall be stored in appropriate containers with tight fitting lids. Trash containers shall be UL approved.~~

~~(20) All safety equipment shall be maintained in good repair and in a safe operating condition.~~

~~(21) Janitorial supplies shall not be stored in the kitchen, food storage area, dining area or client accessible areas.~~

~~(22) Emergency telephone numbers must be posted near a telephone accessible to the clients.~~

(Rule 0940-5-42-.09, continued)

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed June 21, 2007; effective September 4, 2007. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.~~

~~**0940-5-42-.10 INFECTIOUS AND HAZARDOUS WASTE.**~~

~~(1) Each facility must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous wastes. These policies and procedures must comply with the standards of this section and all other applicable state and federal regulations.~~

~~(2) The following waste shall be considered to be infectious waste:~~

~~(a) Waste contaminated by clients who are isolated due to communicable disease, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals";~~

~~(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures;~~

~~(c) Waste human blood and blood products such as serum, plasma, and other blood components;~~

~~(d) All discarded sharps (e.g., hypodermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in client care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories; and,~~

~~(e) Other waste determined to be infectious by the facility in its written policy.~~

~~(3) Infectious and hazardous waste must be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the facility.~~

~~(4) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.~~

~~(a) Contaminated sharps must be directly placed in leakproof, rigid, and puncture resistant containers which must then be tightly sealed;~~

~~(b) Whether disposable or reusable, all containers, bags, and boxes used for containment and disposal of infectious waste must be conspicuously identified. Packages containing infectious waste which pose additional hazards (e.g., chemical, radiological) must also be conspicuously identified to clearly indicate those additional hazards;~~

~~(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste; and~~

(Rule 0940-5-42-.10, continued)

~~(d) Opaque packaging must be used for pathological waste.~~

~~(5) After packaging, waste must be handled and transported by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.~~

~~(6) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords 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.~~

~~(7) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the facility must ensure that proper actions are immediately taken to:~~

~~(a) Isolate the area from the public and all except essential personnel;~~

~~(b) To the extent practicable, repackage all spilled waste and contaminated debris in accordance with the requirements of this section; and~~

~~(c) Sanitize all contaminated equipment and surfaces appropriately. Written policies and procedure must specify how this will be done.~~

~~(8) Except as provided otherwise in this section, a facility must treat or dispose of infectious waste by one or more of the methods specified in this paragraph.~~

~~(a) A facility may treat infectious waste in an on site sterilization or disinfection device, or in an incinerator or a steam sterilizer, which has been designed, constructed, operated and maintained so that infectious waste treated in such a device is rendered non-infectious and is, if applicable, authorized for that purpose pursuant to current rules of the Department of Environment and Conservation. A valid permit or other written evidence of having complied with the Tennessee Air Pollution Control Regulations shall be available for review, if required. Each sterilizing or disinfection cycle must contain appropriate indicators to assure conditions were met for proper sterilization or disinfection of materials included in the cycle, and records kept. Proper operation of such devices must be verified at least monthly, and records of these monthly checks shall be available for review. Waste that contains toxic chemicals that would be volatilized by steam must not be treated in steam sterilizers. Infectious waste that has been rendered to a carbonized or mineralized ash shall be deemed non-infectious, unless otherwise hazardous and subject to the hazardous waste management requirements of the current rules of the Department of Environment and Conservation. Such ash shall be disposable as a (non hazardous) solid waste under current rules of the Department of Environment and Conservation.~~

~~(b) The facility may discharge liquid or semi-liquid infectious waste to the collection sewerage system of a wastewater treatment facility which is subject to a permit pursuant to T.C.A. §69-3-101, et seq., provided that such discharge is in accordance with any applicable terms of that permit and/or any applicable municipal sewer use requirements.~~

~~(c) Any health care facility accepting waste from another state must promptly notify the Department of Environment and Conservation, county and city public health agencies, and must strictly comply with all applicable local, state and federal regulations.~~

(Rule 0940-5-42-.10, continued)

(9) The facility may have waste transported off site for storage, treatment, or disposal. Such arrangements must be detailed in a written contract, available for review. If such off site location is in Tennessee, the facility must ensure that it has all necessary state and local approvals, and such approvals shall be available for review. If the off site location is in another state, the facility must notify in writing all public health agencies with jurisdiction that the location is being used for management of the facility's waste. Waste shipped off site must be packaged in accordance with applicable federal and state requirements. Waste transported to a sanitary landfill in this state must meet the requirements of current rules of the Department of Environment and Conservation.

(10) All garbage, trash and other non-infectious waste shall be stored and disposed of in a manner that shall not permit the transmission of disease, create a nuisance, provide a breeding place for insects and rodents, or constitute a safety hazard. All containers for waste shall be water tight, constructed of easily cleanable material and shall be kept on elevated platforms.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-5-42-.11 RECORDS AND REPORTS.

(1) Reporting. The facility shall submit the following information to the Department:

(a) All reports, forms and correspondence submitted to the FDA, DEA, any other applicable federal agencies or required accreditation organizations.

(b) Written notification of the administration of greater than one hundred (100) milligrams of methadone to a client requires written notification within ten (10) working days, signed by the program physician, which details clinical justification for exceeding one hundred (100) milligrams.

(c) Such reports and information which may be required by the Department to conduct evaluations of narcotic replacement treatment effectiveness or monitor service delivery.

(2) The NRNTF shall report each case of communicable disease to the local county health officer in the manner provided by T.C.A. §68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health. Repeated failure to report communicable diseases shall be cause for revocation of a facility license.

(3) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

(Rule 0940-5-42-.11, continued)

2. ~~aspiration in a non-intubated patient related to conscious/moderate sedation;~~

3. ~~intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;~~

4. ~~volume overload leading to pulmonary edema;~~

5. ~~blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;~~

6. ~~perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;~~

7. ~~burns of a second or third degree;~~

8. ~~falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;~~

9. ~~procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:~~

   (i) ~~procedure related injury requiring repair or removal of an organ;~~

   (ii) ~~hemorrhage;~~

   (iii) ~~displacement, migration or breakage of an implant, device, graft or drain;~~

   (iv) ~~post operative wound infection following clean or clean/contaminated case;~~

   (v) ~~any unexpected operation or reoperation related to the primary procedure;~~

   (vi) ~~hysterectomy in a pregnant woman;~~

   (vii) ~~ruptured uterus;~~

   (viii) ~~circumcision;~~

   (ix) ~~incorrect procedure or incorrect treatment that is invasive;~~

   (x) ~~wrong patient/wrong site surgical procedure;~~

   (xi) ~~unintentionally retained foreign body;~~

   (xii) ~~loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;~~

   (xiii) ~~criminal acts;~~

   (xiv) ~~suicide or attempted suicide;~~

   (xv) ~~elopement from the facility;~~

(Rule 0940-5-42-.11, continued)

~~(xvi) infant abduction, or infant discharged to the wrong family;~~

~~(xvii) adult abduction;~~

~~(xviii) rape;~~

~~(xix) patient altercation;~~

~~(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;~~

~~(xxi) restraint related incidents; or~~

~~(xxii) poisoning occurring within the facility.~~

~~(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:~~

~~1. strike by the staff at the facility;~~

~~2. external disaster impacting the facility;~~

~~3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and~~

~~4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.~~

~~(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.~~

~~(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.~~

~~(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report,~~

(Rule 0940-5-42-.11, continued)

~~then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.~~

~~(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.~~

~~(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.~~

~~(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.~~

~~(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.~~

~~(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.~~

~~(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.~~

~~(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.~~

(Rule 0940-5-42-.11, continued)

~~(4) The NRNTF shall retain legible copies of the following records and reports for thirty-six months following their issuance. They shall be maintained in a single file, and shall be made available for inspection during normal business hours to any person who requests to view them. Each client must be fully informed of the availability of these reports to the public, of their location within the facility, and given an opportunity to inspect the file before entering into any monetary agreement with the facility:~~

~~(a) Local fire safety inspections;~~

~~(b) Local building code inspections, if any;~~

~~(c) Fire Marshall reports;~~

~~(d) Department licensure and fire safety inspections and surveys;~~

~~(e) Federal government surveys and inspections, if any;~~

~~(f) Orders of the Commissioner or Board, if any;~~

~~(g) Comptroller of the Treasury's audit reports and findings, if any; and~~

~~(h) Maintenance records of all safety equipment.~~

~~(5) Inspections.~~

~~(a) The Department is authorized to conduct on site inspections of any facility to verify compliance with these rules and all relevant laws or regulations. A facility shall permit any authorized Department representative to enter upon and inspect any and all facility premises which, for the purposes of these rules, shall include access to all parts of the facility, staff, persons in care, and documents pertinent to initial and continued licensure. Failure to permit entry and inspection is a violation of this rule and may result in the denial of any license applied for or the suspension or revocation of a license.~~

~~(b) If, as a result of an inspection, violations of these rules are identified, the Department may issue a written inspection report that identifies the rules violated and requires the facility to submit a written plan of correction that states what the program will do to correct each of the violations identified. The Department will provide written inspection reports to the facility within 30 days after the on site inspection, unless there is a determination by the SNA that the complexity of the issues or other extenuating circumstances require an extension of this time period. The facility may offer any explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within 30 days of receipt of the inspection report. Failure to submit an acceptable plan of correction may constitute cause for the Department to deny a license or suspend or revoke a license. Nothing in this paragraph will be interpreted to mean that facilities must be afforded an opportunity to correct all violations. Upon the discovery of any violation of these rules, the Department may proceed to suspend or revoke a facility's license in accordance with these rules. In determining the appropriate response to rule violations, the Department will consider whether the violations can be corrected, the facility's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare of the facility's clients and the surrounding community and any other relevant circumstances.~~

(Rule 0940-5-42-.11, continued)

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Amendment filed April 11, 2003; effective June 25, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*~~

~~**0940-5-42-.12 CLIENTS RIGHTS.**~~

~~(1) Confidential Records.~~

~~(a) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in a NRNTF directly or indirectly identifying a client shall be kept confidential and shall not be disclosed by any person except the individual identified; and~~

~~(b) As a court may direct upon its determination that disclosure is necessary for the conduct of proceedings before it and that failure to make such disclosure would be contrary to the public interest or detrimental to either party to the proceedings, consistent with the provisions of 42 C.F.R. Part 2.~~

~~(2) Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a client to any members of the family of a client or to his relatives or friends providing that conditions of 42 C.F.R. Part 2 have been met.~~

~~(3) Clients shall not be abused or neglected.~~

~~(4) Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of clients, and the handling and resolution of complaints.~~

~~(5) Other client rights include:~~

~~(a) Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;~~

~~(b) Right to be free from physical and verbal abuse;~~

~~(c) Right to be informed about the individualized plan of treatment and to participate in the planning, as able;~~

~~(d) Right to be promptly and fully informed of any changes in the plan of treatment;~~

~~(e) Right to accept or refuse treatment;~~

~~(f) Right to confidentiality of client records;~~

~~(g) Right to be informed of the facility's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;~~

~~(h) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the Department; and~~

~~(i) Right to obtain a copy of the facility's most recent completed report of licensing inspection from the facility upon written request. The facility is not required to release a~~

(Rule 0940-5-42-.12, continued)

~~report until the facility has had the opportunity to file a written plan of correction for the violations as provided for in these rules.~~

~~(6) The written policies and procedures shall include provisions for clients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.~~

~~***Authority:*** *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-209, 68-11-302, and 68-11-304 and Executive Order 44 (February 23, 2007).* ~~***Administrative History:***~~ *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

~~**0940-5-42-.13 REPEALED.**~~

~~***Authority:*** *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209 and Executive Order 44 (February 23, 2007).* ~~***Administrative History:***~~ *Original rule filed June 8, 1999; effective August 22, 1999. Repeal filed April 30, 2003; effective July 14, 2003. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

~~**0940-5-42-.14 DISASTER PREPAREDNESS.**~~

~~(1) The administration of every facility shall have in effect and available for all supervisory personnel and staff, written copies of the following required disaster plans, for the protection of all persons in the event of fire and other emergencies for evacuation to areas of refuge and/or evacuation from the building. A detailed log with staff signatures of training received shall be maintained. All employees shall be trained annually as required in the following plans and shall be kept informed with respect to their duties under the plans. A copy of the plans shall be readily available at all times in the telephone operator's position or at the security center. Each of the following plans shall be exercised annually prior to the month listed in each plan:~~

~~(a) Fire Safety Procedures Plan (to be exercised at any time during the year) shall include:~~

~~1. Minor fires.~~

~~2. Major fires.~~

~~3. Fighting the fire.~~

~~4. Evacuation procedures~~

~~5. Staff functions by department and job assignment.~~

~~(b) Tornado/Severe Weather Procedures Plan (to be exercised prior to March) shall include:~~

~~1. Staff duties by department and job assignment.~~

~~2. Evacuation procedures.~~

~~(c) Bomb Threat Procedures Plan (to be exercised at any time during the year):~~

~~1. Staff duties by department and job assignment.~~

~~2. Search team, searching the premises.~~

(Rule 0940-5-42-.14, continued)

3. Notification of authorities.

4. Location of suspicious objects.

5. Evacuation procedures.

(d) Flood Procedures Plan (to be exercised prior to March):

1. Staff duties by department and job assignment.

2. Evacuation procedures.

3. Safety procedures following the flood.

(e) Severe Cold Weather (to be exercised prior to November) and Severe Hot Weather (to be exercised prior to May) Procedures Plans:

1. Staff duties by department and job assignment.

2. Equipment failures.

3. Insufficient HVAC on emergency power.

4. Evacuation procedures.

5. Emergency food service.

(f) Earthquake Disaster Procedures Plan (to be exercised at any time during the year):

1. Staff duties by department and job assignment.

2. Evacuation procedures.

3. Safety procedures.

4. Emergency services.

(2) All facilities shall participate in the Tennessee Emergency Management local/county emergency plans on an annual basis. Participation includes but is not limited to filling out and submitting a questionnaire on a form to be provided by the Tennessee Emergency Management Agency. Documentation of participation must be maintained and shall be made available to survey staff as proof of participation.

Authority: *T.C.A. §§4-5-202 through 4-5-206, 68-11-202, 68-11-204, 68-11-206, and 68-11-209 and Executive Order 44 (February 23, 2007).* ***Administrative History:*** *Original rule filed June 8, 1999; effective August 22, 1999. Per Executive Order 44 (February 23, 2007), rule was transferred from 1200-8-21 on May 15, 2008.*

0940-05-42-.01 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) "Opioid Treatment Program (OTP)" or "Non-Residential Substitution-based Treatment Center for Opiate Addiction" (also be referred to herein as "Facility" or "Program") includes, but is not limited to, standalone clinics offering methadone, products containing buprenorphine such as Subutex and Suboxone, or products containing any other formulation designed to treat opiate addiction by preventing symptoms of withdrawal, with the goal of the service recipient becoming free from any drug which is not medically indicated.

(b) "Advanced Practice Nurse" means a person qualified by the Tennessee Board of Nursing under Rules Chapter 1000-04 as an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs.

(c) "Buprenorphine" means a synthetic opioid agonist-antagonist; the hydrochloride salt is used as an analgesic and as a substitute in the management of opioid addiction. It has been approved by the FDA for detoxification in maintenance treatment of opioid dependence.

(d) "Central Registry" means an electronic system used to register service recipients currently receiving opioid replacement treatment at an OTP. The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS or department) or State Opioid Treatment Authority (SOTA) may require OTPs to initiate a clearance inquiry and service recipient registration into an approved central registry for the purpose of gathering program information, performance data and to prevent simultaneous enrollment in other OTPs.

(e) "Counseling Session" means face-to-face, therapeutic discussion between service recipient(s) and a Facility counselor in a private location for a period of no less than 30 minutes designated to address service recipient addiction issues or coping strategies and Individualized Program Plans.

(f) "DEA" means the United States Drug Enforcement Administration.

(g) "Detoxification" or "Detoxification Treatment" means the dispensing of an opioid agonist treatment medication in decreasing doses to the service recipient 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 service recipient to a drug-free state within that period.

1. "Administrative Detoxification" or "Administrative Withdrawal" means an involuntary withdrawal or discharge from opioid treatment that is usually relatively brief.

2. "Long-Term Detoxification" means a period of opioid replacement therapy services or programs not to exceed 180 days.

3. "Medical Detoxification", "Medical Withdrawal" or "Medically Supervised Withdrawal" means the voluntary and therapeutic withdrawal of the service recipient from opioid treatment.

4. "30-Day Detoxification Treatment" or "Short-Term Detoxification" means a period of continuous detoxification treatment with narcotic replacement therapy not to exceed 30 days in length for the purpose of assisting the opioid dependent client in reaching a drug-free state. An episode of 30-day detoxification is any length of

time in which the client receives narcotic replacement therapy for three or more days.

(h) "Dispense" or "Dispensing" means, for purposes of these rules, to prepare and give out more than one single dose of an opioid drug to a service recipient at a non-residential opioid treatment facility.

(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) "FDA" means the United States Food and Drug Administration.

(k) "Guest Dose" means any dose provided on a temporary basis at a program other than the service recipient's home clinic.

(l) "Home Clinic" means the program where an individual is admitted and primarily treated as a program service recipient.

(m) "Inspection" means any examination by the department or its representatives of a provider 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 a provider 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) "Opioid Maintenance Treatment" means the dispensing of an opioid drug, at relatively stable dosage levels, for a continuous, open-ended period deemed medically necessary by a program physician or medical director, in the treatment of an individual for dependence on heroin or other opioid drug(s). A "maintenance dose" or dose rendered as part of a service recipient's maintenance treatment is the level of opioid replacement therapy considered to consistently suppress signs or symptoms of withdrawal from opioid drugs and opioid drug cravings for individuals with opioid addiction; it usually represents the end of the induction period. It is individualized for each service recipient and may gradually change over time. Clients will be admitted or readmitted to this modality only after careful clinical evaluation by a multidisciplinary team.

(o) "Medical Director" means a physician licensed by the Tennessee Board of Medical Examiners or the Tennessee Board of Osteopathic Examination who has been designated by the governing body of the OTP to be responsible for the administration of all medical services performed by the OTP, including compliance with all federal, state and local laws and rules regarding medical treatment of opioid addiction. The medical director shall have the experience and credentials specified in paragraph 0940-05-42-.29(4) of these rules.

(p) "Medical Record" 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 service recipients.

(q) "Methadone (trade name Dolophine)" means a synthetic opioid agonist which has been approved by the FDA for detoxification and maintenance treatment of opioid addiction.

(r) "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 service recipient progress.

(s) "Office of Licensure" means the Tennessee Department of Mental Health and Substance

Abuse Services (TDMHSAS) Office of Licensure.

(t) "Opiate/Opioid" means a drug that contains opium, derivatives of opium or any of several semi-synthetic or synthetic drugs with opium-like activity.

(u) "Opioid Dependent" means an individual who physiologically needs opioid or other opiate-like drugs to prevent the onset of signs of withdrawal.

(v) "Opioid Replacement Treatment" means the substitution of a prescription drug which has been approved by the FDA for the treatment of addiction to opioids or opiate-like drugs.

(w) "Observed Testing" means testing conducted and witnessed by a Facility staff person to ensure against falsification or tampering or results of a drug screen.

(x) "Prescriber" means a physician or physician assistant with prescribing privileges under the Tennessee Board of Medical Examiners Chapter 0880-02 or 0880-03, respectively, or an advanced practice nurse with a certificate of fitness with privileges to write and sign prescriptions and/or issue legend drugs under Tennessee Board of Nursing Rules Chapter 1000-04.

(y) "Program Director" means the person designated by the Facility's governing body who is responsible for the operation of the Facility, for the overall compliance with federal, state and local laws and regulations regarding the operation of opioid treatment programs, and for all Facility employees including practitioners, agents, or other persons providing services at the Facility.

(z) "Program Physician" means any physician, including the medical director, who is employed by an OTP to provide medical services to service recipients. Any Facility program physician who is not a medical director shall work under the supervision of the Facility's medical director.

(aa) "Prescription Monitoring Program" or "PMP" means a program established by the Tennessee Department of Commerce and Insurance to monitor the prescribing and dispensing of Schedule II, III, IV and V controlled substances.

(bb) "Psychiatrist" means a physician, who specializes in the assessment and treatment of individuals having psychiatric disorders, is certified by the American Board of Psychiatry and Neurology or has the documented equivalent in education and training, and who is fully licensed to practice medicine in the State of Tennessee.

(cc) "Random Testing" means drug screens conducted by the Facility that lack a definite pattern of who and when service recipients are selected for testing; indiscriminate testing.

(dd) "Relapse" means the failure of a service recipient to maintain abstinence from illicit drug use verified through drug screen.

(ee) "Service Recipient Transfer" means any service recipient who changes locations of their home clinic without receiving a discharge status or without a break in treatment between clinics.

(ff) "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. The individual also serves as a liaison with the appropriate federal agencies.

(gg) "Supervising Physician" means a licensed and actively practicing physician who has been identified as accepting the responsibility for supervising physician assistants and advanced practice nurses.

(hh) "TDMHSAS" means the Tennessee Department of Mental Health and Substance Abuse

Services.

(ii) "Treatment" means a broad range of services including outreach, identification, assessment, diagnosis, detoxification, therapy, medical services, lectures/seminars, group process social services, and follow-up or aftercare for individuals with alcohol and other drug problems. The overall goal is to eliminate the alcohol and drug use as a contributing factor to physical, psychological and social dysfunction and to arrest or reverse the progress of any associated problems.

(jj) "Volunteer" means a person who is not paid by the licensee and whose varied skills are used by the licensee to support and supplement the efforts of the paid Facility staff.

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, 33-2-404 and 33-2-407.

0940-05-42-.02 Application of Rules.

(1) In addition to this chapter, the licensee of an OTP shall comply with the following rules:

(a) Chapter 0940-05-02 Licensure Administration and Procedures;

(b) Applicable Life Safety Rules for Business Occupancies (Rule 0940-05-04-.04);

(c) If services are provided to mobile, non-ambulatory service recipients, then Mobile Non-Ambulatory Rule (Rule 0940-05-04-.09);

(d) Rules for Adequacy of Facility Environment and Ancillary Services found in Chapter 0940-05-05; and

(e) Applicable Minimum Program Requirements for All Services and Facilities found in Chapter 0940-05-06.

(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, 33-2-404 and 33-2-407.

0940-05-42-.03 Licensing Procedures.

(1) When making application for a new license, the applicant shall submit an application on a form provided by the department along with a copy of the Certificate of Need (CON) issued by the Tennessee Health Services Development Agency or any other applicable state agency. Any condition placed on the CON will also be placed on the license.

(2) The written application for operation of an OTP shall be filed simultaneously with the Federal Substance Abuse and Mental Health Service Administration (SAMHSA) and the DEA, and/or any other applicable federal agencies.

(3) Service recipients shall not be admitted to the OTP until a license has been issued.

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, 33-2-404 and 33-2-407.

0940-05-42-.04 Designation of State Opioid Treatment Authority (SOTA) and Powers and Duties of SOTA.

(1) The commissioner shall designate an individual within the department to serve as the SOTA to

facilitate oversight and technical assistance to opioid treatment programs. The individual designated shall have demonstrated education and background evidencing comprehensive knowledge of opioid drugs and their effects.

(2) The powers and duties of the SOTA include, but are not limited to, the following:

(a) Facilitating the development and implementation of rules, regulations, standards and best practice guidelines to assure the quality of services delivered by opioid treatment programs;

(b) Acting as a liaison between relevant State and federal agencies;

(c) Reviewing opioid treatment guidelines and regulations developed by the federal government;

(d) Assuring delivery of technical assistance and informational materials to opioid treatment programs as needed;

(e) Performing both the scheduled and unscheduled site visits to opioid treatment programs in cooperation with department licensure office or other governmental oversight agencies, or as designated by the SOTA, when necessary and appropriate, and preparing reports as appropriate to assist the department's licensure office or other governmental oversight agencies;

(f) Consulting with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

(g) Reviewing and approving exceptions to federal and state dosage policies and procedures;

(h) Receiving and addressing service recipient appeals and grievances;

(i) Monitoring of performance outcomes. The following performance indicators may be used to evaluate the impact of the program on service recipients and the community:

1. Service recipient satisfaction.

2. Service recipient employment status.

3. Improvement in medical conditions.

4. Drop-out rate.

5. Recidivism rates.

6. Alcohol use.

7. Criminal arrests.

8. Illicit drug use, as indicated by drug screens.

9. Improvement in social and living standards; and

(j) Working cooperatively with other relevant state agencies to determine the service need in the location of a proposed program.

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, and 33-2-404.

0940-05-42-.05 Policy and Procedures.

(1) The governing body of the Facility shall ensure it 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), in its policies and procedures manual including the name and contact information of the governing body.

(a) Intake, Admissions, and Discharges (0940-05-42-.06);

(b) Service Recipient Record Requirements (0940-05-42-.07);

(c) Multiple Enrollments (0940-05-42-.08);

(d) Orientation (0940-05-42-.09);

(e) Service Recipient Transfers (0940-05-42-.10);

(f) Individual Program Plan (0940-05-42-.11);

(g) Special Populations (0940-05-42-.12);

(h) Professional Services (0940-05-42-.13);

(i) Counseling (0940-05-42-.14);

(j) Medication Management (0940-05-42-.15);

(k) Pharmacotherapy Guidelines (0940-05-42-.16);

(l) Drug Screens (0940-05-42-.17);

(m) Detoxification and Medically Supervised Withdrawal (0940-05-42-.18);

(n) Diversion Control Plan (0940-05-42-.19);

(o) Central Registry (0940-05-42-.20);

(p) Reporting Requirements (0940-05-42-.21);

(q) Quality of Care (0940-05-42-.22);

(r) Infectious Hazardous Waste (0940-05-42-.23);

(s) Infection Control (0940-05-42-.24);

(t) Managing Disruptive Behavior (0940-05-42-.25);

(u) Hours of Operation (0940-05-42-.26);

(v) Service Recipients' Rights (0940-05-42-.27);

(w) Community Relations (0940-05-42-.28); and

(x) Personnel and Staffing Requirements (0940-05-42-.29).

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, and 33-2-404.

0940-05-42-.06 Intake, Admissions, and Discharges.

(1) Prior to admission to the Facility, each potential service recipient shall be evaluated by the medical director or program physician and clinical staff who have been determined to be qualified by education, training, and experience to perform or coordinate the provision of such assessments. The purpose of such assessments shall be to determine whether opioid substitution or detoxification will be the most appropriate treatment modality for the service recipient. No prospective service recipient shall be processed for admission until it has been verified that the service recipient meets all applicable criteria.

(2) Except as otherwise authorized by law, no person shall be admitted for treatment without written authorization from the service recipient and, if applicable, parent, guardian or responsible party. The following information shall be explained by a trained staff person to the service recipient and other consenters and documented, in writing, in the service recipient's file:

(a) The Facility's services and treatment;

(b) The specific conditions that will be treated;

(c) Explanation of treatment options, detoxification rights, and clinic charges, including the fee agreement, signed by the prospective service recipient or the service recipient's legal representative; and

(d) The Facility's rules regarding service recipient conduct and responsibilities.

(3) No standardized routines or schedules of increases or decreases of medications may be established or used.

(4) A Facility physician shall document that treatment is medically necessary. The admissions and initial dosing decision ultimately rests with the medical director or his or her designated program physician.

(5) A Facility shall only admit and retain service recipients whose known needs can be met by the Facility in accordance with its licensed program purpose and description and applicable federal and state statutes, laws and regulations.

(6) Drug dependent pregnant females shall be given priority for admission and services when a Facility has a waiting list for admissions and it is determined that the health of the mother and/or unborn child is more endangered than is the health of other service recipients waiting for services.

(7) No Facility shall provide a bounty, free services, medication or other reward for referral of potential service recipients to the clinic.

(8) Initial Assessment. Within seven days of admission, the Facility shall complete an initial assessment. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if admission is determined appropriate. The initial assessment shall include:

(a) A physical examination;

(b) Relevant health history (e.g., determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis (TB), HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy);

(c) A personal and family medical and mental health history;

(d) A determination of currently prescribed medications;

(e) Personal and family history of substance abuse;

(f) An evaluation of other substances of abuse;

(g) Determination of current opioid dependence;

(h) Determination of length of addiction;

(i) A full toxicology screen to identify use of drugs including, but not limited to, opioids, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and THC;

(j) A tuberculosis screen;

(k) A screening test for syphilis;

(l) Other tests as necessary or appropriate (e.g., CBC, EKG, chest x-ray, hepatitis B surface antigen and hepatitis B antibody, HIV testing). Tests not directly conducted by the Facility at admission shall be conducted within seven days after admission. The Facility is responsible for obtaining and maintaining documentation of required laboratory tests performed by an alternative provider. Alternative providers may not supply toxicology screens unless they meet the required quality guidelines, content and timelines.

(9) Comprehensive Assessment. Within 30 days of admission, the Facility shall have completed a comprehensive assessment to include the following items. It shall be attached to the service recipient's chart no later than five days after it is developed. It shall reflect that detoxification is an option for treatment and supported by the Facility's program and has been discussed with the service recipient. It shall also integrate information obtained in the initial assessment. The Facility shall obtain complete medical records from other providers with service recipient's written consent.

(a) Whenever possible and with service recipient consent, the intake process shall include a family member or significant other to assist in provision of accurate information and a full understanding and retention of instructions given to the service recipient.

(b) The evaluation shall include information obtained from:

1. The service recipient;

2. Family members, when applicable and permitted;

3. Friends and peers, when appropriate and permitted; and

4. Other appropriate and permitted collateral sources.

(c) The psychosocial evaluation shall include information about the service recipient's:

1. Personal strengths;

2. Individualized needs;

3. Abilities and/or interests;

4. Presenting problems including a thorough analysis of the service recipient's addictive behaviors such as:

(i) Licit and illicit drugs used, including alcohol;

(ii) Amount(s) and method(s) used;

(iii) Frequency of use;

(iv) Duration of use;

(v) Symptoms of physical addiction;

(vi) History of treatment for addictive behaviors;

(vii) Adverse consequences of use; and

(viii) Inappropriate use of prescribed substances;

5. Urgent needs, including suicide risk;

6. Previous behavioral health services, including:

(i) Diagnostic information;

(ii) Treatment information; and

(iii) Efficacy of current or previously used medication;

7. Physical health history and current status;

8. Diagnoses;

9. Mental status;

10. Current level of functioning;

11. Pertinent current and historical life situation information, including his or her:

(i) Age;

(ii) Gender;

(iii) Employment history;

(iv) Legal involvement;

(v) Family history;

(vi) History of abuse; and

(vii) Relationships, including natural supports.

12. Use of alcohol and tobacco;

13. Need for, and availability of, social supports;

14. Risk-taking behaviors;

15. Level of educational functioning;

16. Medications prescribed that are not a target of treatment or concern;

17. Medication allergies or adverse reactions to medications;

18. Adjustment to disabilities/disorders; and

19. Motivation for treatment.

(d) The psychosocial assessment shall result in the preparation of a concise interpretive multidisciplinary summary that:

1. Is based on the assessment data;

2. Describes and evaluates the level and severity of the individual's addictive behaviors;

3. Is used in the development of the individual plan of care; and

4. Identifies any co-occurring disabilities or disorders that should be addressed in the development of the individual plan of care.

(10) The following behavioral signs which support the diagnosis shall be discussed and documented in the service recipient's file, although none are required for admission:

(a) Unsuccessful efforts to control use;

(b) Time spent obtaining drugs or recovering from the effects of abuse;

(c) Continual use despite harmful consequences;

(d) Obtaining opioids illegally;

(e) Inappropriate use of prescribed opioids;

(f) Giving up or reducing important social, occupational or recreational activities;

(g) Continuing use of the opioids despite known adverse consequences to self, family or society; and

(h) One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone or other appropriate medications.

(11) Within 72 hours of admission, the Facility shall conduct an inquiry with the Central Registry in accordance with Rule 0940-05-42-.20.

(12) Non-Admissions. The Facility shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs shall identify the reasons why the persons were not admitted and what referrals were made for them by the Facility.

(13) Discharge and Aftercare Plans. A Facility shall complete an individualized discharge and aftercare plan for service recipients who complete their course of treatment.

(a) Upon admission a Facility shall begin development of a service recipient's discharge plan.

(b) All discharge and aftercare plans shall include documentation that the Facility's counseling and/or medical staff has discussed with the service recipient an individualized detoxification program appropriate to the service recipient as required in section 0940-05-42-.18 herein.

(c) The service recipient's discharge planning shall include the development of a menu of treatment resources available to the service recipient in his or her community. This menu shall be developed in consultation with the service recipient. And shall be in writing and made available to the service recipient upon discharge. The Facility shall assist the service recipient in obtaining the appropriate referral.

(d) The discharge plan shall be completed within seven days of discharge by the person who

has primary responsibility for coordinating or providing for the care of the service recipient. It shall include a final assessment of the service recipient's status at the time of discharge and aftercare planning. If applicable, parents or guardian, or responsible persons may participate in discharge and aftercare planning. The reason for any service recipient not participating in discharge and aftercare planning shall be documented in the service recipient's record.

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, and 33-2-404.

0940-05-42-.07 Service Recipient Record Requirements.

(1) Facilities shall organize and coordinate service recipient records in a manner which demonstrates that all pertinent service recipient information is accessible to all appropriate staff and to the SOTA and TDMHSAS. The service recipient Central Registry I.D. Number shall be shown on each page of the service recipient's record.

(a) Records shall be preserved for not less than 10 years even if the Facility discontinues operations. The records may be generated, maintained, or transferred in whole or in part to any recording medium that assures accurate preservation of the record.

(b) The Facility shall discuss final storage or disposition of the Facility's records with TDMHSAS 90 days in advance of the closing of a Facility.

(2) The Facility shall document that the following assessments are completed prior to the development of the Individualized Program Plan (IPP).

(a) Screening. The sources and methods of verification shall have been recorded in the prospective service recipient's case folder. The screening process shall include:

1. Verification, to the extent possible, of a prospective service recipient's identity, including name, address, date of birth and other identifying data.

2. Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence, determination by medical examination performed by a program physician of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group, and determination of current Diagnostic and Statistical Manual (DSM) diagnosis.

3. Medical history, including past and family medical history, HIV status, pregnancy, a six-month history of prescriber medications, over-the-counter medications used frequently, and the patterns of specific usage of alcohol or other drugs for the past 30 days, and active medical problems.

4. Verification of other prescribed controlled medications through the PMP.

5. Psychiatric history and current mental status exam.

6. Within 14 days of admission, physical assessment and laboratory tests, including drug screens, HIV status, if the prospective service recipient consents to be tested, pregnancy, sexually transmitted diseases, Mantoux tuberculosis tests, Hepatitis C, and others as directed by the SOTA.

7. Pregnancy tests for females at admission and at least annually thereafter, unless otherwise indicated.

8. Determination if the prospective service recipient needs special services, such as treatment for alcoholism or psychiatric services, and determination that the Facility is capable of addressing these needs either directly or through referral.

9. If a prospective service recipient is 18 years of age or older, verification of

dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of two years or verification of one year of opioid dependence and one documented unsuccessful attempt at clinical treatment. If clinically appropriate, the program physician may waive these dependency and detoxification requirements for service recipients released from penal institutions (within six months after release), for pregnant service recipients with a verified pregnancy and for previously treated service recipients.

10. If a prospective service recipient is under 18 years of age, verification of two documented unsuccessful attempts at detoxification within a twelve month period. Additionally, no person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian or responsible adult designated by the SOTA consents in writing to such treatment.

(3) A voluntary, written, program-specific informed consent to treatment from each service recipient at admission to include:

(a) Information about all treatment procedures, services and other policies and regulations throughout the course of treatment, including clinic charges in the form of a fee agreement signed by the service recipient;

(b) Consent to the individualized, prescribed therapy before dosing begins, including information about potential interactions with and adverse reactions to other substances, including those reactions that might result from interactions and adverse reactions to alcohol, other prescribed or over-the-counter pharmacological agents, other medical procedures and food;

(c) Information to each service recipient that the goal of opioid treatment is stabilization of functioning;

(d) Information that detoxification from opioids over 30 to 180 days is a treatment alternative to long-term maintenance;

(e) Acknowledgement that the service recipient has been informed of the Facility's rules regarding service recipient conduct and responsibilities and continuing documentation of the service recipient's compliance with the Facility's policies;

(f) Acknowledgement that the service recipient has been informed of his or her rights (0940-05-42-.27);

(g) Information that at regular intervals, in full consultation with the service recipient, the program shall discuss the service recipient's present level of functioning, course of treatment and future goals; and

(h) Information that the service recipient may choose to withdraw from or be maintained on the medication as s/he desires unless medically contraindicated;

(4) A narrative biopsychosocial history completed within 30 days of the service recipient's admission;

(5) Medical reports including results of the physical examination; past and family medical history; review of systems; laboratory reports, including results of required toxicology screens; and progress notes, including documentation of current dose and other dosage data. Information in the medical record shall be entered by physicians and other licensed health professionals;

(6) Dated case entries of all significant contacts with service recipients, including a record of each counseling session in chronological order;

(7) Dates and results of case conferences for service recipients;

(8) The initial treatment plan, any amendments to the plan, reviews of the plan and the long-term,

individualized treatment plan, including any amendments to that document and reviews of the plan;

(9) Documentation that services listed in the plan are available and have been provided or offered;

(10) Documentation that the service recipient was informed about the process and factors considered in decisions impacting service recipient treatment (for example, take-home medication privileges, changes in counseling sessions, changes in frequency of toxicology screens) or any other significant change in treatment, both positive and negative;

(11) A record of correspondence with the service recipient, family members and other individuals and a record of each referral for services and its results;

(12) Documentation that the service recipient was provided a copy of the Facility's rules and regulations and a copy of the service recipient's rights and responsibilities and that these items were discussed with her or him;

(13) A closing summary, including reasons for discharge and any referral. In the case of death, the reported cause of death shall be documented;

(14) A written fee agreement as detailed in Rules Chapter 0940-05-42-.06 dated and signed by the service recipient (or the service recipient's legal representative) prior to provision of any services. This fee agreement shall include an explanation of the financial aspects of treatment and the consequences of nonpayment of required fees, including the procedures for medically supervised withdrawal in the event the service recipient (or service recipient's legal representative) becomes unable to pay for treatment;

(15) Documentation of Central Registry clearance as required under these rules; and

(16) All other information and documents as required by the SOTA and these rules.

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, and 33-2-404.

0940-05-42-.08 Multiple Enrollments.

(1) The Facility shall have a procedure which shall ensure that no service recipient is enrolled in more than one opioid treatment program.

(2) The procedure shall take into account requirements for service recipient confidentiality.

(3) The Facility shall obtain a release of information from the service recipient in order to check the records by telephone or fax of every opioid treatment program within Tennessee and those opioid treatment programs within 75 miles of the Facility site so as to ensure that the service recipient is not currently enrolled in those programs as well. The release of information shall state that its purpose is to obtain information and records developed during prior admission(s) not contacts with admission. Results of that check shall be contained in the clinical record. This check shall be duplicated if the service recipient is discharged and readmitted at any time.

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, and 33-2-404.

0940-05-42-.09 Orientation.

(1) The Facility shall provide orientation to service recipients within 24 hours of admission for treatment and again within 30 days following the admission date. The orientation shall be designed to educate the service recipient and ensure that the service recipient understands the Facility's program.

(2) Orientation shall be done by a designated staff person who has been determined to be qualified by education, training and experience to perform the task.

(3) Facilities shall ensure that each service recipient signs a statement confirming that the following information has been explained to the service recipient:

(a) The expected benefits of the treatment that the service recipient is expected to receive;

(b) The service recipient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence; and

(c) An explanation of individualized program planning.

(4) Facilities shall ensure that each service recipient signs a statement confirming that he or she has been offered detoxification services as an admission alternative and that the following has been discussed with the service recipient:

(a) An explanation of the types of detoxification services offered by the Facility, including administrative detoxification; and

(b) An individualized assessment of the medical risks and benefits of detoxification for the service recipient.

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, and 33-2-404.

0940-05-42-.10 Service Recipient Transfers.

(1) If a prospective service recipient has previously been discharged from treatment at another methadone clinic or facility, the admitting facility shall initiate an investigation into the prospective service recipient's prior treatment history, inquiring of the last program attended and the reasons for discharge from treatment.

(2) Service recipients who were terminated from a prior Facility or program due to non-compliance shall be admitted as a new service recipient.

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, and 33-2-404.

0940-05-42-.11 Individualized Program Plan.

(1) A Facility shall develop an Individualized Program Plan (IPP) for each service recipient within 30 days of admission. Each service recipient shall be involved in the development and review of his/her IPP. The initial IPP and all reviews shall be signed by the service recipient and program physician. IPPs shall document the following:

(a) A consistent pattern of substance abuse treatment services and medical care appropriate to individual service recipient needs;

(b) Detoxification as an option for treatment that is supported by the Facility; and

(c) A discharge plan that has been discussed with the service recipient.

(2) The admission requirements of 0940-05-42-.06 shall first be completed prior to the development of an IPP.

(3) Medical care, including referral for necessary medical service, and evaluation and follow-up of service recipient complaints shall be compatible with current and accepted standards of medical practice. All service recipients shall receive a medical examination at least annually. 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 in this annual medical examination and review of service recipient medical records in each service recipient's record.

(4) In recognition of the varied medical needs of service recipients, the case history, IPPs,

detoxification plan and discharge planning shall be reviewed at least every 90 days for service recipients in treatment less than one year and at least annually for service recipients in treatment more than one year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review shall also include an assessment of the current dosage and schedule and the rehabilitative progress of the individual, as part of a determination that additional medical services are indicated. If this review results in a determination that additional or different medical services are indicated the Facility shall ensure that such services are made available to the service recipient, either at the Facility or by referral to the appropriate medical professional.

(5) When the program physician prescribes other controlled substances to service recipients in the Facility, the Facility shall ensure that such prescription is in accord with all applicable statutes and regulations and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any service recipient unless the physician first sees the service recipient and assesses the service recipient's potential for abuse of such medications.

(6) As part of the rehabilitative services provided by the Facility, each service recipient shall be provided with individual and group counseling appropriate to his/her needs. The frequency and duration of counseling provided to service recipients shall be in conformity with 0940-05-42-.14 and be consistent with the Individualized Program Plan. Individualized Program Plans shall indicate a specific level of counseling services needed by the service recipient as part of the rehabilitative process.

(7) All service recipients shall receive HIV and hepatitis risk reduction education appropriate to their needs.

(8) When appropriate, each service recipient shall be enrolled in an education program, or be engaged in vocational activity (vocational evaluation, education or skill training) or make documented efforts to seek gainful employment. Deviations from compliance with these requirements shall be explained in the service recipient's record. 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 service recipients who demonstrate a need for such services. The Facility can fulfill this responsibility by providing support services directly or by appropriate referral. Support service recommended and utilized shall be documented in the service recipient's record. Each Facility shall have policies for matching service recipient's needs to treatment.

(9) All facilities will develop and implement policies for matching service recipient's needs to treatment. These policies may include treatment phasing in which the intensity of medical, counseling and rehabilitative services provided to a service recipient are individualized for each service recipient depending upon the service recipient's phase of treatment.

(10) If the service recipient experiences a relapse, his/her IPP shall document evidence of intensified services provided. Such evidence shall include, but is not limited to, an increase in individual or group counseling session(s) and a reduction in the service recipient's take-home privileges.

(11) Discussion shall be held with the service recipient 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 service recipient at the time of the discussion and documented in the service recipient's record. The service recipient shall sign and date a statement indicating that she or he wishes to remain within the program in a maintenance format. If the service recipient 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, and 33-2-404.

0940-05-42-.12 Special Populations.

(1) The OTP shall ensure that physicians are knowledgeable in the management of opioid

dependence in a context of chronic pain and pain management. The OTP may not prohibit a service recipient diagnosed with chronic pain from receiving medication-assisted therapy for either maintenance or withdrawal in a program setting.

(a) The OTP shall ensure continuity of care and communication between programs or physicians regarding service recipients receiving treatment in both an opioid treatment program and a facility or physician's office for purposes of pain management, with service recipient consent.

(b) If the service recipient refuses consent for the two entities to communicate and coordinate care, the OTP shall document refusal and may make clinically appropriate decisions regarding take-home medication privileges, an increase in counseling, and continuation in treatment.

(2) The OTP shall ensure that service recipients with mental health needs are identified through the evaluation process and referred to appropriate treatment.

(a) The OTP shall monitor service recipients during withdrawal to identify the emergence of symptoms of mental illness.

(b) The OTP shall establish linkages with mental health providers in the community.

(3) The Facility shall have a policy regarding treatment of co-morbid disorders such as psychiatric and medical disorders. The goal of the treatment shall be to provide treatment for these disorders in as seamless a fashion as possible, maximizing service recipient convenience and compliance with appointments and recommendations. The Facility shall ensure a smooth referral process and interchange of information.

(4) The OTP shall address abuse of alcohol and other non-opioid substances within the context of the medication-assisted therapy effort.

(a) The Facility shall ensure that staff is trained and knowledgeable regarding current effective strategies for treating abuse of alcohol, opioids, methadone, amphetamines, cocaine, barbiturates, benzodiazepines and other drugs.

(b) Ongoing multi-drug use is not necessarily a reason for discharge unless the service recipient refuses recommended, more intensive levels of care, to include but not be limited to intensive outpatient and residential clinical treatment. The treatment team shall consider the service recipient's condition and address the situation from an individualized clinical perspective.

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, and 33-2-404.

0940-05-42-.13 Professional Services.

(1) In addition to the alcohol and drug treatment service provided, the Facility shall provide a continuum of services to service recipients to address the needs as indicated in the assessment and history in the areas of social, family and peer interactions; employment and educational needs; financial status; emotional and psychological health; physical health; legal issues; and community living skills and housing needs. Such services may be provided directly by the agency or indirectly by referral to other service providers. Referral agreements with frequently used providers shall be documented. The provision of such services to individual service recipients must be documented in the service recipient record.

(2) Facilities shall be able to document a referral agreement with a local hospital health care facility or licensed health care professional.

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, and 33-2-404.

0940-05-42-.14 Counseling.

(1) Counseling is essential to promote and guide the service recipient to a more productive life style of abstinence from illicit medications or drugs due to so many opioid addicted service recipients also abusing other illicit or prescription substances. The primary counselor is responsible for developing and implementing the service recipient's plan of care, in coordination with the medical staff. The plan of care shall address the social, environmental, psychological and familial issues maintaining the service recipient's maladaptive patterns of drug consumption and other high risk and/or destructive behaviors. The counselor is responsible for assisting the service recipient to alter life styles and patterns of behavior in order to improve the service recipient's ability to function adaptively in his or her family and community.

(2) The clinical staff caseload ratio shall:

(a) Reflect an appropriate clinical mix of sex, race and ethnicity representative of the population served;

(b) Allow the Facility to provide adequate:

1. Psychosocial assessment;

2. Treatment planning; and

3. Individualized counseling;

(c) Allow for regularly scheduled counseling sessions; and

(d) Allow service recipients access to their primary counselor if more frequent contact is merited by need or is requested by the service recipient.

(3) For all service recipients, the following counseling schedule shall be followed:

(a) During the first 30 days of treatment, counseling session(s) shall take place at least two times per week;

(b) During the next 90 days of treatment (day 31 to day 120), counseling session(s) shall take place at least one time per week;

(c) During the following 90 days of treatment (day 121 to day 210), counseling session(s) shall take place at least two times per month;

(d) For subsequent 90 day periods of treatment (day 211 forward), counseling session(s) shall take place as needed or indicated in the service recipient's IPP, but not less frequently than monthly as long as the service recipient is compliant.

(4) Exceptions to frequency of counselor to service recipient contact shall be clearly justified by Facility program documentation. The program physician or prescribing professional evaluating the service recipients eligibility for take-home doses shall carefully consider the service recipient's participation in the counseling sessions as a factor in his or her decision although justified lack of participation (such as for reasons of employment) shall not be held against the service recipient in the take-home decision.

(5) The primary counselor or medical staff is responsible for documentation of significant contact with each service recipient, which shall be filed in the service recipient record.

(6) The documentation shall include a description of:

(a) The reason for or nature of the contact;

(b) The service recipient's current condition;

(c) Significant events occurring since prior contact;

(d) The assessment of the service recipient's status; and

(e) A plan for action or further treatment that addresses the goals of the treatment plan.

(7) Each entry shall be completed within 24 hours of the contact and shall be clearly dated and initialed or signed by the staff person involved.

(8) Opportunities for family involvement in counseling shall be provided and documented.

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, and 33-2-404.

0940-05-42-.15 Medication Management.

(1) Opioid Drugs. Facilities shall develop and implement written policies and procedures for prescription, dispensing and administration of opioid drugs and their security. No standardized routines or schedules of increases or decreases of medications may be established or used. These policies and procedures shall include the following:

(a) Administration.

1. A program physician shall perform a medical assessment to determine the service recipient's initial dose and schedule. The physician shall communicate the initial dose and schedule to the person supervising medication.

2. The proper initial dose shall be based on the clinical judgment of the program physician who has examined the service recipient and who has considered all available relevant information, including, but not limited to, drug screens, quantitative methadone levels, service recipient interview, and specific circumstances pertaining to the individual service recipient.

3. A physician may assign such dose and schedule by verbal order only on an emergency basis. If a verbal order is given, the physician shall examine the service recipient within 72 hours. Both the verbal order and the results of the physical examination shall be documented in the service recipient's record. Verbal orders must be taken by a licensed nurse or physician assistant, qualified by training and experience, and categorically approved by the medical staff of the Facility. Upon hearing the order, the receiver shall record the order in the service recipient's record, and then shall read back the written order to the issuing professional to assure that the order is understood clearly. "Oral" and "Telephone" orders must be documented as such and staff recording must sign their name and title. "Oral" and "Telephone" orders must be countersigned by the physician no later than 72 hours.

4. The initial dose of methadone may not exceed 30 milligrams. Only in extraordinary circumstances may the total dose for the first day exceed 40 milligrams. A transferring service recipient may receive an initial dosage of no more than the last daily dosage authorized at the former facility unless in the clinical judgment of the medical director, there are extenuating circumstances documented in the records which justify an initial dosage that is greater than the last daily dosage authorized at the former facility.

5. Subsequent doses shall be authorized by a prescriber, as defined by Rule 0940-05-42-.01(2)(x). Additional dosage may be dispensed in the first day where the prescriber documents that the initial dose does not suppress withdrawal symptoms. Service recipients are stabilized on methadone when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the service recipient comfortable for at least 24 hours with no need to resort

to illicit opioids to satisfy opioid cravings.

6. No dosage increases shall occur on the days that the Facility is closed.

7. No methadone may be administered unless the prospective service recipient has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures shall be completed on the next working day. No take-home medication may be given in such an emergency.

8. The administration of greater than 100 milligrams of methadone to a service recipient requires written notification to the SOTA within 10 working days, signed by the program physician, which details clinical justification for exceeding 100 milligrams.

9. No dose of methadone in excess of 120 milligrams may be ordered or administered without the prior approval of the SOTA.

10. Benzodiazepine Use. If a service recipient has a positive benzodiazepine screen:

(i) The treatment team shall meet with the service recipient within 14 days of receiving the results of the screen, to develop a benzodiazepine action plan in the service recipient's record. The plan shall be reviewed and signed by the medical director;

(ii) If the plan requires the service recipient to become clean from benzodiazepines, a time period for detoxification shall be established. The plan must contain a justification for any time period longer than 90 days;

(iii) The Facility shall provide detoxification treatment services either directly or through referral to another provider of detoxification treatment services;

(iv) If the plan calls for the continued use of benzodiazepines, the Facility shall coordinate the care with a qualified prescriber and document this coordination in the service recipient's record;

(v) The plan shall contain requirements for counseling, frequency of urine drug screens, and the consequences for failing to comply with the action plan on take-home privileges, and continued treatment at the OTP; and

(vi) The plan and weekly progress notes about plan implementation shall be documented in the service recipient's record.

(b) Any opioid drug prescribed and administered shall be documented on an individual medication administration record that is filed with the IPP. The record shall include:

1. Name of medication;

2. Date prescribed;

3. Dosage;

4. Frequency of administration;

5. Route of administration;

6. Date and time administered; and

7. Documentation of staff administering medication or supervising self-administration.

(c) Take-home doses of methadone or buprenorphine shall be handled in accordance with applicable rules of the Substance Abuse and Mental Health Administration or other applicable federal agency.

1. All requests for take-home exceptions shall be reviewed and approved by the SOTA and any other applicable federal agency.

2. The Facility shall check the PMP database prior to requesting any take-home or dosing exceptions and shall submit this report to the SOTA with the exception request.

3. The Facility shall provide counseling prior to providing take-home doses to any service recipient. Progress notes in the service recipient's record shall document the counseling provided.

4. The Facility shall document in the service recipient's record the basis for approving "take-home" medication for the service recipient. The following criteria shall be considered in determining the service recipient's eligibility for "take-home" medications.

(i) Cessation of illicit drug use;

(ii) Regularity of program attendance;

(iii) Length of time and level of treatment in medication therapy (ability to responsibly self-medicate);

(iv) Absence of known recent criminal activity (especially drug dealing);

(v) Absence of serious behavioral problems;

(vi) Absence of abuse of drugs including excessive use of alcohol;

(vii) Other special needs of the service recipient, such as split dosing, physical health needs, pain treatment, etc.;

(viii) Capacity to safely store "take-home" medication within the service recipient's home;

(ix) Stability of the home environment and social relationships;

(x) Service recipient's work, school, or other daily-life activity schedule; and

(xi) Hardship experienced by the service recipient in traveling to and from the Facility.

(d) Adverse drug reactions and errors shall be reported to a program physician immediately and corrective action initiated. The adverse reaction or error shall be recorded in the drug administration record, the nurse progress notes and the IPP, and all persons who are authorized to administer medication or supervise self-medication shall be alerted.

(e) All medications shall be stored in a locked safe when not being administered or self-administered.

(f) Medication orders and dosage changes shall be written or printed on a form which clearly displays the physician's signature. The dosage dispensed, prepared or received shall be recorded and accounted for by written or printed notation in a manner which achieves a

perpetual and accurate inventory at all times. Every dose shall be recorded in the service recipient's individual medication record at the time the dose is dispensed or administered. If initials were used, the full signature and credentials of the qualified person administering or dispensing shall appear at the end of each page on the medication sheet. The perpetual inventory shall be totaled and recorded in milligrams daily.

(g) Computer-based Recording.

1. Any such computerized system shall have the capability of producing a hard-copy printout of any medical or dosing order data which the OTP is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. Any computerized system shall, upon the request of the SOTA, send or provide such a printout within 48 hours excluding weekends.

2. In the event that an OTP which utilizes such a computerized system experiences system down-time, the OTP must have a written or readily retrievable auxiliary policy and procedure for documentation of all medical and dosing orders. The auxiliary procedure shall ensure that each medical or dosing order is authorized, and that all appropriate data are retained for on-line data entry as soon as the computer system is available for use again.

(h) The Facility shall check the PMP database upon admission of the service recipient, at least every six months to determine if controlled substances other than methadone are being prescribed for the service recipient, and thereafter as clinically indicated. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred.

(i) Guest Dosing.

1. Guest dosing shall be provided for a maximum of 14 days. Anything beyond 14 days shall be approved by the SOTA before dosing occurs.

2. Service recipients shall have been enrolled at the home clinic for a minimum of 30 days before being eligible for a guest dose. Service recipients enrolled less than 30 days at the home clinic shall be eligible for guest dosing only if approved by the SOTA.

3. Service recipients shall have two consecutive clean urine drug screens before being eligible for a guest dose unless the medical director determines that the benefits of guest dosing outweigh the risks and documents the justification for granting guest dosing privileges in the service recipient's record.

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, and 33-2-404.

0940-05-42-.16 Pharmacotherapy Guidelines.

(1) The Facility shall develop pharmacotherapy guidelines for opioid replacement treatment for service recipients covering the Facility's own prescribing and review of prescriptions from other physicians. These shall minimally include:

(a) Procedures to ensure that service recipients' 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 including, but not limited to, the loss of take-home privileges, to ensure compliance with this rule; and

(c) If a Facility is unable to acquire information about a service recipient's prescriptions, the Facility shall document efforts made to obtain information about prescriptions from

outside physicians in the service recipient's record.

Authority: T.C.A. §§ 4-3-1601, 4-4-103, 33-1-302, 33-1-305, 33-1-309, 33-2-302, and 33-2-404.

0940-05-42-.17 Drug Screens.

(1) Random urine drug screening and other adequately tested toxicological procedures shall be used for the purposes of assessing the service recipient's abuse of drugs and evaluating a service recipient's progress in treatment.

(2) Drug screening procedures shall be individualized and shall include at least weekly random drug screens for newly admitted service recipients during the first 30 days of treatment and at least monthly thereafter.

(3) Service recipients on a monthly schedule whose drug screen reports indicate drug abuse shall be returned to a weekly schedule for at least two weeks, or longer, if clinically indicated.

(4) More frequent collection and analysis of samples during medically-supervised or other types of withdrawal may occur.

(5) Collection of observed specimens on an unannounced basis when using urine as a screening mechanism may occur if the staff believes that observation is necessary based on service recipient behavior or need.

(6) Each sample collected shall be screened to include, but not be limited to:

(a) Opioids including synthetics at common levels of dosing;

(b) Methadone or any other medication used by the Facility's program as an intervention for that service recipient;

(c) Benzodiazepines;

(d) Cocaine;

(e) Meth-amphetamine/amphetamines;

(f) Tetrahydrocannabinol (THC); and

(g) Other drugs as indicated by individual service recipient use patterns, community standards, regional variation or clinical indication (e.g., carisoprodol, barbituates) or drugs that are heavily used in the locale of the service recipient or as directed by the SOTA.

(7) Collection and testing shall be done in a manner that assures that urine collected from service recipients is unadulterated. Such collection and testing may include random direct observation conducted professionally, ethically and in a manner which respects service recipients' privacy.

(8) Positive Test. Any refusal to participate in a random drug test shall be considered a positive test. A positive test is a test that results in the presence of any drug or substances listed in section (6) of this rule that is illegal or for which the service recipient cannot provide a valid prescription or any drug or substance prohibited by the opioid treatment program or SOTA; the presence of medication which is documented as part of the service recipient's treatment plan shall not be considered a positive test.

(9) A positive drug test result after the first six months in an opioid treatment program shall result in the following:

(a) Upon the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include

weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision; and

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days;

(b) Upon a second positive drug test result within six months of the first positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory documented treatment team meetings with the service recipient;

(c) Upon a third positive drug test result within six months of the second positive drug test result, the opioid treatment program shall:

1. Provide mandatory and documented weekly counseling, which shall include weekly meetings with a counselor who is qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. Provide mandatory and documented treatment team meetings with the service recipient which shall include, at a minimum: the need for continuing treatment; a discussion of other treatment alternatives; and documentation that the service recipient has been advised that the service recipient may be discharged for continued positive drug tests; and

(d) Upon a fourth positive drug test result within six months of the third positive drug test result, opioid treatment program shall:

1. Through an assessment of the service recipient's IPP, address the on-going multi-drug use through increased group and individual counseling, intensive outpatient and residential clinical treatment. The treatment team shall consider each service recipient's condition and address the situation from an individualized clinical perspective;

2. Immediately revoke the take-home privilege for a minimum of 30 consecutive days; and

3. If the service recipient refuses recommended, more intensive levels of care, the service recipient shall be immediately enrolled in an individualized, medically supervised detoxification plan for up to two weeks, followed by immediate discharge from the opioid treatment program.

(10) The Facility shall document both the results of toxicological tests and the follow-up therapeutic action taken in the service recipient record.

(11) Treatment programs shall work carefully with toxicology laboratories to ensure valid, appropriate results of toxicological screens. Workplace testing standards are not appropriate for urine testing.

(12) The Facility shall ensure that its physicians demonstrate competence in interpretation of "false negative" and "false positive" laboratory results as they relate to physiological issues, differences among laboratories, and factors that impact absorption, metabolism and elimination of opioids.

(13) The program physician shall thoroughly evaluate a positive toxicological screen for any potentially licit substance such as benzodiazepines, carisoprodol, barbiturates and amphetamines. The Facility shall verify with appropriate releases of information that:

(a) The service recipient has been prescribed these medications by a licensed prescriber for a legitimate medical purpose; and

(b) The prescribing physician is aware that the service recipient is enrolled in an opioid treatment program.

(14) If the service recipient refuses the release of information to contact his or her physician but can produce prescriptions and/or other evidence of legitimate prescription (such as current medication bottles, fully labeled), the team shall consider the service recipient's individual situation and the possibility that he or she may be dismissed from the care of his or her physician if the physician discovers that the service recipient is in medication-assisted treatment. The program physician shall make the ultimate decision as to the service recipient's continuing care in the clinic and the circumstances of that care.

(15) Absence of methadone or other medications prescribed by the Facility for the service recipient shall be considered evidence of possible medication diversion and evaluated by the physician accordingly.

(16) As appropriate and necessary, the SOTA shall develop guidelines for frequency of toxicological screening for alternative treatment modalities such as buprenorphine.

(17) The Facility shall access the PMP:

(a) Upon admission of a service recipient;

(b) Before the initial administration of methadone or other treatment in an opioid treatment program;

(c) After any positive drug test for prescription medication;

(d) Every six months to determine if controlled substances other than methadone are being prescribed for the service recipient. The service recipient's record shall include documentation of the check of the PMP database and the date upon which it occurred; and

(e) Each PMP access shall confirm that the service recipient is not seeking prescription medication from multiple sources.

(18) Nothing contained in this rule shall preclude any opioid treatment program from administering any additional drug tests it determines necessary.

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, and 33-2-404.

0940-05-42-.18 Detoxification and Medically Supervised Withdrawal.

(1) The Facility shall offer detoxification services as an admission alternative. All potential service recipients shall be offered long-term detoxification as an admission alternative; however, a Facility may choose to offer short-term detoxification for those service recipients who desire such a service.

(2) No standardized routines or schedules of increases or decreases of medications may be

established or used.

(3) The program physician shall ensure onsite medical supervision and oversight of the detoxification program.

(4) For persons projected to be involved in detoxification for six months or less, except as described in 0940-05-42-.17(9)(d), the Facility must offer the service recipient counseling as described in 0940-05-42-.14(3).

(5) Exceptions or refusal to participate in the detoxification program shall be documented and tracked by the Facility.

(6) The program physician shall determine on an individualized basis the appropriate dosage of opioid agonist medication to ensure stabilization during detoxification.

(7) Urine and/or other toxicological screening instruments shall be used by Facility staff during detoxification in order to demonstrate the absence of use of alternative licit and/or illicit drugs.

(8) In detoxification programs of 30 days or less duration, the Facility shall have a policy that does not allow more than one unsupervised or take-home medication per week for persons served. A Facility operating on a seven day per week basis (pursuant to 0940-05-42-.26) shall not allow take-home unsupervised-medications. This section shall not apply to detoxification programs conducted pursuant to Rule 0940-05-42-.17(9)(d) or administrative detoxification as defined in 0940-05-42-.18(12).

(9) In detoxification programs of more than 30 days duration, the Facility shall have a policy that allows the persons served to have the opportunity for take-home medications.

(10) The Facility shall have a policy regarding detoxification from opioid agonist medication that shall include:

(a) Individualized determination of a schedule of detoxification that is:

1. Well tolerated by the service recipient; and

2. Consistent with sound medical practices;

(b) Implementation of a higher stabilizing dose if deemed medically necessary;

(c) Assurances that voluntary detoxification shall be discontinued in the event of relapse and that provisions for maintenance treatment shall be made;

(d) Evaluation and/or testing for pregnancy prior to detoxification; and

(e) Provision for continuing care after the last dose of methadone or other treatment medication.

(11) Counseling services provided in conjunction with detoxification services shall be designed to:

(a) Explore other modalities of care including drug and alcohol treatment following detoxification or discharge;

(b) Motivate the service recipient to continue to receive services or to develop a plan for recovery following discharge; and

(c) Identify triggers for relapse and a coping plan for dealing with each, detailed and in writing and given to the service recipient prior to discharge. The plan shall be developed in conjunction with the service recipient.

(12) In the event the service recipient becomes unable to pay for treatment, the Facility shall develop

procedures for administrative detoxification or medically supervised withdrawal, including an appropriate time frame over which the procedure would take place. The schedule of withdrawal may be brief, less than 30 days if necessary. Such procedures shall include documentation of referral of the service recipient to alternative treatment resources. For persons involved in detoxification for 14 days or less, the Facility must offer a minimum of four counseling sessions per week.

(a) The Facility shall develop policies and procedures clearly describing under what circumstances a service recipient may be subject to administrative withdrawal. Administrative withdrawal may result from:

1. Non-payment of fees. The Facility shall make every effort to consider all clinical data including service recipient participation and compliance with treatment prior to initiating administrative withdrawal for non-payment. If the service recipient has a history of compliance and cooperation with treatment, the Facility shall document every effort to explore alternatives to administrative withdrawal with the service recipient prior to onset of withdrawal. If a service recipient has been in maintenance treatment for two years or more and subsequently cannot pay, the service recipient shall begin participation in a medically-supervised detoxification program for up to two weeks or as deemed medically necessary;

2. Disruptive conduct or behavior considered to have an adverse effect on the Facility, staff or service recipient population of such gravity as to justify the involuntary withdrawal and discharge of a service recipient. Such behaviors may include violence, threat of violence, dealing drugs, diversion of pharmacological agents, repeated loitering, and/or flagrant noncompliance resulting in an observable, negative impact on the Facility, staff and other service recipients; or

3. Other reasons as determined by the Facility and approved by the SOTA.

(b) Medically supervised withdrawal occurs as a voluntary and therapeutic withdrawal agreed upon by staff and service recipient. In some cases the withdrawal may be against the advice of clinical staff (against medical advice).

1. The Facility shall supply a schedule of dose reduction well tolerated by the service recipient.

2. The Facility shall offer supportive treatment including increased counseling sessions and referral to a self-help group or other counseling provider as appropriate.

3. If the service recipient leaves the Facility's program abruptly against medical advice, the Facility may readmit the service recipient within 30 days without a formal reassessment procedure. The Facility shall document attempting to assist the service recipient in any issues which may have triggered his or her abrupt departure.

4. The Facility shall make provisions for continuing care for each service recipient following the last dose of medication and for re-entry to maintenance treatment if relapse occurs or if the service recipient should reconsider withdrawal.

5. Female service recipients shall have a negative pregnancy screen prior to the onset of either administrative or medically-supervised withdrawal.

(13) For detoxification or withdrawal, the Facility shall have in place a detailed relapse prevention plan developed by the counselor in conjunction with the service recipient and a copy of which shall be given to the service recipient prior to the administration of the final dose.

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, and 33-2-404.

0940-05-42-.19 Diversion Control Plan.

(1) Each clinic shall prepare a Diversion Control Plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate medical treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control functions described in the Diversion Control Plan.

The Diversion Control Plan shall contain, at a minimum, a random call-back program with mandatory compliance.

(a) This call-back shall be in addition to the regular schedule of clinic visits.

(b) Each service recipient receiving three or more consecutive take-home medications shall be called back randomly within the three-month period immediately following the previous call-back.

(c) Upon call back a service recipient shall report to the clinic within 24 hours of notification, with all take-home medications. The quantity and integrity of packaging shall be verified for all doses. If a take-home dose shows evidence of tampering, the clinic shall impose uniform sanctions for violating take-home policies, including sanctions for a service recipient's tampering with a take-home dose.

(d) Service recipients shall be informed of consequences for violating the take-home policy.

(e) The Facility shall maintain individual call-back results in the service recipient record.

(2) Diversion control plans shall minimize the diversion of methadone or other opioid treatment medications to illicit use. The plan shall include:

(a) Clinical and administrative continuous monitoring of the potential for and actual diversion including an investigation, tracking and monitoring system of incidents of diversion; and

(b) Proactive planning and procedures for problem identification, correction and prevention signed by the Facility medical staff and the service recipient.

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, and 33-2-404.

0940-05-42-.20 Central Registry.

(1) All facilities shall participate in the department's Central Registry.

(2) Service recipients shall be informed of the Facility's participation in the Central Registry; and, 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 OTP, within 72 hours of admission the Facility shall initiate a clearance inquiry by submitting to the approved Central Registry the name, date of birth, anticipated date of admission or discharge and any other relevant information required for the clearance procedure or as required by the SOTA. No person who is reported by the Central Registry to be participating in another such Facility shall be admitted to an OTP, or in the event a dual enrollment is found, the service recipient shall be discharged from one OTP in order to continue enrollment at another OTP. The SOTA shall be notified within 24 hours of any service recipient who is found by an OTP to be simultaneously enrolled in another OTP.

(4) Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed 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.

(5) If a Facility operates within 75 miles of an OTP in an adjoining state, the SOTA may direct the Facility to share service recipient information with the OTP in the other state to prevent simultaneous enrollment of persons in more than one OTP facility.

(6) The Facility shall develop policies and procedures to address a service recipient's multiple enrollment and cumulative time in all prior opioid replacement treatment episodes with other opioid treatment programs or Facilities in Tennessee as well as procedures for contacting opioid treatment programs or Facilities in an adjoining state if within 75 miles of a Tennessee OTP.

(7) Within five days of completion of the service recipient's IPP, the OTP shall submit to the Central Registry such information as is required by the SOTA and the department.

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, and 33-2-404.

0940-05-42-.21 Reporting Requirements.

(1) The Facility shall submit the following information to the department:

(a) All reports, forms and correspondence submitted to or received from the FDA, DEA, any other applicable federal agencies or accreditation organizations shall be provided to the SOTA within five business days of sending or receiving such documents.

(b) Such reports and information which may be required by the department to conduct evaluations of opioid replacement treatment effectiveness or monitor service delivery.

(2) The OTP shall report each case of communicable disease to the local county health officer in the manner provided by T.C.A. § 68-5-102 and Chapter 1200-14 of the Rules of the Tennessee Department of Health. Repeated failure to report communicable diseases shall be cause for revocation of a Facility license.

(3) The Facility shall report within 24 hours to the Office of Licensure and the SOTA the abuse of a service recipient or an unexpected occurrence or accident that results in death or serious injury to a service recipient or any action taken against the Facility by the DEA, accrediting body or other state, local or federal agency. Additionally, the following are examples of events that should be reported:

(a) Medication errors that caused or had the potential to cause harm to the service recipient;

(b) Criminal acts;

(c) Suicide or attempted suicide;

(d) Rape;

(e) Neglect of a service recipient;

(f) Service recipient altercations;

(g) Service recipient abuse;

(h) Misappropriation of service recipient funds;

(i) Restraint related incidents; or

(j) Poisoning occurring within the Facility.

(4) Specific incidents that might result in a disruption of the delivery of health care services at the Facility shall be reported to the Office of Licensure and the SOTA within seven days after the Facility learns of the incident. These specific incidents include the following:

(a) Strike by the staff at the Facility;

(b) External disaster impacting the Facility;

(c) Disruption of any service vital to the continuous, safe operation of the Facility or to the health and safety of its service recipients and personnel;

(d) Fires at the Facility which disrupt the provision of service recipient care services or cause harm to service recipients or staff, or which are reported by the Facility to any entity, including, but not limited to, a fire department charged with preventing fires; and

(e) Improper disclosure of a service recipient's protected health information.

(5) Within seven days of any event described in (3), the Facility shall file a report with the Office of Licensure and the SOTA on the incident consisting of the following:

(a) The actions implemented to prevent the reoccurrence of the event;

(b) The time frames for the action(s) to be implemented;

(c) The person(s) designated to implement and monitor the action(s); and

(d) The strategies for the measurements of effectiveness to be established.

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, and 33-2-404.

0940-05-42-.22 Quality of Care.

(1) The Facility shall develop and implement a plan for continuous quality improvement. At a minimum, the plan shall include:

(a) Structured assessment of the program which addresses Facility program management, staffing, policies and procedures and general operations.

(b) A service delivery assessment which, at a minimum, shall evaluate appropriateness of the IPP and services delivered, completeness of documentation in service recipients' records and quality of and participation in staff training programs, linkage to a utilization of primary care and other out-of-program services, and availability of services and medications for other conditions (e.g. prenatal, tuberculosis, HIV).

(c) An assessment of the aggregate cost of services per service recipient per week for services rendered.

(d) An assessment of medication-related issues including take-home procedures, security, inventory and dosage issues.

(e) Such process shall serve to continuously monitor the Facility's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement process shall be delegated to a staff person who has been determined to be qualified by education, training and experience to perform such tasks. The medical director shall be actively involved in the process.

(f) A Facility shall participate in additional quality improvement outcome studies as directed by the SOTA.

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, and 33-2-404.

0940-05-42-.23 Infectious Hazardous Waste.

(1) Each Facility shall develop, maintain and implement written policies and procedures for the definition and handling of its infectious wastes. These policies and procedures shall comply with the standards of this section and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste contaminated by service recipients who are isolated due to communicable diseases, as provided in the U.S. Centers for Disease Control "Guidelines for Isolation Precautions in Hospitals."

(b) Cultures and stocks of infectious agents including specimen cultures collected from medical and pathological laboratories, cultures and stocks of infectious agents from research and industrial laboratories, wastes from the production of biologicals, discarded live and attenuated vaccines, culture dishes and devices used to transfer, inoculate, and mix cultures.

(c) Waste human blood and blood products such as serum, plasma, and other blood components.

(d) All discarded sharps (e.g., hypothermic needles, syringes, Pasteur pipettes, broken glass, scalpel blades) used in service recipient care or which have come into contact with infectious agents during use in medical, research, or industrial laboratories.

(e) Other waste determined to be infectious by the Facility in its written policy.

(3) Infectious and hazardous waste shall be segregated from other waste at the point of generation (i.e., the point at which the material becomes a waste) within the Facility.

(4) Waste shall be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging shall provide for containment of the waste from the point of generation up to the point of proper treatment of disposal. Packaging shall be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported, prior to treatment and disposal.

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, and 33-2-404.

0940-05-42-.24 Infection Control.

(1) The Facility shall have policies and procedures to be followed for infection control, including:

(a) Reporting all suspected or diagnosed cases of infectious disease including tuberculosis, AIDS, and sexually transmitted disease (STD) promptly to the regional health department in accordance with 42 CFR, Part 2; T.C.A. §§ 68-10-101 et seq., 68-9-201 and 68-5-102; and Chapter 1200-14 of the Rules of the Tennessee Department of Health.

(b) Management of service recipients who are infected with Hepatitis B or C virus, HIV/AIDS or other STD.

(c) Nondiscrimination of employees and service recipients regarding their HIV/AIDS status.

(d) Use of standard precautions for prevention of transmission of HIV/AIDS, Hepatitis B or C Virus, and other blood borne pathogens.

(e) Infectious disease skin or blood testing will be made on a voluntary basis for any service recipient who requests it, and be documented in appropriate records. If a clinic does not have the capacity to conduct pelvic exams, the clinic shall establish and document a relationship with a community health care provider so that referrals can be made and

care can be coordinated.

(f) Assurance that a service recipient's HIV, other STD, and tuberculosis status will be kept confidential in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Service Recipient Records regulations at 42 CFR Part 2.

(g) Documentation on the establishment of linkages between the Facility and the local health department to ensure service recipients receive appropriate medical care relative to their infection and/or exposure to tuberculosis, Hepatitis B or C; and STD (including HIV), i.e., establish contact between the health department and the Facility to communicate appropriate information to assure that the service recipient receives appropriate care.

(h) Informed consent of service recipients before screening and treatment.

(i) Conducting case management activities to ensure that individuals receive appropriate treatment services for HIV/AIDS, Hepatitis B or C Virus and other sexually transmitted diseases.

(j) Procedures to ensure that the Facility, either directly or through arrangements with other public or private non-profit entities, will make available tuberculosis (TB) services in accordance with current Tennessee TB Guidelines for Alcohol and Drug Treatment Facilities (TB Guidelines), established by the Department of Health TB Elimination Program and the department, including:

1. Counseling the service recipients about TB;

2. Screening all service recipients for TB and, if applicable, testing service recipients at high risk for TB to determine whether the service recipients have been infected with TB;

3. Providing for or referring the service recipients infected with TB for appropriate medical evaluation and treatment; and

4. Conducting case management activities to ensure that service recipients receive such 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, and 33-2-404.

0940-05-42-.25 Managing Disruptive Behavior.

(1) The Facility shall develop policies and procedures which address the methods for managing disruptive behavior. If restrictive procedures are used to manage disruptive behaviors, written policies and procedures shall govern their use and shall minimally address the following:

(a) Any restrictive procedure shall be used by the Facility only after all less restrictive alternatives for dealing with the problem behavior have been systematically tried or considered and have been determined to be inappropriate or ineffective:

1. The service recipient shall have given prior written consent to any restrictive measures taken with him/her by the staff;

2. The restrictive procedure(s) shall be documented in the IPP, be justifiable as part of the plan, and meet all requirements that govern the development and review of the plan;

3. Only qualified personnel may use restrictive procedures and shall be adequately trained in their use; and

4. The adaptive or desirable behavior shall be taught to the service recipient in conjunction with the implementation of the restrictive procedures.

(b) A policy which states physical holding shall be implemented in such a way as to minimize any physical harm to the service recipient and may only be used in an emergency situation to assure the physical safety of the service recipient or others nearby or to prevent significant destruction of property that puts the service recipient or persons nearby in danger.

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, and 33-2-404.

0940-05-42-.26 Hours of Operation.

(1) A Facility's hours of operation shall accommodate persons involved in activities such as school, homemaking, child care and variable shift work.

(a) Dosing and counseling shall be available at least six hours per day from Monday through Friday and at least three hours on Saturday. On Sundays, dosing shall be available at least three hours and counseling may be provided in order to accommodate a service recipient's schedule.

(b) All clinics shall be open seven days per week and 365 days per year with the exception of being closed on four nonconsecutive days for holidays. Facilities shall notify the SOTA and service recipients of the date of any holiday when the Facility will be closed at least 14 days in advance of the holiday.

(c) Any Facility may also be closed for one mandatory training day, if required by the SOTA.

(d) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, and referral services, at least six days per week. Medical exams shall be provided on days when new admissions to the clinic occur.

(e) Any service recipient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, such as holidays, not to exceed two consecutive days.

(f) Facilities shall provide the SOTA with at least two weeks' notice prior to any change in Facility hours.

(g) A Facility that intends to voluntarily close shall notify TDMHSAS no later than 90 days prior to closure. In order to assure continuity of care, any Facility which closes, either voluntarily or involuntarily, shall comply with all directions received from the TDMHSAS regarding the orderly transfer of service recipients and their records.

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, and 33-2-404.

0940-05-42-.27 Service Recipients' Rights.

(1) All applications, certificates, records, reports and all legal documents, petitions and records made or information received pursuant to treatment in an OTP directly or indirectly identifying a service recipient shall be kept confidential and shall not be disclosed by any person except the individual identified.

(2) Nothing in this rule shall prohibit disclosure, upon proper inquiry, of information as to the current medical condition of a service recipient to any member of the Facility of a service or to the service recipient's relatives or friends in accordance with T.C.A. § 33-3-103; Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations at 45 Code of Regulations (CFR) Parts 160 and 164, Subparts A and E; and Confidentiality of Alcohol and Drug Abuse Service Recipient Records regulations at 42 CFR Part 2.

(3) Service recipients shall not be abused or neglected.

(4) Facilities shall develop and implement written policies and procedures regarding the rights and responsibilities of service recipients under Rules 0940-05-06-.07 and 0940-05-06-.08 and the handling and resolution of complaints.

(5) Other service recipient rights include:

(a) Right to a humane treatment environment that affords reasonable protection from harm, exploitation, and coercion;

(b) Right to be informed about the IPP and to participate in the planning, as able;

(c) Right to be promptly and fully informed of any changes in the plan of treatment;

(d) Right to accept or refuse treatment;

(e) Right to receive a written notice of the address and telephone number of the state licensed authority, i.e. the Department; and

(f) Right to obtain from the Facility, upon written request, a copy of the Facility's most recent completed report of licensing compliance inspection. The Facility is not required to release a report until the Facility has had the opportunity to file a written plan of compliance for any violations as provided for in these rules.

(6) The written policies and procedures shall include provisions for service recipients and others to present complaints, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

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, and 33-2-404.

0940-05-42-.28 Community Relations.

The Facility shall have policies and procedures for community relations to include the following:

(1) A Facility shall be responsible for ensuring that its service recipients do not cause unnecessary disruption to the community or act in a manner that would constitute disorderly conduct or harassment by loitering on the Facility's property.

(2) Each Facility shall provide TDMHSAS, when requested, with a specific plan describing the efforts it will make to avoid disruption of the community by its service recipients and the actions it will take to assure responsiveness to community needs. This plan shall, at a minimum:

(a) Identify Facility personnel who will function as community relations coordinators and define the goals and procedures of the community relations plan.

(b) Include policies and procedures or resolve community problems, including service recipient loitering and medication diversion, to ensure that Facility operations do not affect community life adversely.

(c) Include procedures for soliciting service recipient and community ideas about medication assisted treatment, addressing community concerns and the Facility's presence in the community.

(3) Each Facility shall document community relations efforts and community contacts, including the resolution of issues identified by community members or service recipients.

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, and 33-2-404.

0940-05-42-.29 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 and each individual file shall include:

(a) Identifying information including name, current address, current telephone number, and emergency contact person(s).

(b) A 10-year employment history or a complete employment history if the person has not worked in 10 years.

(c) Records of educational qualifications, if applicable.

(d) Date of employment.

(e) Documentation of training and orientation of the person's duties and responsibilities.

(f) Any records relevant to the employee's performance.

(g) Evidence that any professional license required as a condition of employment is current and in good standing.

(h) Annual verification of basic skills and annual evaluation of personnel performance. Included shall be written verification that the employee has reviewed the evaluation and has had an opportunity to comment on it.

(i) Training and development activities designed to educate the staff in meeting the needs of the service recipients being served, including STD/HIV education.

(2) Tuberculosis.

(a) All new employees, including volunteers who have routine contact with service recipients, shall be tested within three business days of employment for latent tuberculosis infection utilizing the two-step Mantoux method or a single interferon-gama release blood assay (IGRA).

(b) Employees shall have a test for tuberculosis annually and at the time of exposure to active tuberculosis and three months after exposure. Annual tuberculosis testing of previously TST-negative employees and volunteers shall be performed by the one-step Mantoux method.

(c) Employee records shall include the date and type of annual tuberculin tests given to the employee, date of tuberculin test results, and, if applicable, date and results of chest x-ray and any drug treatment for tuberculosis.

(3) Staffing.

(a) Program Director. The governing body of each Facility shall designate in writing a program 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 opioid treatment programs, and for all employees including practitioners, agents, or other persons providing services at the Facility. Facilities shall notify the SOTA in writing within 10 calendar days whenever there is a change in program director.

(b) Medical Director. The governing body of each Facility shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state and local laws and regulations regarding the medical treatment of opioid addiction. No physician may serve as medical director of more than one OTP without the prior written approval of the SOTA. Facilities shall notify the SOTA

in writing within 10 calendar days whenever there is a change in medical director.

(c) Program Physician. Facilities are required to provide sufficient physician services to provide the medical treatment and oversight necessary to serve service recipient needs.

1. Physician services include, but are not limited to, performing medical history and physical exams, determining a diagnosis under current DSM criteria, determination of opioid dependence, ordering take-home privileges, discussing cases with the treatment team and issuing any emergency orders.

2. The OTP shall provide on-site prescriber services of one hour per week for every 35 service recipients. At least 12.5% of the required prescriber services per week shall be provided by a physician.

(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 Tennessee law or regulations.

(e) Nurses. Facilities shall ensure that adequate nursing care is provided at all times the Facility is in operation and that a nurse is present at all times medication is administered at the Facility. Facilities that do not employ a registered nurse to supervise the nursing staff shall ensure that licensed practical nurses adhere to written protocols and are properly supervised consistent with Rules Chapter 1000-02 Rules and Regulations of Licensed Practical Nurses.

(f) Counselors. There shall be sufficient group and individual counseling available to meet the needs of the service recipient population.

(4) Staff Qualifications.

(a) Medical Director. All medical directors shall be licensed to practice medicine or osteopathy in Tennessee, shall maintain their licenses in good standing and shall have the following experience and/or credentials:

1. Three years of documented experience in the provision of services to persons who are addicted to alcohol or other drugs, including at least one year of experience in the treatment of opioid addiction; or

2. Board eligibility in psychiatry and two years of documented experience in the treatment of persons who are addicted to alcohol or other drugs; or

3. Certification as an addiction medicine specialist by the American Society of Addiction Medicine (ASAM) or Board certification as an addiction medicine specialist.

(b) Waiver from Medical Director Qualifications. Facilities that are unable to secure the services of a medical director who meets the requirements of subparagraph (a) above may apply to the TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, in consultation with the SOTA, may grant such a waiver when there is showing that:

1. The Facility has made good faith efforts to secure a qualified medical director, but has failed;

2. The Facility can secure the services of a licensed physician who is willing to serve as medical director and participate in the training plan;

3. A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-

service training by a medical consultant who meets the qualifications specified in subparagraph (a) above; and

4. A medical consultant who meets the requirements of subparagraph (a) above shall be available, consistent with a training plan approved by the SOTA, to oversee the training of the medical director and the delivery of medical services at the Facility requesting the waiver.

(c) Program Physician. All Facility physicians shall be licensed to practice medicine in Tennessee, shall maintain their licenses in good standing and shall have at least one year of documented experience in the treatment of persons addicted to alcohol or other drugs.

(d) Waiver from Program Physician Qualifications. Facilities seeking to employ a program physician, in addition to the medical director, but are unable to secure the services of a program physician who meets the requirements of subparagraph (c) above may apply to the TDMHSAS Office of Licensure for a waiver. The TDMHSAS Office of Licensure, in consultation with the SOTA, may grant such a waiver when there is a showing that:

1. The Facility has made good faith efforts to secure a qualified program physician, but has failed;

2. The Facility can secure the services of a licensed physician who is willing to serve as program physician and participate in the training plan;

3. A training plan has been developed which is acceptable to the SOTA and which consists of a combination of continuing education in addiction medicine and in-service training by the Facility's medical director; and

4. The Facility employs a qualified medical director who has the experience and credentials specified in subparagraph (a) above, has completed the training program specified in subparagraph (b) above or has completed the continuing education specified in subparagraph (e) below.

(e) Current Medical Directors and Program Physicians. All physicians serving as medical director or program physicians as of the effective date of these rules who do not meet the criteria specified above will be deemed qualified provided that the Facility notifies the Office of Licensure and the SOTA in writing that within two years from the effective date of these rules the physician serving as medical director or program physician will obtain 50 hours of continuing education in addiction medicine approved by the SOTA. At least 25 hours of this continuing education shall be obtained within one year from the effective date of these rules.

(f) Nurses. All registered nurses and licensed practical nurses shall be licensed to practice in Tennessee and shall maintain their license in good standing.

(g) Counselors. All counselors shall be qualified by training, education and/or two years' experience in addiction treatment under appropriate clinical supervision in order to provide addiction counseling services. All unlicensed counselors should be encouraged to complete the process of obtaining appropriate licensure and/or certification.

(h) Program Directors. All Facility program directors shall have at least one year of supervisory or administrative experience in the field of addiction treatment.

(i) Professional Practice. All professional staff including, but not limited to, physicians, physician assistants, nurses and counselors may perform only those duties that are within the scope of their applicable professional practice acts and Tennessee licenses.

(5) Staff Training and Orientation. Prior to working with service recipients, all staff providing treatment or services shall be oriented in accordance with these rules and shall thereafter receive additional

training with these rules.

(a) Orientation shall include instruction in:

1. The Facility's written policies and procedures regarding its purposes and description; service recipient rights, responsibilities, and complaints; confidentiality; and other policies and procedures that are relevant to the employee's range of duties and responsibilities;

2. The employee's assigned duties and responsibilities; and

3. Reporting service recipient progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services.

(b) Additional training consisting of a minimum of eight clock hours of training or instruction shall be provided annually for each staff member who provides treatment or services to service recipients. Such training shall be in subjects that relate to the employee's assigned duties and responsibilities, and in subjects about current clinical practice guidelines for opioid replacement treatment. In-house training for staff may be substituted for external training with the approval of the SOTA. The following areas shall receive emphasis during training:

1. Dosage level as determined through a physician's clinical decision-making and the individual service recipient's needs;

2. Counseling;

3. Drug screens and urinalysis;

4. Phases of treatment;

5. Treating multiple substance abuse;

6. Opioid treatment during pregnancy and diseases;

7. HIV and other infectious diseases;

8. Co-morbid psychiatric conditions;

9. FDA-approved drugs for the treatment of opioid addiction, including methadone and buprenorphine;

10. Take-home medication practices;

11. Chronic pain and pain management; and

12. Referring service recipients for primary care or other specialized services.

(c) The SOTA may require facilities to attend mandatory training in addition to any other training required by these rules.

(d) Facilities shall maintain records documenting that each staff member has received the required annual training.

(6) Employee Drug Screening. Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug screening of all Facility employees. Each sample collected shall be screened for opioids, methadone, amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by the SOTA.

(7) A minimum of one on-duty staff member certified in cardiopulmonary resuscitation (CPR) and trained in the Abdominal Thrust Technique and First Aid shall be maintained.

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, and 33-2-404.

Repeals

Chapter 0940-05-42 Minimum Program Requirements for Alcohol and Drug Abuse Non-Residential Opiate Treatment Facilities is repealed in its entirety.

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, and 33-2-404.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

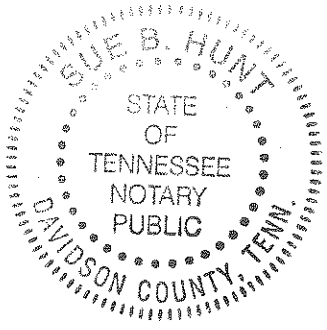
Board Member	Aye	No	Abstain	Absent	Signature (if required)

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 (board/commission/ other authority) on 05/22/2012 (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: *(11/15/11)*

Rulemaking Hearing(s) Conducted on: (add more dates). *(01/05/12)*



Date: 5/22/12

Signature:

Name of Officer: E. Douglas Varney

Title of Officer: Commissioner

Subscribed and sworn to before me on: May 22, 2012

Notary Public Signature: Sue B. Hunt

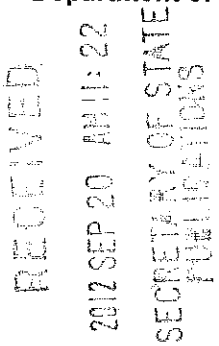
My commission expires on: July 8, 2013

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

Robert E. Cooper, Jr.
Attorney General and Reporter

9-19-12
Date

Department of State Use Only



Filed with the Department of State on: 9/20/12

Effective on: 12/19/12

Tre Hargett
Secretary of State

G.O.C. STAFF RULE ABSTRACT

DEPARTMENT:	Finance and Administration
DIVISION:	Bureau of TennCare
SUBJECT:	Long Term Care Services and Supports under CHOICES Program
STATUTORY AUTHORITY:	Tennessee Code Annotated, Sections 71-5-105 and 71-5-109
EFFECTIVE DATES:	December 25, 2012 through June 30, 2013
FISCAL IMPACT:	The promulgation of these rules is anticipated to decrease state expenditures by $17,930,000 in FY 2013.
STAFF RULE ABSTRACT:	These rules replace emergency rules previously promulgated on the same subject. These rules allow for changes to the Nursing Facility Level of Care requirements for entry into CHOICES, TennCare's program of long term services and supports for individuals who are elderly or physically disabled.

Impact on Local Governments

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

The rules are not anticipated to have an impact on local governments.

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.

Copy of response to comment is included with filing.

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
DIVISION OF HEALTH CARE FINANCE AND ADMINISTRATION
BUREAU OF TENNCARE
310 Great Circle Road
NASHVILLE, TENNESSEE 37243

September 20, 2012

Mr. Jesse Samples, Executive Director
Tennessee Health Care Association
2809 Foster Avenue
Nashville, TN 37210

Dear Mr. Samples:

Thank you for your comments regarding the Permanent Rule implementing changes in TennCare's level of care (LOC) criteria for Medicaid reimbursement of nursing facility (NF) services. This letter responds to your specific recommendations, and also addresses several of the comments made in your letter.

TennCare has consistently supported the move away from a purely cost-based reimbursement methodology for NF services and toward a system of payment that better takes into account the acuity of residents served. As you are aware, this was part of the Long-Term Care Community Choices Act (LTC CCA) of 2008. It is important to note that THCA and the industry did not want to move forward with implementing that new methodology at the same time that the State was integrating NF services into the managed care program. Accordingly, we agreed to allow time for the system to stabilize before changing the reimbursement methodology.

We further agreed to delay moving forward with changing reimbursement methodologies when it was decided that the State would have to implement a reduction in provider rates (including NFs) during Fiscal Year 2012.

Moreover, shortly after the LTC CCA was passed, we learned that the State would not be able to implement LOC changes that would ultimately help to better target NF services to higher acuity residents due to Maintenance of Effort (MOE) requirements of the American Recovery and Reinvestment Act of 2009 and subsequently the Affordable Care Act of 2010. It was only in late 2011 that we reached agreement in principle with CMS on a strategy to revise LOC criteria while maintaining compliance with MOE provisions, and in mid-2012 that we received formal approval of an amendment that would allow us to begin implementing these changes on July 1, 2012. To that end, as you note, an additional $8 million state ($23.6 million total) in non-recurring funds was recommended by the Governor and approved by the General Assembly to help compensate facilities for the increase in the

acuity mix of residents in FY 2013, while we are working with you and with LTSS stakeholders broadly to determine how best to implement a new reimbursement methodology that better reflects acuity, while also aligning incentives in order to promote the highest quality of care for NF residents.

We are happy to work with THCA and with other industry representatives, as well as members of the LTSS stakeholder community broadly in the development of a new reimbursement methodology. In fact, based on your recommendations, we have already begun the process of working with Meyers and Stauffer to analyze MDS data and to then assist us in modeling various types of reimbursement options. We are happy to work with THCA to request any analyses you believe should be conducted as we explore options for acuity-based reimbursement and share that information along with other alternative models in our broader stakeholder discussions. I feel confident that, working together, we can develop a new methodology that will accomplish our shared goals of better matching payment to the acuity of residents served, while also promoting the highest quality of care for our members.

We respectfully disagree with your characterization that CHOICES Group 3 is a "low level of service benefit," and particularly that it is "becoming the primary service group for people needing long-term services and supports." As has been explained, this is the level of service typically received by a significant percentage of persons receiving HCBS prior to implementation of these changes, based on an individualized assessment of their needs. Bear in mind that these individuals also have access to other Medicaid benefits, including home health, as well as services available through Medicare (if the person is dual eligible as 90 percent of CHOICES members are), private insurance or other funding sources, and unpaid supports provided by family members and other caregivers.

Further, as you know, the LOC process has been specifically designed to allow persons with an acuity score of less than nine (9) whose needs cannot be safely met within the array of benefits available if enrolled in Group 3 to meet NF LOC and to have access to NF services or alternatively, a more comprehensive package of HCBS.

With respect to the primary LTSS service group, we monitor CHOICES enrollment, including how people come into the program, on a monthly basis. Since the beginning of Statewide implementation, Group 1 (persons receiving NF services) has consistently been the "primary" LTSS Service group, both in terms of total enrollment and in terms of how people are coming into the program.

At the outset of LOC changes, we said our intent was that roughly 20-25% of applicants for NF care would be diverted to more cost-effective home and community-based alternatives that would help to delay the need for NF placement. Upon analyzing data from the TennCare PAE System (TPAES) beginning with implementation of LOC changes on July 1, the rate of diversion from NFs we are seeing is at the low end of the anticipated range. With more than two months of data, the percentage of people applying for NF services that have been diverted to CHOICES Group 3 for HCBS has been just over 21% (21.04). Of course, as their needs change, level of care will be re-evaluated, and at the point that NF LOC is met, more comprehensive HCBS or NF care will be available.

Our denial rate (applicants that do not qualify for *any* LTSS) among persons applying to receive NF services remains flat at 9% (it typically runs around 9-10%), which we would expect, since people that would have qualified in the past would still qualify for services—HCBS (rather than NF services) when they have lesser needs. The remaining roughly 70% of NF applicants are in fact qualifying for NF LOC.

NF services thus continue as the "primary" CHOICES group at 20,809 members and 64.58% of the total CHOICES population as of September 1, 2012.

With respect to re-submission of PAEs, the TennCare Rules are very clear that a PAE may always be resubmitted. However, any deficiencies in a submitted PAE application must be cured prior to disposition of the PAE to preserve the PAE submission date for payment purposes. In fact, as I shared with you in an earlier email, one of the most significant issues we have seen is that providers are not always submitting an accurate assessment of the member's level of functioning in the PAE and supporting documentation. It is likely that providers became accustomed to the very low threshold that existed prior to July 1, and have not yet adjusted to the need for a more thorough assessment along with supporting documentation of the person's functional needs. In several cases where concerns have been raised about a person's ability to be safely served in Group 3, we have found that in fact the person has an acuity score of nine (9) and meets NF LOC; however, comprehensive, accurate information was not submitted in the initial application. In many such instances, staff here have assisted NFs in getting the right information in order to ensure that the person's actual level of functioning was accurately represented, and NF LOC was approved.

Regarding the timeliness of processing PAEs, this too is something that we monitor on an ongoing basis, ever-vigilant of the eight working day processing time line. Our managers receive a daily report of aged PAEs, so that we always know how many days remain for timely determination. Between July 1 and August 31, 2012, we received a total of 6,937 PAEs (5,210 Nursing Facility and 1,727 HCBS). Of those nearly 7,000 PAEs, a total of three (3) PAEs (.0004) were not adjudicated within the eight day timeframe. In each case, the decision was one day late (on the 9th day). In addition, there were four (4) PAEs adjudicated timely for which the decision was subsequently revised upon audit. I cannot express how hard the staff of the PAE unit have worked to process between 700 and in some cases nearly a thousand PAEs each week in a timely manner, reviewing not just one, but in many cases, two levels of care. It is therefore incredibly disheartening when unfounded allegations are made regarding the timeliness of their work. I would ask that in the future, if facilities make such allegations, you provide specific examples to TennCare, allowing us the opportunity to research and respond.

With respect to the MCOs' role in the LOC process, this has been very clearly defined in their contracts and other documents, with training and ongoing monitoring to ensure that they are fulfilling their contracted functions. It does appear, however, that NFs may have some confusion regarding the MCOs' role--particularly in instances in which a member is not yet Medicaid eligible, and therefore does not have an MCO. We will provide additional information to NFs via a memo and training bulletin very soon.

Finally, regarding your specific comments, you requested that we reconsider the 30-day period for which we will allow a member's previous LOC determination to stand once he has elected hospice and then subsequently chooses to withdraw his hospice election and re-enroll in CHOICES. The purpose of this period is to simplify the administrative process for persons who change their minds. In any other case, when a person is withdrawing their hospice election, we believe the reasonable likelihood is that the person's condition has improved such that hospice is no longer appropriate, in which case, re-evaluation of LOC is appropriate. In considering your recommendation, we reviewed 25 hospice re-enrollment requests. Of those 25, 6 were within 30 days of the hospice election, all indicating that the patient or family opted to disenroll from hospice services. The remaining 19 were more than 30 days from the hospice election, ranging from 3 months (only 1) to 8 months, but most were 6-8 months. In each of those 19 instances, there was an indication that the patient improved such that the physician was no longer ordering hospice services, in which case, re-evaluation of LOC was necessary to determine whether placement in a NF was appropriate. Upon review of this data, we have elected to stay with the 30-day period in effect in the Emergency Rule.

With respect to LOC, there is no "exception process." Rather, there are specific LOC criteria—both for persons to qualify for NF placement, and for persons "at risk" of NF placement. One of the components of the State's LOC criteria for NF placement (required for enrollment into CHOICES Group 1 or 2) is meeting the "at-risk" criteria, but being determined by TennCare to not qualify for enrollment into CHOICES Group 3. This is described in TennCare Rule 1200-13-01-.10(4). In instances where TennCare has determined that the person's needs cannot be safely met in CHOICES Group 3 (see the *NF LOC Guide* pp. 14-16, and TennCare Rule Sections 1200-13-01-.05(4), 1200-13-01-.05(5), and 1200-13-01-.05(6)), but the person satisfies the criteria set forth at 1200-13-01-.10(4)(c)1.(i) and (c)2.(iii) on an ongoing basis, the person will meet NF LOC.

Applicants that are denied NF LOC are always notified of the opportunity to appeal the denial of the PAE. They are not notified of an "exception" (as noted above, there is no "exception"); rather they are notified of the specific reasons they did not meet NF LOC, and afforded the opportunity to request a fair hearing regarding the State's decision.

Thank you again for your comments and recommendations. We will continue to carefully monitor these processes going forward to make sure that they are working as we intended, and to ensure that people are able to receive an appropriate level of services and supports.

Respectfully,

Patti Killingsworth

C: Darin Gordon, Deputy Commissioner

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

The rules are not anticipated to have an effect on small businesses.

Department of State
Division of Publications
312 Rosa L. Parks Avenue, 8th Floor Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Fax: 615-741-5133
Email: register.information@tn.gov

For Department of State Use Only

Sequence Number: 09-10-12
Rule ID(s): 5310
File Date: 9/26/12
Effective Date: 12/25/12

Rulemaking Hearing Rule(s) Filing Form

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

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

Revision Type (check all that apply):

X Amendments
___ New
___ Repeal

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

Chapter Number	**Chapter Title**
1200-13-01	TennCare Long-Term Care Program
Rule Number	**Rule Title**
1200-13-01-.01	Purpose
1200-13-01-.02	Definitions
1200-13-01-.05	TennCare CHOICES Program
1200-13-01-.08	Personal Needs Allowance (PNA), Patient Liability, Third Party Insurance and Estate Recovery for Persons Receiving LTC
1200-13-01-.10	Medical (Level of Care) Eligibility Criteria for Medicaid Reimbursement of Care in Nursing Facilities

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Rule title 1200-13-01-.08 Personal Needs Allowance (PNA), Patient Liability, Third Party Insurance and Estate Recovery for Persons Receiving LTC in the Table of Contents is amended by replacing "LTC" with "LTSS" so as amended Rule title 1200-13-01-.08 shall read as follows:

Rule 1200-13-01-.08 Personal Needs Allowance (PNA), Patient Liability, Third Party Insurance and Estate Recovery for Persons Receiving ~~LTC~~ LTSS

Rule title 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for Medicaid Reimbursement of Care in Nursing Facilities in the Table of Contents is deleted its entirety and replaced with a new Rule title 1200-13-01-.10 which shall read as follows:

Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for ~~Medicaid~~ TennCare Reimbursement of Care in Nursing Facilities, CHOICES HCBS and PACE

Paragraph (1) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and replaced with a new Paragraph (1) which shall read as follows:

(1) The purpose of this Chapter is to set forth requirements pertaining to the Long-Term ~~Care (LTC)~~ Services and Supports (LTSS; formerly and also known as the Long-Term Care or LTC) delivery system.

The introductory language to Subparagraph (2) of Rule 1200-13-01-.01 Purpose is amended by deleting "LTC" and replacing it with "LTSS" so as amended the introductory language shall read as follows:

(2) The Bureau of TennCare (Bureau) offers the following ~~LTC~~ LTSS programs and services:

Subparagraphs (a) and (b) of Paragraph (2) of Rule 1200-13-01-.01 Purpose are deleted in their entirety and subsequent Subparagraphs re-lettered accordingly.

~~(a) Nursing Facility (NF) services.~~

~~1. Until such time as the TennCare CHOICES in Long-Term Care Program (CHOICES) is implemented in a particular Grand Division, NF services shall be administered by the Bureau under a Fee-for-Service (FFS) system and in accordance with this Chapter.~~

~~2. At the time that CHOICES is implemented in a particular Grand Division, NF services for eligible residents of that Grand Division shall be administered by the Managed Care Organizations (MCOs) under the Managed Care System and in accordance with this Chapter.~~

~~3. At the time that CHOICES is fully implemented statewide, all NF services shall be administered by the MCOs under the Managed Care System and in accordance with this Chapter.~~

~~(b) Statewide Home and Community Based Services Waiver for the Elderly and Disabled (Statewide E/D Waiver). (See Rule 1200-13-01-.17.)~~

~~1. Until such time that CHOICES is implemented in a particular Grand Division, the Statewide E/D Waiver shall offer home and community based services (HCBS) to eligible residents of that Grand Division under a FFS system and in accordance with this Chapter.~~

~~2. At the time that CHOICES is implemented in a particular Grand Division, the Statewide E/D Waiver shall terminate in that Grand Division and HCBS for eligible residents of that Grand Division shall be administered by the MCOs under the Managed Care System and in accordance with this Chapter. The HCBS waivers for persons with mental retardation (MR) are not affected by the implementation of CHOICES.~~

~~3. At the time that CHOICES is fully implemented statewide, the Statewide E/D Waiver shall terminate and all HCBS other than those offered under the HCBS waivers for individuals with MR or the Program of All-Inclusive Care for the Elderly (PACE) shall be administered by the MCOs under the Managed Care System and in accordance with this Chapter.~~

Part 2. of Subparagraph (c) re-lettered as (a) of Paragraph (2) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and replaced with a new Part 2. which shall read as follows:

2. HCBS for the elderly and adults who have Physical Disabilities.

~~2. HCBS for adults who are elderly or physically disabled.~~

Paragraph (3) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and replaced with a new Paragraph (3) which shall read as follows:

(3) Individuals receiving ~~LTC services~~ LTSS shall be enrolled in Managed Care Contractors (MCCs) as follows:

(a) Individuals receiving TennCare-reimbursed ~~LTC services~~ LTSS, other than those enrolled in the PACE Program or persons approved for immediate Eligibility pursuant to these rules, are also enrolled in a TennCare MCO for primary care, behavioral health services, and acute care services.

(b) In addition to enrollment in an MCO, the following ~~LTC recipients~~ LTSS Enrollees, other than those enrolled in the PACE Program or persons approved for Immediate Eligibility pursuant to these rules, are enrolled with the TennCare Pharmacy Benefits Manager for coverage of prescription drugs:

1. Children under the age of twenty-one (21); and

2. Adults aged twenty-one (21) and older who are not Medicare beneficiaries.

(c) Children under the age of twenty-one (21) who are ~~LTC recipients~~ LTSS Enrollees are also enrolled with the TennCare Dental Benefits Manager (DBM) for coverage of dental services.

Subparagraph (d) ALA – Administrative Lead Agency of Paragraph (4) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and subsequent Subparagraphs re-lettered accordingly.

~~(d) ALA – Administrative Lead Agency~~

Subparagraphs (k) and (l) re-lettered as (j) and (k) of Paragraph (4) of Rule 1200-13-01-.01 Purpose are deleted in their entirety and replaced with new Subparagraphs (j) and (k) which shall read as follows:

(j) DIDD – Tennessee Department of Intellectual and Developmental Disabilities (formerly known as Tennessee Department of Finance and Administration's Division of Intellectual Disabilities Services or DIDS)

(k) DMH – Tennessee Department of Mental Health and Substance Abuse Services (formerly known as the Tennessee Department of Mental Health and Developmental Disabilities)

~~(k) DIDS – Tennessee Department of Finance and Administration's Division of Intellectual Disabilities Services~~

~~(l) DMHDD – Tennessee Department of Mental Health and Developmental Disabilities~~

Subparagraph (m) E/D-Elderly and/or Disabled re-lettered as (l) of Paragraph (4) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and subsequent Subparagraphs re-lettered accordingly.

~~(ml) E/D – Elderly and/or Disabled~~

Subparagraph (u) ICF/MR re-lettered as (s) of Paragraph (4) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and subsequent Subparagraphs re-lettered accordingly.

~~(us) ICF/MR – Intermediate Care Facility for persons with Mental Retardation (or pursuant to federal law, Intermediate Care Facility for the Mentally Retarded)~~

Paragraph (4) of Rule 1200-13-01-.01 Purpose is amended by adding new Subparagraphs (t) and (u) and re-lettering the current re-lettered Subparagraphs (t) and (u) as (v) and (w) with subsequent Subparagraphs re-lettered accordingly so as amended the new Subparagraphs (t) and (u) shall read as follows:

(t) ICF/IID – Intermediate Care Facility for Individuals with Intellectual Disabilities (formerly and also known as Intermediate Care Facility for persons with Mental Retardation or ICF/MR.

(u) ID – Intellectual Disability(ies) (formerly and also known as MR).

Subparagraph (x) re-lettered as (w) of Paragraph (4) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and replaced with a new Subparagraph (w) which shall read as follows:

(w~~x~~) LTC – Long-Term Care (also known as LTSS)

Paragraph (4) of Rule 1200-13-01-.01 Purpose is amended by adding a new Subparagraph (x) and re-lettering the current re-lettered Subparagraph (x) as (y) with subsequent Subparagraphs re-lettered accordingly so as amended the new Subparagraph (x) shall read as follows:

(x) LTSS – Long-Term Services and Supports (formerly and also known as LTC)

Subparagraph (bb) of Paragraph (4) of Rule 1200-13-01-.01 Purpose is deleted in its entirety and replaced with a new Subparagraph (bb) which shall read as follows:

(bb) MR – Mental Retardation (also known as ID)

Paragraph (4) of Rule 1200-13-01-.01 Purpose is amended by adding a new Subparagraph (tt) and re-lettering the current Subparagraph (tt) as (uu) so as amended the new Subparagraph (tt) shall read as follows:

(tt) TPAES – TennCare Pre-Admission Evaluation System

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

Rule 1200-13-01-.02 Definitions is deleted in its entirety and replaced with a new Rule 1200-13-01-.02 which shall read as follows:

1200-13-01-.02 Definitions.

(1) Activities of Daily Living (ADLs). ~~(a)~~ Routine self-care tasks that people typically perform independently on a daily basis. One of the components of Level of Care eligibility for ~~LTC~~ LTSS is a person's ability to independently perform (or the amount of assistance needed to perform) certain ADLs, such as:

(a)~~1.~~ Personal hygiene and grooming;

(b)~~2.~~ Dressing and undressing;

(c)~~3.~~ Self feeding;

(d)4. Functional transfers (getting into and out of bed or wheelchair, getting onto or off toilet, etc.);

(e)5. Bowel and bladder management; and

(f)6. Ambulation (walking with or without use of an assistive device, e.g., walker, cane or crutches; or using a wheelchair).

~~(2) Administrative Lead Agency (ALA). The approved agency or agencies with which the Bureau contracts for the provision of covered services through the Statewide E/D Waiver.~~

(2) Adult Care Home. For purposes of CHOICES:

(a) A ~~State-licensed~~ CBRA ~~that offers~~ licensed by the DOH (see Rule 1200-08-36) that offers twenty-four (24) hour residential care and support in a single family residence to no more than five (5) elderly or disabled adults who meet NF LOC, but who prefer to receive care in the community in a smaller, home-like setting. The provider must either live on-site in the home, or hire a resident manager who lives on-site so that the person primarily responsible for delivering care on a day-to-day basis is living in the home with the individuals for whom he is providing care.

(b) Coverage shall not include the costs of Room and Board.

(c) Pursuant to State law, licensure is currently limited to Critical Adult Care Homes for persons who are ventilator dependent or adults with traumatic brain injury.

(3) Adult Day Care.

(a) Community-based group programs of care lasting more than three (3) hours per day but less than twenty-four (24) hours per day and delivered in an Adult Day Care facility permanently licensed by DHS or a Mental Retardation Adult Habilitation Day Facility licensed by DMH, or as of July 1, 2012, by DIDD.

(b) Services shall be provided pursuant to an individualized POC by a licensed provider not related to the participating adult.

(c) The provider shall be responsible for the provision of all assistance and supervision required by program participants. Such assistance is a component of the Adult Day Care benefit and shall not be billed as a separate HCBS.

(4) Advance Determination. A decision made by the Bureau in accordance with the process and requirements described in Rule 1200-13-01-.05(6) that an Applicant would not qualify to enroll in CHOICES Group 3 (including Interim CHOICES Group 3) when enrollment into CHOICES Group 3 has not actually been denied or terminated, and which may impact the person's NF LOC eligibility (see Rule 1200-13-01-.10(4)(b)(2)(i)(II) and 1200-13-01-.10(4)(b)(2)(ii)(II)).

(5) Applicant. A person applying for TennCare-reimbursed LTSS, for whom a PAE has been submitted to TennCare, and/or by or on behalf of whom a Medicaid application has been submitted to DHS. For purposes of compliance with the Linton Order, the term shall include all individuals who have affirmatively expressed an intent to be considered for current or future admission to a NF or requested that their name be entered on any "wait list." All individuals who contact a NF to casually inquire about the facility's services or admissions policies shall be informed by the facility of that individual's right to apply for admission and be considered for admission on a nondiscriminatory basis and in conformance with Rule 1200-13-01-.06.

~~(5) Applicant. For purposes of compliance with the Linton Order, an individual who seeks admission to a NF and is not limited to those individuals who have completed an official application or have complied with the NF's preadmission requirements. The term shall include all individuals who have affirmatively expressed an intent to be considered for current or future admission to the NF or requested that their name be entered on any "wait list." Individuals who only make casual inquiry concerning the NF or its admission practices, who request information on these subjects, or who do not express any intention that they wish to be actively considered for admission shall not be considered Applicants. All individuals, whether Applicants or Non-Applicants, who contact a NF to casually inquire about the facility's services or admissions policies shall be informed by the facility of that individual's right to apply for admission and be considered for admission on a nondiscriminatory basis and in conformance with Rule 1200-13-01-.06.~~

(6) Area Agencies on Aging and Disability (AAAD). Agencies designated by the Commission on Aging and Disability or its successor organization to plan for and provide services to the elderly and disabled within a defined geographic area as provided by T.C.A. Title 71, Chapter 2.

(7) Arlington IDMR Waiver. HCBS Waiver for persons with IDMR under Section 1915(c) of the Social Security Act (limited to members of the Arlington class certified in United States v. Tennessee, et al.).

(8) Assisted Care Living Facility (ACLF) Services.

~~(a) For purposes of CHOICES:~~

(a) CBRA to NF care in an ACLF licensed by the DOH pursuant to Rule 1200-08-25 that provides and/or arranges for daily meals, personal care, homemaker and other supportive services or health care including medication oversight (to the extent permitted under State law), in a home-like environment to persons who need assistance with ADLs.

~~1. CBRA to NF care that provides and/or arranges for Personal Care, Homemaker and other supportive services or health care including medication oversight (to the extent permitted under State law), in a home-like environment to persons who need assistance with ADLs.~~

~~2.~~(b) Coverage shall not include the costs of Room and Board.

~~(b) For purposes of the Statewide E/D Waiver:~~

~~1. Personal Care Services, Homemaker Services, and medication oversight (to the extent permitted under State law) provided in a home-like environment in a licensed ACLF.~~

~~2. Coverage shall not include the costs of Room and Board.~~

(9) Assistive Technology. Assistive devices, adaptive aids, controls or appliances that enable an Enrollee to increase his ability to perform ADLs or to perceive or control his environment. Examples include, but are not limited to, "grabbers" to pick objects off the floor, a strobe light to signify the smoke alarm has been activated, etc.

(10) At Risk for Institutionalization. A requirement for eligibility to enroll in CHOICES Group 3 (including Interim CHOICES Group 3), whereby an individual does not meet the NF LOC criteria in place as of July 1, 2012, but meets the NF LOC criteria in place as of June 30, 2012, as defined in TennCare Rule 1200-13-01-.10(4) such that, in the absence of the provision of a moderate level of home and community based services and supports, the individual's condition and/or ability to continue living in the community will likely deteriorate, resulting in the need for more expensive institutional placement.

(11) Attendant Care. For purposes of CHOICES, services to a Member who, due to age and/or ~~p~~Physical Disablities ~~disability~~, needs more extensive assistance than can be provided through intermittent Personal Care Visits (i.e., more than four (4) hours per occurrence or visits at intervals of less than four (4) hours between visits) to provide hands-on assistance and related tasks as specified below, and that may also include safety monitoring and/or supervision.

(a) Attendant Care may include assistance with the following:

1. ADLs such as bathing, dressing and personal hygiene, eating, toileting, transfers and ambulation.

2. Continuous safety monitoring and supervision during the period of service delivery.

(b) For Members who require hands-on assistance with ADLs, ~~a~~Attendant ~~c~~Care may also include the following homemaker services that are essential, although secondary, to the hands-on assistance with ADLs needed by the Member in order to continue living at home because there is no household member, relative, caregiver, or volunteer to meet the specified need, such as:

1. Picking up the Member's medications or shopping for the Member's groceries.

2. Preparing the Member's meals and/or educating caregivers about preparation of nutritious meals for the Member.

3. Household tasks such as sweeping, mopping, and dusting in areas of the home used by the Member, changing the Member's linens, making the Member's bed, washing the Member's dishes, and doing the Member's personal laundry, ironing and mending.

(c) Attendant Care shall not be provided for Members who do not require hands-on assistance with ADLs.

(d) Attendant Care shall be primarily provided in the Member's place of residence, except as permitted by rule and within the scope of service (e.g., picking up medications or shopping for groceries) when accompanying or transporting the Member into the community pursuant to Rule 1200-13-01-.05(8)(~~m~~n), or under exceptional circumstances as authorized by an MCO in the POC to accommodate the needs of the Member.

(e) A single Contract Provider staff person or Consumer-Directed Worker may provide Attendant Care services to multiple CHOICES Members in the same home and during the same hours, as long as he can provide the services safely and appropriately to each Member. Such arrangements shall be documented in each Member's POC. In such instances, the total units of service provided by the staff person shall be allocated among the CHOICES Members, based on the percentage of total service units required by each Member on average. The Provider shall bill the MCO only once for each of the service units provided, and shall not bill an MCO or multiple MCOs separately to provide services to multiple Members at the same time.

~~(f) Attendant Care shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services, or while a Member is receiving Adult Day Care services.~~

(f) Regardless of payer, Attendant Care shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services, or while a Member is receiving Adult Day Care services.

(g) Attendant Care shall not include:

1. Care or assistance including meal preparation or household tasks for other residents of the same household;

2. Yard work; or

3. Care of non-service related pets and animals.

(12) Back-up Plan.

(a) A written plan that is a required component of the POC for all CHOICES Members receiving Companion Care or non-residential CHOICES HCBS in their own homes and that specifies unpaid persons ~~as~~ and in the case of services provided through Consumer Direction, ~~well as~~ paid Consumer-Directed Workers and/or Contract Providers (as applicable and in accordance with 1200-13-01-.05(9)(h)(8)) who are available, and have agreed to serve as back-up, and who will be contacted to deliver needed care in situations when regularly scheduled CHOICES HCBS providers or Workers are unavailable or do not arrive as scheduled.

(b) A CHOICES Member or his Representative may not elect, as part of the Back-up Plan, to go without services.

(c) The Back-up Plan shall include the names and telephone numbers of persons and agencies to contact and the services to be provided by each of the listed contacts. The Member and his Representative (as applicable) shall have primary responsibility for the development and implementation of the Back-up Plan for consumer-directed services with assistance from the FEA as needed.

(13) Bed Hold. The policy by which NFs ~~providing~~ receiving Level 1 reimbursement for NF care and ICFs/IID~~MR~~ are reimbursed for holding a resident's bed while he is away from the facility, in accordance with this Chapter.

(14) Bureau of TennCare (Bureau). The division of ~~F&A~~ the Department of Finance and Administration, the single state Medicaid agency that administers the TennCare Program. For the purposes of this Chapter, the Bureau shall represent the State of Tennessee.

(15) Care Coordinator. For purposes of CHOICES, a person who is employed or contracted by an MCO to perform the continuous process of care coordination:

(a) Assessing a Member's physical, behavioral, functional, and psychosocial needs;

(b) Identifying the physical health, behavioral health, and ~~LTC services~~ LTSS and other social support services and assistance (e.g., housing or income assistance) necessary to meet identified needs;

(c) Ensuring timely access to and provision, coordination and monitoring of physical health, behavioral health, and ~~LTC services~~ LTSS needed to help the Member maintain or improve his physical or behavioral health status or functional abilities and maximize independence; and

(d) Facilitating access to other social support services and assistance needed in order to ensure the Member's health, safety and welfare, and as applicable, to delay or prevent the need for more expensive institutional placement.

~~(16) Caregiver. For purposes of the Statewide E/D Waiver, one or more adult individuals who sign an agreement with the ALA to provide services to an Enrollee participating in the Waiver to meet the needs of the Enrollee during the hours when Waiver services are not being provided by the ALA~~

~~(17) Case Management. For purposes of the Statewide E/D Waiver, services that will assist individuals who receive Waiver services in gaining access to needed Waiver and other Medicaid State Plan services, as well as needed medical, social, educational, and other services, regardless of the funding source for the services.~~

~~(18) Case Manager. For purposes of the Statewide E/D Waiver:~~

~~(a) The individual who is responsible for development of the POC and for ongoing monitoring of the provision of services included in the Enrollee's POC. Case Managers shall initiate and oversee the process of assessment and reassessment of the Enrollee's LOC and the review of POCs at such intervals as are specified in the Waiver rules and policies.~~

~~(b) A Case Manager is prohibited from providing any other services to an Enrollee for whom he serves as Case Manager under the Waiver.~~

(16~~19~~)Centers for Medicare and Medicaid Services (CMS). The agency within the United States Department of Health and Human Services that is responsible for administering Titles XVIII, XIX, and XXI of the Social Security Act.

(17~~20~~)Certification.

(a) A process by which a Physician who is licensed as a doctor of medicine or doctor of osteopathy signs and dates a PAE signifying the following:

1. The person requires the requested level of institutional care or reimbursement (Level 1 NF, Level 2 NF, Enhanced Respiratory Care, or ICF/IID~~MR~~) or, in the case of a Section 1915(c) HCBS Waiver program or PACE, requires HCBS as an alternative to the applicable level of institutional care for which the individual would qualify; and

2. The requested ~~LTC services~~ LTSS are medically necessary for the individual.

(b) Consistent with requirements pertaining to certification of the need for SNF care set forth at 42 CFR § 424.20 and in Section 3108 of the Affordable Care Act, certification of the need for NF care may be performed by a nurse practitioner, ~~or~~ clinical nurse specialist, or physician assistant, ~~neither~~ none of

whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a ~~p~~Physician.

(c) Physician certification is not required for CHOICES HCBS.

(18~~21~~)CHOICES. See "TennCare CHOICES in Long-Term ~~Care~~ Services and Supports."

(19) CHOICES 1 and 2 Carryover Group.

(a) Individuals who were enrolled in CHOICES Group 1 or CHOICES Group 2 as of June 30, 2012, but who, upon redetermination, no longer qualify for enrollment due solely to the State's modification of its NF LOC criteria.

(b) Subject to the requirements set forth in 1200-13-01-.05(3)(b)6., Members eligible for TennCare in the CHOICES 1 and 2 Carryover Group may continue to qualify in this group after June 30, 2012, so long as they continue to meet NF financial eligibility, continue to meet the NF LOC criteria in place as of June 30, 2012, and remain continuously enrolled in the CHOICES 1 and 2 Carryover Group and in CHOICES Group 1 or CHOICES Group 2.

(20~~23~~)CHOICES 217-Like Group. Individuals age sixty-five (65) and older and adults age twenty-one (21) and older with P~~p~~hysical D~~d~~isabilities who meet the NF LOC criteria, who could have been eligible for HCBS under 42 C.F.R. § 435.217 had the State continued its Section 1915(c) Statewide E/D Waiver and who need and are receiving CHOICES HCBS as an alternative to NF care. This group ~~exists only in the Grand divisions of Tennessee where CHOICES has been implemented, and participation~~ is subject to the Enrollment Target for CHOICES Group 2.

(21~~22~~)CHOICES At-Risk Demonstration Group.

(a) Individuals age sixty-five (65) and older and adults age twenty-one (21) and older with P~~p~~hysical D~~d~~isabilities who meet NF financial eligibility requirements for TennCare-reimbursed LTSS, meet the NF LOC in place on June 30, 2012, but not the NF LOC in place on July 1, 2012, and who, in the absence of CHOICES HCBS available through CHOICES Group 3, are At Risk for Institutionalization as defined in these rules.

(b) Members eligible for TennCare in the CHOICES At-Risk Demonstration Group on December 31, 2013, may continue to qualify in this group after December 31, 2013, so long as they continue to meet NF financial eligibility, continue to be At Risk for Institutionalization as defined in these rules, and remain continuously enrolled in the CHOICES At-Risk Demonstration Group and in CHOICES Group 3.

(22~~24~~)CHOICES Group 1. Individuals of all ages who are receiving TennCare-reimbursed care in a NF.

(23~~25~~)CHOICES Group 2. Individuals age sixty-five (65) and older and adults age twenty-one (21) and older with P~~p~~hysical D~~d~~isabilities who meet the NF LOC criteria and who qualify for TennCare either as SSI recipients or in an institutional category (i.e., as Members of the CHOICES 217-Like demonstration population), and who need and are receiving CHOICES HCBS as an alternative to NF care. The Bureau has the discretion to apply an Enrollment Target to this group, as described in this Chapter.

(24~~26~~)CHOICES Group 3. Individuals age sixty-five (65) and older and adults age twenty-one (21) and older with P~~p~~hysical D~~d~~isabilities who qualify for TennCare as SSI recipients, who do not meet the NF LOC, but who, in the absence of CHOICES HCBS, are At Risk for Institutionalization, as defined by the State. The Bureau has the discretion to apply an Enrollment Target to this group, as described in this Chapter.

(25~~27~~)CHOICES Home and Community Based Services (HCBS). Services specified in Rule 1200-13-01-.05(8)(l~~k~~) that are available only to eligible persons enrolled in CHOICES Group 2 or CHOICES Group 3 as an alternative to long-term care institutional services in a ~~n~~Nursing ~~f~~Facility or to delay or prevent placement in a ~~n~~Nursing ~~f~~Facility. Only CHOICES HCBS are eligible for Consumer Direction. CHOICES HCBS do not include Home Health or Private Duty Nursing services or any other HCBS that are covered by Tennessee's Title XIX State Plan or under the TennCare demonstration for all eligible Enrollees, although such services are subject to estate recovery and shall be counted for purposes of determining whether a CHOICES ~~m~~Member's needs can be safely met in the community within his or her Individual ~~c~~Cost ~~n~~Neutrality ~~c~~Cap.

(2628)CHOICES Member. An individual who has been enrolled by the Bureau into CHOICES.

(2729)Chronic Ventilator Care Reimbursement. The rate of ~~Medicaid~~ reimbursement provided for NF services, including enhanced respiratory care assistance, delivered by a NF that meets the requirements in Rule 1200-13-01-.03(5) to residents determined by the Bureau to meet the medical eligibility criteria in Rule 1200-13-01-.10(5)(d).

(2830)Community Personal Needs Allowance. See "Personal Needs Allowance (PNA)."

(2931 Community-Based Residential Alternatives (CBRA) to institutional care. For purposes of CHOICES:

(a) Residential services that offer a cost-effective, community-based alternative to NF care for individuals who are elderly and/or adults with Pphysical Ddisabilities, and meet NF LOC.

(b) CBRAs include, but are not limited to:

1. CBRA facilities such as ACLFs and Adult Care Homes; and

2. Companion Care.

(3032)Companion Care. For purposes of CHOICES:

(a) A consumer-directed residential model in which a CHOICES Member may choose to select, employ, supervise and pay, using the services of an FEA, ~~on a monthly basis~~ a live-in companion who will be present in the Member's home and provide frequent intermittent assistance or continuous supervision and monitoring throughout the entire period of service duration.

(b) Such model shall be available only for a CHOICES Member who requires and does not have available through family or other caregiving supports frequent intermittent assistance with ADLs or supervision and monitoring for extended periods of time that cannot be accomplished more cost-effectively with other non-residential services.

(c) A CHOICES Member who requires assistance in order to direct his Companion Care may designate a Representative to assume CD of Companion Care services on his behalf, pursuant to requirements for Representatives otherwise applicable to CD.

~~(d) Companion Care shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services, or while a Member is receiving Adult Day Care services.~~

(d) Regardless of payer, Companion Care shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving Short-Term NF services or Adult Day Care services.

(e) Companion Care is only available through CD.

(3133)Competent Adult. For purposes of Self-Direction of Health Care Tasks in CD, a person age twenty-one (21) or older who has the capability and capacity to evaluate knowledgeably the options available and the risks attendant upon each and to make an informed decision acting in accordance with his own preferences and values. A person is presumed competent unless a decision to the contrary is made.

(3234)Consumer Direction (CD) of Eligible CHOICES HCBS. For purposes of CHOICES, the opportunity for a Member assessed to need Eligible CHOICES HCBS (limited to Attendant Care, Personal Care Visits, In-Home Respite Care, or Companion Care) to elect to direct and manage (or to have a Representative direct and manage) certain aspects of the provision of such services, primarily the hiring, firing, and day-to-day supervision of Consumer-Directed Workers delivering the needed service(s).

(3335)Consumer-Directed Worker (Worker).

(a) An individual who has been hired by a CHOICES Member participating in CD of Eligible CHOICES HCBS or by his Representative to provide one or more Eligible CHOICES HCBS to the Member.

(b) Does not include an employee of an agency that is being paid by an MCO to provide CHOICES HCBS to the Member.

~~(36) Continuity of Care Period. For purposes of CHOICES:~~

~~(a) The period of time immediately following implementation of CHOICES in a Grand Division during which a Member shall continue to receive the same LTC services, as specified in the POC in place prior to CHOICES implementation, from the same LTC providers, regardless of whether such providers have elected to participate in the MCO's network.~~

~~(b) Such period shall be at least thirty (30) days following implementation, but in the case of CHOICES Group 2 Members, shall continue for up to ninety (90) days or until a comprehensive needs assessment has been performed and a new POC has been developed.~~

(3437) Contract Provider. A provider who is under contract with an Enrollee's MCO. Also called "Network Provider" or "In-Network ~~p~~Provider."

(35) Cost-Effective Alternative (CEA) Service.

(a) A service that is not a covered service but that is approved by TennCare and CMS and provided at an MCO's discretion. There is no entitlement to receive these services.

(b) CEA services may be provided because they are:

1. Alternatives to covered TennCare services that, in the MCO's judgment, are cost effective; or

2. Preventive in nature and offered to avoid the development of conditions that, in the MCO's judgment, would require more costly treatment in the future.

(c) CEA services need not be determined medically necessary except to the extent that they are provided as an alternative to covered ~~Medicaid~~ TennCare services. Even if medically necessary, CEA services are not covered services and are provided only at an MCO's discretion.

(d) For purposes of CHOICES, CEA services may include the provision of CHOICES HCBS as an alternative to NF care when the Enrollment Target for CHOICES Group 2 has been reached as described in Rule 1200-13-01-.05.

(3639) Cost Neutrality Cap. For purposes of CHOICES Group 2, the average cost of the level of NF reimbursement that would be paid if the Member were institutionalized. The Cost Neutrality Cap functions as a limit on the total cost of HCBS that can be provided to the individual in the home or community setting, including CHOICES HCBS, HH Services and PDN Services. The Cost Neutrality Cap shall be individually applied.

(3740) Dental Benefits Manager (DBM). See "Dental Benefits Manager" in Rule 1200-13-13-.01.

(38) Department of Intellectual and Developmental Disabilities (DIDD). The State entity contracted by TennCare to serve as the OAA for day-to-day operation of the HCBS waivers for persons with ID. Formerly known as the Division of Intellectual Disabilities Services (DIDS).

(3941) Designated Correspondent. A person or agency authorized by an individual on the PAE form to receive correspondence related to NF or ICF/IID~~MR~~ services on his behalf.

(4042) Disenrollment. The voluntary or involuntary termination of an individual's enrollment in an ~~LTC~~ LTSS Program.

~~(43) Division of Intellectual Disabilities Services (DIDS). The division of F&A that serves as the OAA for day-to-day operations of the HCBS Waivers for persons with MR. Formerly the Division of Mental Retardation Services.~~

(4144)Electronic Visit Verification (EVV) system. An electronic system that paid caregivers use to check-in at the beginning and check-out at the end of each period of service delivery. The system is used to monitor Member receipt of specified CHOICES HCBS and also to generate claims for submission by the provider.

(4245)Eligible CHOICES HCBS. For purposes of CD, CHOICES HCBS that may be consumer-directed are limited to Attendant Care, Personal Care Visits, In-Home Respite Care, or Companion Care. Eligible CHOICES HCBS do not include ~~h~~Home ~~h~~Health or ~~p~~Private ~~d~~Duty ~~n~~Nursing services.

(4346)Employer of Record. The Member participating in CD of Eligible CHOICES HCBS or a Representative designated by the Member to assume the CD of Eligible CHOICES HCBS functions on the Member's behalf.

(4447)Enhanced Respiratory Care Reimbursement. Specified levels of reimbursement (i.e., Chronic Ventilator Care, Tracheal Suctioning and Ventilator Weaning) provided for NF services ~~, including enhanced respiratory care assistance, or ventilator weaning services and care during the post weaning period,~~ delivered by a SNF ~~NF~~ that meets the requirements set forth in Rule 1200-13-01-.03(5) to persons determined by the Bureau or an MCO, as applicable, to meet specified medical eligibility criteria for such level of ~~Medicaid~~ reimbursement.

(4548)Enrollee. A ~~Medicaid~~ TennCare-eligible individual who is enrolled in a TennCare ~~LTC~~ LTSS Program.

(4649)Enrollment Target.

(a) The maximum number of individuals who can be enrolled in CHOICES Group 2 or CHOICES Group 3 at any given time, subject to the exceptions provided in this Chapter.

(b) The Enrollment Target is not calculated on the basis of "unduplicated participants." Vacated slots in CHOICES Group 2 or CHOICES Group 3 may be refilled immediately, rather than being held until the next program year, as is required in the HCBS Waiver programs.

(c) Persons enrolled in CHOICES Group 2 prior to July 1, 2012, who remain enrolled in CHOICES Group 2 and continue to qualify for TennCare in the CHOICES 1 and 2 Carryover Group shall be counted against the Enrollment Target for CHOICES Group 2.

(4750)Expenditure Cap. For purposes of CHOICES Group 3, the annual limit on expenditures for CHOICES HCBS, excluding Minor Home Modifications, that a CHOICES Group 3 Member can receive. The Expenditure Cap shall be $15,000 (fifteen thousand dollars) per Member per calendar year.

(4851)Expiration Date.

(a) A date assigned by the Bureau at the time of approval of a PAE after which TennCare reimbursement will not be made unless a new PAE is submitted and approved, or 365 days after the PAE Approval Date when the PAE has not been used.

(b) A PAE is "used" when the individual has begun receiving ~~LTC services~~ LTSS based on the LOC approved in the PAE.

(c) A PAE is "expired" when the individual has not begun receiving ~~LTC services~~ LTSS on or before the 365th day or when an assigned approval end date is reached or as specified in 1200-13-01-.10(2)(e).

(d) The first claim for reimbursement may be submitted after the 365th day, so long as the first date of service is on or before the 365th day.

(4952)Federal Estate Recovery Program (FERP). A federal program set forth under Section 1917(b) of the Social Security Act that requires states offering Medicaid-reimbursed ~~LTC services~~ LTSS to seek adjustment or recovery for certain types of medical assistance from the estates of individuals who were age fifty-five (55) or older at the time such assistance was received, and from permanently institutionalized individuals of any age. For both mandatory populations, the State may elect to recover up to the total cost of all medical assistance provided.

(a) For persons age fifty-five (55) and older, the State is obligated to seek adjustment or recovery for NF (including ICF/IIDMR) services, HCBS, and related hospital and prescription drug services.

(b) For permanently institutionalized persons, states are obligated to seek adjustment or recovery for the institutional services.

(5053)Fee-for-Service (FFS) System. An arrangement whereby the Bureau, rather than the MCO, is responsible for arranging for covered ~~LTC services~~ LTSS and paying claims for these services.

(5154)Fiscal Employer Agent (FEA). An entity contracting with the Bureau and/or an MCO that helps CHOICES Members participating in CD of Eligible CHOICES HCBS. The FEA provides both financial administration and supports brokerage functions for CHOICES Members participating in CD of Eligible CHOICES HCBS. This term is used by the IRS to designate an entity operating under Section 3504 of the IRS code, Revenue Procedure 70-6, and Notice 2003-70 as the agent to Members for the purpose of filing certain federal tax forms and paying federal income tax withholding, FICA, and FUTA taxes. The FEA also files state income tax withholding and unemployment insurance tax forms and pays the associated taxes and processes payroll based on the ~~e~~Eligible CHOICES HCBS authorized and provided.

(5255)Grand Divisions. See "Grand Divisions" in Rule 1200-13-13-.01.

(5356)Health Care Tasks. For CHOICES Members participating in CD, those medical, nursing, or HH Services, beyond ADLs, that:

(a) A person without a functional disability or a caregiver would customarily perform without the assistance of a licensed health care provider;

(b) The person is unable to perform for himself due to a functional or cognitive limitation;

(c) The treating physician, advanced practice nurse, or registered nurse determines can safely be performed in the home and community by an unlicensed Consumer-Directed Worker under the direction of a Competent Adult or caregiver; and

(d) Enable the person to maintain independence, personal hygiene, and safety in his own home.

~~(57) Home (of an Enrollee). For purposes of the Statewide E/D Waiver, the residence or dwelling in which the Enrollee resides in Tennessee, excluding hospitals, NFs, ICFs/MR, ACLFs, Homes for the Aged (Residential Homes for the Aged), and other CBRAs.~~

(5458)Home and Community Based Services (HCBS). Services that are provided under the authority of a Section 1915(c) HCBS waiver or (in the case of CHOICES) a Section 1115 waiver pursuant to a written POC as an alternative to ~~LTC institutional services~~ institutional LTSS in a NF or an ICF/IIDMR to individuals for whom there has been a determination that, but for the provision of such services, the individuals would require the LOC provided in the institution to which the HCBS offer an alternative, or in the case of CHOICES Group 3, are At Risk for Institutionalization. HCBS may also include optional or mandatory services that are covered by Tennessee's Title XIX State Plan or under the TennCare demonstration for all eligible enrollees, including ~~h~~Home ~~h~~Health or ~~p~~Private ~~d~~Duty ~~n~~Nursing.

(5559)Home and Community Based Services (HCBS) Waiver. A Waiver approved by CMS under the Section 1915(c) authority.

(5660)Home-Delivered Meals.

(a) Nutritionally well-balanced meals, other than those provided under Title III C-2 of the Older Americans Act, that provide at least one-third but no more than two-thirds of the current daily Recommended Dietary Allowance (as estimated by the Food and Nutrition Board of Sciences – National Research Council) and that will be served in the Enrollee's home. Special diets shall be provided in accordance with the individual POC when ordered by the Enrollee's physician.

~~(b) Home-Delivered Meals shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services.~~

(b) Regardless of payer, Home-Delivered Meals shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services.

(5761)Home Health (HH) Services. See "Home Health Services" in Rule 1200-13-13-.01.

(5862)Homemaker Services.

(a) General household activities and chores such as sweeping, mopping, and dusting in areas of the home used by the Member, changing the Member's linens, making the Member's bed, washing the Member's dishes, doing the Member's personal laundry, ironing or mending, meal preparation and/or educating caregivers about preparation of nutritious meals for the Member, assistance with maintenance of a safe environment, and errands such as grocery shopping and having the Member's prescriptions filled.

(b) Provided only for the Member (and not for other household members) and only when the Member is unable to perform such activities and there is no other caregiver or household member available to perform such activities for the Member.

(c) Effective July 1, 2012, provided only as part of Personal Care Visits and Attendant Care services for Members who also require hands-on assistance with ADLs. Homemaker Services authorized in an approved POC ~~plan of care~~ on or before June 30, 2012, shall continue to be provided for no more than ninety (90) days after July 1, 2012, pending a reassessment of the Member's needs and modifications to the Member's POC ~~plan of care~~ to comport with the new benefit structure, as well as individual notice of action, when required. Homemaker Services shall not be continued pending resolution of any appeal filed on or after July 1, 2012, as Homemaker Services are no longer covered as a stand-alone benefit. Homemaker Services are not covered for anyone ~~that~~ who does not also require hands-on assistance with ADLs.

~~(d) Shall not be provided to Members living in a receiving CBRA facility or receiving Short-Term NF services.~~

(d) Regardless of payer, shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services.

(5963)ICF/IID~~MR~~ Eligible. An individual determined by DHS to qualify for Medicaid ICF/IID~~MR~~ services and determined by the Bureau to meet the ICF/IID~~MR~~ LOC.

(6064)ICF/IID~~MR~~ PAE ~~Approval~~ Effective Date. The beginning date of LOC eligibility for Medicaid-reimbursed care in an ICF/IID~~MR~~ or HCBS Waiver services offered as an alternative to care in an ICF/IID~~MR~~, for which the ICF/IID~~MR~~ PAE has been approved by the Bureau.

(6165)ICF/IID~~MR~~ PAE Form. The assessment form used by the Bureau to document the current medical and habilitative needs of an individual with MR and to document that the individual meets the Medicaid LOC eligibility criteria for care in an ICF/IID~~MR~~.

(6266)Identification Screen (Level I). See "PreAdmission Screening/Resident Review."

(6367)Immediate Eligibility.

(a) A mechanism by which the Bureau may elect, based on a preliminary determination of an individual's eligibility for the CHOICES 217-Like Group, to enroll the individual into CHOICES Group 2 and provide immediate access to a limited package of CHOICES HCBS pending a final determination of eligibility.

(b) To qualify an individual must:

1. Be applying to receive covered CHOICES HCBS;

2. Be determined by the Bureau to meet NF LOC;

3. Have submitted an application for financial eligibility determination to DHS;

4. Be expected to qualify in the CHOICES 217-Like Group based on review of the financial information provided by the applicant; and

5. Meet all other specified criteria for enrollment into CHOICES Group 2, subject to categorical and financial eligibility determination.

(c) Immediate Eligibility shall only be for Specified CHOICES HCBS (no other covered services) and for a maximum of forty-five (45) days.

(d) Immediate Eligibility is not available for individuals who are already enrolled in TennCare or for persons who may qualify in the CHOICES At-Risk Demonstration Group.

(6468)Immediate Family Member~~:~~. For purposes of employment as a ~~c~~Consumer-~~d~~Directed Worker in CHOICES~~:~~, a spouse, parent, grandparent, child, grandchild, sibling, mother-in-law, father-in-law, sister-in-law, brother in-law, daughter-in-law, and son-in-law. Adopted and step members are included in this definition.

(6569) Individual Acuity Score. The weighted value assigned by TennCare to:

(a) The response to a specific ADL or related question in the PAE for NF LOC that is supported by the medical evidence submitted with the PAE; or

(b) A specific skilled or rehabilitative service determined by TennCare to be needed by the applicant on a daily basis or at least five (5) days per week for rehabilitative services based on the medical evidence submitted with the PAE and for which TennCare would authorize level 2 or ~~e~~Enhanced ~~r~~Respiratory ~~c~~Care ~~r~~Reimbursement in a NF.

(6670)Individual Cost Neutrality Cap. See "Cost Neutrality Cap."

~~(71) Individual Plan of Care (POC). For purposes of the Statewide E/D Waiver, an individualized written POC that serves as the fundamental tool by which the Bureau ensures the health and welfare of Enrollees and that meets the requirements of this Chapter.~~

(6772)In-Home Respite Care. For purposes of CHOICES:

(a) Services provided to Members unable to care for themselves, furnished on a short-term basis in the Member's place of residence, because of the absence or need for relief of those family members or other unpaid caregivers normally providing the care; and

~~(b) Shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services.~~

(b) Regardless of payer, shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services.

(6873) Inpatient Respite Care. For purposes of CHOICES:

(a) Services provided to individuals unable to care for themselves, furnished on a short-term basis in a licensed NF or licensed CBRA facility, because of the absence or need for relief of those family members or other unpaid caregivers normally providing the care.

~~(b) Shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services.~~

(b) Regardless of payer, shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services.

(6974)Inpatient Nursing Care. Nursing services that are available twenty-four (24) hours per day by or under the supervision of a licensed practical nurse or registered nurse and which, in accordance with general medical practice, are usually and customarily provided on an inpatient basis in a NF. Inpatient Nursing Care includes, but is not limited to, routine nursing services such as observation and assessment of the individual's medical condition, administration of legend drugs, and supervision of nurse aides; and other skilled nursing therapies or services that are performed by a licensed practical nurse or registered nurse.

(7075)Institutional Personal Needs Allowance. See "Personal Needs Allowance (PNA)."

(7176)Interim CHOICES Group 3 (open only between July 1, 2012, and December 31, 2013).

(a) Individuals age sixty-five (65) and older and adults age twenty-one (21) and older with Pphysical Ddisabilities who qualify for TennCare as SSI recipients or as mMembers of the CHOICES At-Risk Demonstration Group, and who are At Risk for Institutionalization as defined in these rules. There will be no Enrollment Target applied to Interim CHOICES Group 3.

(b) Members enrolled in Interim CHOICES Group 3 on December 31, 2013, may continue to qualify in this group after December 31, 2013, so long as they continue to meet NF financial eligibility, continue to be At Risk for Institutionalization, can be safely served in Interim CHOICES Group 3, and remain continuously enrolled in the CHOICES At-Risk Demonstration Group and in CHOICES Group 3.

(7277)Intermediate Care Facility for Individuals ~~Persons~~ with Intellectual Disabilities ~~Mental Retardation (or pursuant to federal law, Intermediate Care Facility for the Mentally Retarded)~~ (ICF/IIDMR) (formerly and also known as Intermediate Care Facility for persons with Mental Retardation or ICF/MR). A licensed facility approved for Medicaid reimbursement that provides specialized services for individuals with IDMR or related conditions and that complies with current federal standards and certification requirements set forth in 42 C.F.R., Part 483.

(7378)Involuntary Transfer or Discharge. Any transfer or discharge that is opposed by the resident or a Representative of the resident of a NF or ICF/IIDMR. For purposes of compliance with the requirements of this Chapter, a discharge or transfer is involuntary when the NF initiates the action to transfer or discharge.

(7479)Legally Appointed Representative. Any person appointed by a court of competent jurisdiction or authorized by legal process (e.g., power of attorney for health care treatment, declaration for mental health treatment) to determine the legal and/or health care interests of an individual and/or his estate.

(7580)Level of Care (LOC). Medical eligibility criteria for receipt of an institutional service, HCBS offered as an alternative to the institutional service, or in the case of persons At Risk for Institutionalization, to delay or prevent institutional placement. An individual who meets the LOC criteria for NF care is an individual who has been determined by the Bureau to meet the medical eligibility criteria established for that service.

(7681)Level 1 Nursing Facility (NF) Care Reimbursement. The level of ~~Medicaid~~ reimbursement provided for NF services delivered to residents eligible for TennCare ~~Medicaid~~-reimbursement of NF services determined by the Bureau to meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(4) by a NF that meets the requirements set forth in Rule 1200-13-01-.03(3), and in accordance with the reimbursement methodology for Level 1 NF Care set forth in Rule 1200-13-01-.03(6).

(7782)Level 2 Nursing Facility (NF) Care Reimbursement. The level of ~~Medicaid~~ reimbursement provided for NF services delivered to residents eligible for TennCare ~~Medicaid~~-reimbursement of NF services determined by the Bureau to meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5) by a NF that meets the requirements set forth in Rule 1200-13-01-.03(4), and in accordance with the reimbursement methodology for Level 2 NF Care set forth in Rule 1200-13-01-.03(7).

(7883)Linton. The lawsuit known as Linton v. Tennessee Commissioner of Health and Environment resulting in a series of Orders issued by the United States District Court and the Sixth Circuit Court of Appeals regarding ~~LTC~~ NF services.

~~(84) Long-Term Care (LTC) Enrollee or Participant. An individual who is participating in a TennCare LTC Program.~~

(7985)Long-Term Care (LTC) Ombudsman. An individual with expertise and experience in the fields of ~~LTC~~ LTSS and advocacy, who assists in the identification, investigation, and resolution of complaints that are made by, or on behalf of, NF residents, and persons residing in CBRA settings, including ACLFs and Adult Care Homes. The Tennessee LTC Ombudsman Program is administered by the TCAD.

(80) Long-Term Services and Supports (LTSS) Enrollee or Participant. An individual who is participating in a TennCare LTSS Program.

(8186)Long-Term Services and Supports ~~(LTC)~~ (LTSS) Program. One of the programs offering ~~LTC services~~ LTSS to individuals enrolled in TennCare. ~~LTC~~ LTSS Programs include institutional programs (NFs and ICFs/~~II~~IDMR~~)~~, ~~as well as~~ HCBS offered ~~either~~ through CHOICES or through a Section 1915(c) HCBS Waiver Program, and the PACE Program.

(8287)Managed Care Organization (MCO). See "Managed Care Organization" in Rule 1200-13-13-.01.

(8388)Managed Care System. A system under which the MCOs are responsible for arranging for services and paying claims for delivery of these services to ~~m~~Members enrolled in their plans.

~~(89) Medicaid Eligible. For purposes of this Chapter, an individual who has been determined by DHS to be financially eligible to have Medicaid reimbursement for covered LTC services.~~

(84) Medicaid. As used in this Chapter, the term Medicaid refers to:

(a) The Social Security Act Title XIX program administered by the Single State Agency through CMS and any of the waivers granted to the State of Tennessee; or,

(b) Specific categories of eligibility established by Title XIX. The eligibility category in which a person qualifies for TennCare may determine the benefits the person is eligible to receive, and his cost sharing obligations.

(8590)Medicaid Only Payer Date (MOPD). The date a NF certifies that Medicaid reimbursement for NF services will begin because the ~~a~~Applicant has been admitted to the facility and all other primary sources of reimbursement (including Medicare and private pay) have been exhausted. (This does not preclude the ~~a~~Applicant's responsibility for payment of ~~p~~Patient ~~l~~Liability as described in these rules.) The MOPD must be known (and not projected) as it will result in the determination of eligibility for Medicaid reimbursement of NF services and in many cases, eligibility for Medicaid, as well as a capitation payment and payments for Medicaid services ~~(including, but not limited to LTC)~~ received, including but not limited to LTSS. The PAE may be submitted without an MOPD date, in which case the MOPD shall be submitted by the facility when it is known. Enrollment into CHOICES Group 1 and eligibility for reimbursement of NF services shall be permitted only upon submission of a MOPD. The effective date of CHOICES enrollment and Medicaid reimbursement of NF services shall not be earlier than the MOPD.

(8691)Medicare Savings Program. The mechanisms by which low-income Medicare beneficiaries can get assistance from Medicaid in paying for their Medicare premiums, deductibles, and/or coinsurance. These programs include the Qualified Medicare Beneficiary (QMB) program, the Specified Low Income Medicare Beneficiary (SLMB) program, and the Qualified Individual (QI) program.

(8792) Member. See "CHOICES Member."

(8893)Mental Illness (MI). For the purposes of compliance with federal PASRR regulations, an individual who meets the following requirements on diagnosis, level of impairment and duration of illness:

(a) The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd Edition, which is a schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder; other psychotic disorder; or another mental disorder that may lead to a chronic disability; but is not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder;

(b) The level of impairment must result in functional limitations in major life activities within the past three (3) to six (6) months that would be appropriate for the individual's developmental stage; or

(c) The treatment history of the individual has at least one of the following: a psychiatric treatment more intensive than outpatient care more than once in the past two (2) years, or within the last two (2) years, due to a mental disorder, the individual has experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

(8994)Mental Retardation (MR) and Related Conditions. For the purposes of compliance with federal PASRR regulations, an individual is considered to have MR if he has a level of retardation (mild, moderate, severe and profound) as described in the American Association on Mental Deficiency's Manual on Classification in Mental Retardation (1983).

(a) MR refers to significantly subaverage general intellectual functioning, indicated by an IQ test score of 70 or below, existing concurrently with deficits in adaptive behavior and manifested during the developmental period (i.e., prior to age eighteen).

(b) The provisions of this Paragraph also apply to persons with "related conditions", as defined by 42 C.F.R. § 435.1010, which states: "Persons with related conditions" means individuals who have a severe, chronic disability that meets all of the following conditions:

1. It is attributable to:

(i) Cerebral palsy or epilepsy, or

(ii) Any other condition, other than MI, found to be closely related to MR because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of persons with MR, and requires treatment or services similar to those required for these persons.

2. It is manifested before the person reaches age twenty-two (22).

3. It is likely to continue indefinitely.

4. It results in substantial functional limitations in three or more of the following areas of major life activity:

(i) Self-care;

(ii) Understanding and use of language;

(iii) Learning;

(iv) Mobility;

(v) Self-direction; and

(vi) Capacity for independent living.

(9095) Minor Home Modifications. ~~(a)~~ For purposes of CHOICES:

(a)~~1.~~ Included are the following:

1.~~(i)~~ The provision and installation of certain home mobility aids, including but not limited to:

(i)~~(I)~~ Wheelchair ramps and modifications directly related to and specifically required for the construction or installation of the ramps;

(ii)~~(II)~~ Hand rails for interior or exterior stairs or steps; or

(iii)~~(III)~~Grab bars and other devices.

2.~~(ii)~~ Minor physical adaptations to the interior of a Member's place of residence that are necessary to ensure his health, welfare and safety, or which increase his mobility and accessibility within the residence, including but not limited to:

(i)~~(I)~~ Widening of doorways; or

(ii)~~(II)~~ Modification of bathroom facilities.

(b)~~2.~~ Excluded are the following:

1.~~(i)~~ Installation of stairway lifts or elevators;

2.~~(ii)~~ Adaptations that are considered to be general maintenance of the residence;

3.~~(iii)~~ Adaptations that are considered improvements to the residence;

4.~~(iv)~~ Adaptations that are of general utility and not of direct medical or remedial benefit to the individual, including but not limited to:

(i)~~(I)~~ Installation, repair, replacement or roof, ceiling, walls, or carpet or other flooring;

(ii)~~(II)~~ Installation, repair, or replacement of heating or cooling units or systems;

(iii)~~(III)~~Installation or purchase of air or water purifiers or humidifiers;

(iv)~~(IV)~~Installation or repair of driveways, sidewalks, fences, decks, and patios; and

(v)~~(V)~~ Adaptations that add to the total square footage of the home are excluded from this benefit.

(c)~~3.~~ All services shall be provided in accordance with applicable State or local building codes.

(d)~~4. Minor Home Modifications shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services, except as provided in Rule 1200-13-01-.05 to facilitate transition to the community.~~

(d)4. Regardless of payer, Minor Home Modifications shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting. Minor Home Modifications shall not be provided to Members receiving Short-Term NF services, except as provided in Rule 1200-13-01-.05 to facilitate transition to the community.

~~(b) For purposes of the Statewide E/D Waiver:~~

~~1. Included are the following:~~

~~(i) The provision and installation of certain home mobility aids, including but not limited to:~~

~~(I) Ramps;~~

~~(II) Rails;~~

~~(III) Non-skid surfacing;~~

~~(IV) Grab bars;~~

~~(ii) Other devices and minor home modifications that facilitate mobility; and~~

~~(iii) Modifications to the home environment to enhance safety.~~

~~2. Excluded are those adaptations or improvements to the home that are of general utility and that are not of direct medical or remedial benefit to the individual, including but not limited to:~~

~~(i) Carpeting;~~

~~(ii) Roof repair; or~~

~~(iii) Central air conditioning.~~

~~3. Adaptations that add to the total square footage of the home are excluded from this benefit.~~

~~4. All services shall be provided in accordance with applicable State or local building codes.~~

(9196)Natural Supports. For purposes of CHOICES:

(a) Unpaid support and assistance critical to ensuring the health, safety, welfare and quality of life of a Member residing in the community delivered by family members, friends, neighbors, and other entities including clubs, churches and community organizations.

(b) May be supplemented, but not supplanted by paid HCBS in order to help sustain the Natural Supports over time, and to help insure the delivery of cost effective community based care.

(9297)Network Provider. See "Contract Provider."

(9398)Non-Contract Provider. A provider who does not have a contract with an Enrollee's MCO. Also called "Out-of-Network Provider."

(9499)Notice. When used in rules and regulations pertaining to NFs, information that must be provided by the facility to "residents" or "~~a~~Applicants," and shall also include notification to the person identified in a PAE application as the resident's or ~~a~~Applicant's ~~d~~Designated ~~represenative~~ Correspondent and any other individual who is authorized by law to act on the resident's or ~~a~~Applicant's behalf or who is in fact acting on the resident's or ~~a~~Applicant's behalf in dealing with the NF.

(95100)Notice of Disposition or Change. A notice issued by DHS of an individual's financial eligibility for ~~Medicaid~~ TennCare, including the effective date for which a person may qualify for ~~Medicaid~~ TennCare reimbursement of ~~LTC services~~ LTSS, subject to ~~l~~Level of ~~c~~Care and other applicable eligibility/enrollment criteria as defined in this Chapter.

(96101)Nursing Facility (NF). A Medicaid-certified NF ~~approved by the Bureau~~.

(97102)Nursing Facility (NF) Eligible. An individual determined by DHS to qualify for ~~Medicaid~~ TennCare reimbursement of NF services and determined by the Bureau to meet NF ~~l~~Level of ~~c~~Care.

(98) One-Time CHOICES HCBS. Certain CHOICES HCBS which occur as a distinct event or which may be episodic in nature (occurring at irregular intervals or on an as needed basis for a limited duration of time), including In-Home Respite Care, Inpatient Respite, Assistive Technology, Minor Modifications, and Pest Control.

(99) Ongoing CHOICES HCBS. Certain CHOICES HCBS which are delivered on a regular and ongoing basis, generally one or more times each week, or (in the case of Community-Based Residential Alternatives and PERS) on a continuous basis, including Community-Based Residential Alternatives, Personal Care Visits, Attendant Care, Home-Delivered Meals, Personal Emergency Response Systems, and Adult Day Care.

(100103)Out-of-Network Provider. See "Non-Contract Provider."

(101) PACE Carryover Group.

(a) Individuals who were enrolled in PACE as of June 30, 2012, but who, upon redetermination, no longer qualify for enrollment due solely to the State's modification of its NF LOC criteria.

(b) Members eligible for TennCare in the PACE Carryover Group may continue to qualify in this group after June 30, 2012, so long as they:

1. Continue to meet NF financial eligibility;

2. Continue to meet the NF LOC criteria in place as of June 30, 2012;

3. Meet all other eligibility requirements for PACE in the Medicaid State Plan; and

4. Remain continuously enrolled in PACE.

(102~~104~~)PAE ~~Approval~~ Effective Date. The beginning date of LOC eligibility for ~~Medicaid~~ TennCare-reimbursed ~~care in a NF~~ LTSS for which the PAE has been approved by the Bureau and which, for purposes of care in a NF, cannot precede completion of the PASRR process.

(103~~105~~)Patient Liability. The amount determined by DHS that a ~~Medicaid~~ TennCare Eligible is required to pay for covered services provided by a NF, an ICF/IID~~MR~~, an HCBS waiver program, or CHOICES.

~~(106) Personal Care Assistance/Attendant Services. For purposes of the Statewide E/D Waiver:~~

~~(a) Intermittent provision of direct assistance with activities such as toileting, bathing, dressing, personal hygiene, eating, meal preparation (excluding the cost of food), budget management, attending appointments, and interpersonal and social skill building to enable the Enrollee to live in a community setting.~~

~~(b) Personal Care Assistance/Attendant Services shall not be provided to Enrollees living in a CBRA facility or receiving Short-Term NF services, or while an Enrollee is receiving Adult Day Care services.~~

~~(107) Personal Care Services. For purposes of the Statewide E/D Waiver:~~

~~(a) Services provided to assist the Enrollee with ADLs and related essential household tasks (e.g., making the bed, washing soiled linens or bedclothes that require immediate attention), and other activities that enable the Enrollee to remain in the home, as an alternative to NF care, including the following:~~

~~1. Assistance with ADLs (e.g., bathing, grooming, personal hygiene, toileting, feeding, dressing, ambulation);~~

~~2. Assistance with cleaning that is an integral part of personal care and is essential to the health and welfare of the Enrollee; and/or~~

~~3. Assistance with maintenance of a safe environment.~~

~~(b) Personal Care Services shall be primarily provided in the Enrollee's place of residence, except under exceptional circumstances as authorized in the POC to accommodate the needs of the Enrollee.~~

~~(c) Personal Care Services shall not be provided to Enrollees living in a CBRA facility or receiving Short-Term NF services, or while an Enrollee is receiving Adult Day Care services.~~

(104~~108~~)Personal Care Visits. For purposes of CHOICES:

(a) Visits to a Member who, due to age and/or Physical Disabilities, needs assistance that can be provided through intermittent visits of limited duration not to exceed four (4) hours per visit and two (2) visits per day at intervals of no less than four (4) hours between visits to provide hands-on assistance and related tasks as specified below.

(b) Personal Care Visits may include assistance with ADLs such as bathing, dressing and personal hygiene, eating, toileting, transfers and ambulation.

(c) For Members who require hands-on assistance with ADLs, Personal Care Visits may also include the following homemaker services that are essential, although secondary, to the hands-on assistance with ADLs needed by the Member in order to continue living at home because there is no household member, relative, caregiver, or volunteer to meet the specified need, such as:

1. Picking up the Member's medications or shopping for the Member's groceries.

2. Preparing the Member's meals and/or educating caregivers about the preparation of nutritious meals for the Member.

3. Household tasks such as sweeping, mopping, and dusting in areas of the home used by the Member, changing the Member's linens, making the Member's bed, washing the Member's dishes, and doing the Member's personal laundry, ironing and mending.

(d) Personal Care Visits shall not be provided for ~~m~~Members who do not require hands-on assistance with ADLs.

(e) Personal Care Visits shall be primarily provided in the Member's place of residence, except as permitted within the scope of service (e.g., picking up medications or shopping for groceries), when accompanying or transporting the Member into the community pursuant to rule 1200-13-01-.05(8)(~~m~~n), or under exceptional circumstances as authorized by an MCO in the POC to accommodate the needs of the Member.

(f) A single Contract Provider staff person or Consumer-Directed Worker may provide Personal Care Visits to multiple CHOICES ~~m~~Members in the same home and during the same hours, as long as he can provide the services safely and appropriately to each ~~m~~Member. Such arrangements shall be documented in each ~~m~~Member's plan of care. In such instances, the total units of service provided by the staff person shall be allocated among the CHOICES ~~m~~Members, based on the percentage of total service units required by each ~~m~~Member on average. The Provider shall bill the MCO only once for each of the service units provided, and shall not bill an MCO or multiple MCOs separately to provide services to multiple ~~m~~Members at the same time.

~~(g) Personal Care Visits shall not be provided to Members living in a CBRA facility or receiving Short-Term NF services, or while a Member is receiving Adult Day Care services.~~

(g) Regardless of payer, Personal Care Visits shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services, or while a Member is receiving Adult Day Care services.

(h) Personal care visits shall not include:

1. Companion or sitter services, including safety monitoring and supervision.

2. Care or assistance including meal preparation or household tasks for other residents of the same household.

3. Yard work.

4. Care of non-service related pets and animals.

(105~~109~~)Personal Emergency Response System (PERS). ~~(a)~~ For purposes of CHOICES:

~~1.~~(a) An electronic device that enables certain Members at high risk of institutionalization to summon help in an emergency. The Member may also wear a portable "help" button to allow for mobility. The system is programmed to signal a response center once the "help" button is activated. The response center is staffed by trained professionals who assess the nature of the emergency, and obtain assistance for the individual, as needed. PERS services are limited to those Members who have demonstrated mental and physical capacity to utilize such system effectively and who live alone or who are alone with no caregiver for extended periods of time, such that the Member's safety would be compromised without access to a PERS.

~~2.~~(b) ~~PERS shall not be provided to Members living in a receiving CBRA facility or receiving Short-Term NF services.~~

~~2.~~(b) Regardless of payer, PERS shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA (including Companion Care) or Short-Term NF services.

(106~~110~~)Personal Needs Allowance (PNA). A reasonable amount of money that is deducted by DHS from the individual's funds pursuant to federal and State law and the Medicaid State Plan in the application of post-eligibility provisions and the calculation of Patient Liability for ~~LTC services~~ LTSS. The PNA is set aside for clothing and other personal needs of the individual while in the institution (Institutional PNA), and to also pay room, board and other living expenses in the community (Community PNA).

(107~~111~~)Pest Control.

(a) The one-time or intermittent use of sprays, poisons and traps, as appropriate, in the ~~Enrollee's~~ Member's residence (excluding NFs or ACLFs) to regulate or eliminate the intrusion of cockroaches, wasps, mice, rats and other species of household pests into the household environment thereby removing an environmental issue that could be detrimental to a ~~frail elderly or disabled Enrollee's~~ Member's health and physical well-being.

~~(b) Pest control shall not be provided to Enrollees living in a CBRA facility or receiving Short-Term NF services.~~

(b) Regardless of payer, shall not be provided to Members living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving Short-Term NF services.

(c) A treatment visit for Pest Control is a visit by the Pest Control provider to the ~~Enrollee's~~ Member's residence during which the Pest Control treatment is applied.

(d) Shall not be provided solely as a preventive measure. There must be documentation of a need for this service either through Care Coordinator direct observation or determination through a needs assessment that a household pest is causing or is expected to cause more harm than is reasonable to accept.

(e) Shall not include treatment for termites, bed bug infestations or any pest infestation that cannot be addressed through intermittent visits as provided through the current benefit and reimbursement structure.

(108~~112~~)Pharmacy Benefits Manager (PBM). See "Pharmacy Benefits Manager" in Rule 1200-13-13-.01.

(109~~113~~)Physical Disabilities.

(a) One or more medically diagnosed chronic, physical impairments, either congenital or acquired, that limit independent, purposeful physical movement of the body or of one or more extremities, as evidenced by substantial functional limitations in one or more ADLs that require such movement—primarily mobility or transfer—and that are primarily attributable to the physical impairments and not to cognitive impairments or mental health conditions.

(b) An individual with cognitive impairments or mental health conditions who also has one or more Pphysical Ddisabilities as defined above may qualify as "Physically Disabled," and may be enrolled into ~~the Statewide E/D Waiver or~~ CHOICES Group 2 ~~(as applicable)~~ or CHOICES Group 3 so long as such individual can be safely served in the community and at a cost that does not exceed the individual's Cost Neutrality Cap or Expenditure Cap, as applicable. This includes consideration of whether or not the ~~statewide E/D Waiver~~ CHOICES Group 2 or CHOICES Group 3 benefit package, ~~(~~as applicable~~),~~ ~~can~~ adequately addresses any specialized service needs the applicant may have pertaining to the cognitive impairment or mental health condition, as applicable.

(110~~114~~)Physically Disabled. For purposes of enrollment into CHOICES Group 2 or CHOICES Group 3, an adult aged twenty-one (21) or older who has one or more Pphysical Ddisabilities.

(111~~115~~)Physician. A doctor of medicine or osteopathy who has received a degree from an accredited medical school and who is licensed to practice his profession in Tennessee.

~~(116) Physician's Plan of Care (POC). For purposes of the Statewide E/D Waiver, an individualized written POC developed by the Enrollee's Physician and included on the PAE and reviewed as needed or at least every ninety (90) days.~~

(112~~117~~)Plain Language. Any notice or explanation written at a level that does not exceed the sixth grade reading level as measured by the Flesch Index, Fog Index, or Flesch-Kincaid Index.

(113) Plan of Care. A written document that is developed through a person-centered planning process based on an individualized assessment of an Enrollee's needs that specifies the types and frequency of LTSS that the Enrollee receives.

(114~~118~~)PreAdmission Evaluation (PAE). A process of assessment by the Bureau used to determine an individual's medical (or LOC) eligibility for TennCare-reimbursed care in a NF or ICF/IIDMR, and in the case of NF services, the appropriate level of reimbursement for such care, as well as eligibility for HCBS as an alternative to institutional care, or in the case of persons At Risk for Institutionalization, in order to delay or prevent NF placement. For purposes of CHOICES, the PAE application shall be used for the purposes of determining LOC and for persons enrolled in CHOICES Group 2, calculating the Member's Individual Cost Neutrality Cap.

(115~~119~~)PreAdmission Screening/Resident Review (PASRR). The process by which the State determines whether an individual who resides in or seeks admission to a Medicaid-certified NF has, or is suspected of having, MI or MR, and, if so, whether the individual requires specialized services and is appropriate for NF placement.

(a) Identification Screen (Level I). The initial screening conducted to determine which NF Applicants or residents have MI or MR and are subject to PASRR. Individuals with a supportable primary diagnosis of Alzheimer's disease or dementia will also be detected through the Identification Screen. NFs are responsible for ensuring that all Applicants receive a Level I identification screen prior to admission to the facility, and for submission of the Level I Identification Screen to the Bureau.

(b) PASRR Evaluation (Level II). The process whereby a determination is made about whether the individual identified in the Level I screen requires the level of services provided by a NF or another type of facility and, if so, whether the individual requires specialized services. These reviews shall be the responsibility of the DMH~~DD~~ and/or DID~~S~~D, as applicable.

(116~~120~~)Private Duty Nursing (PDN) Services. See "Private Duty Nursing Services" in Rule 1200-13-13-.01.

(117~~121~~)Program of All-Inclusive Care for the Elderly (PACE). A program for dually eligible Enrollees in need of ~~LTC services~~ LTSS that is authorized under the Medicaid State Plan, Attachment 3.1-A, #26.

(118~~122~~)Provider. See "Provider" in Rule 1200-13-13-.01. Provider does not include Consumer-Directed Workers (see Consumer-Directed Worker); nor does Provider include the FEA (see Fiscal Employer Agent).

(119~~123~~)Qualified Assessor. A practicing professional who meets the qualifications established by TennCare to certify the accuracy of a level of care assessment as reflected in the PAE application. For the CHOICES program, Qualified Assessors shall include only the following: a licensed physician, nurse practitioner,

physician assistant, registered or licensed nurse, or licensed social worker.

(120~~124~~)Qualifying Income Trust (QIT). See "Qualified Income Trust" in DHS Rules Chapter 1240-03-03.

~~(125) Recertification. For purposes of the Statewide E/D Waiver, the process approved by the Bureau by which the Enrollee's Physician assesses the medical necessity of continuation of Waiver services and certifies in writing that the Enrollee continues to require Waiver services.~~

(121~~126~~)Related Conditions. See "Mental Retardation (MR) and Related Conditions."

(122~~127~~) Representative.

(a) In general, for CHOICES Members, a Representative is an individual who is at least eighteen (18) years of age and is authorized by the Member to participate in care planning and implementation and to speak and make decisions on the Member's behalf, including but not limited to identification of needs, preference regarding services and service delivery settings, and communication and resolution of complaints and concerns.

(b) As it relates to CD of Eligible CHOICES HCBS, a Representative is an individual who is authorized by the Member to direct and manage the Member's Worker(s), and signs a Representative Agreement. The Representative for CD of Eligible CHOICES HCBS must also:

1. Be at least eighteen (18) years of age;

2. Have a personal relationship with the Member and understand his support needs;

3. Know the Member's daily schedule and routine, medical and functional status, medication regimen, likes and dislikes, and strengths and weaknesses; and

4. Be physically present in the Member's residence on a regular basis or at least at a frequency necessary to supervise and evaluate workers.

(123~~128~~)Representative Agreement. The agreement between a CHOICES Member electing CD of Eligible CHOICES HCBS who has a Representative direct and manage the Member's Worker(s) and the Member's Representative that specifies the roles and responsibilities of the Member and the Member's Representative.

(124~~129~~)Reserve Capacity. The State's right to maintain some capacity within an established Enrollment Target to enroll individuals into CHOICES HCBS under certain circumstances. These circumstances could include, but are not limited to:

~~(a) Accommodation of a phased in implementation of CHOICES;~~

~~(b)~~(a) Discharge from a NF;

~~(c)~~(b) Discharge from an acute care setting where institutional placement is otherwise imminent; or

~~(d)~~(c) Other circumstances which the State may establish from time to time in accord with this Chapter.

~~(130) Respite Care. For purposes of the Statewide E/D Waiver, Respite Care services:~~

~~(a) Are provided to Enrollees unable to care for themselves.~~

~~(b) Are furnished on a short-term basis because of the absence or need for relief of those persons normally providing the care.~~

~~(c) May be provided Inpatient or in-home.~~

~~(d) Shall not be provided to Enrollees living in a CBRA facility or receiving Short-Term NF services.~~

(125~~131~~)Risk Agreement.

(a) An agreement signed by a Member who will receive CHOICES ~~Group 2~~ HCBS (or his Representative) that includes, at a minimum:

1. Identified risks to the Member of residing in the community and receiving HCBS;

2. The possible consequences of such risks, strategies to mitigate the identified risks; and

3. The Member's decision regarding his acceptance of risk.

(b) For Members electing to participate in CD, the Risk Agreement must include any additional risks associated with the Member's decision to act as the Employer of Record, or to have a Representative act as the Employer of Record on his behalf.

(126~~132~~)Room and Board. Lodging, meals, and utilities that are the responsibility of the individual receiving HCBS in a CBRA facility. The kinds of items that are considered "Room and Board" and are therefore not reimbursable by ~~Medicaid~~ TennCare include:

(a) Rent, or, if the individual owns his home, mortgage payments, depreciation, or mortgage interest;

(b) Property taxes;

(c) Insurance (title, mortgage, property and casualty);

(d) Building and/or grounds maintenance costs;

(e) Resident "raw" food costs including individual special dietary needs (the cost of preparing, serving, and cleaning up after meals is not included);

(f) Household supplies necessary for the room and board of the individual;

(g) Furnishings used by the resident;

(h) Utilities (electricity, water and sewer, gas);

(i) Resident telephone; or

(j) Resident cable or pay television.

~~(133) Safety Plan. For purposes of the Statewide E/D Waiver, an individualized plan by which the ALA ensures the health, safety, and welfare of Enrollees who do not have twenty-four (24) hour caregiver services and which meets the requirements of this Chapter.~~

(127~~134~~) Self-Determination IDMR Waiver. Tennessee's Self Determination Waiver under Section 1915(c) of the Social Security Act.

(128~~135~~)Self-Direction of Health Care Tasks.

(a) The decision by a CHOICES Member participating in CD to direct and supervise a paid Worker delivering Eligible CHOICES HCBS in the performance of Health Care Tasks that would otherwise be performed by a licensed nurse.

(b) The Self-Direction of Health Care Tasks is not a service, but rather health care-related duties and functions (such as administration of medications) that a CHOICES Member participating in CD may elect to have performed by a Consumer-Directed Worker as part of the delivery of Eligible CHOICES HCBS he is authorized to receive.

(129~~136~~)Service Agreement. The agreement between a CHOICES Member electing CD of Eligible CHOICES HCBS (or the Member's Representative) and the Member's Consumer-Directed Worker that specifies the roles and responsibilities of the Member (or the Member's Representative) and the Worker.

(1230~~137~~)Short-Term Nursing Facility (NF) Care. For purposes of CHOICES:

(a) The provision of NF care for up to ninety (90) days to a CHOICES Group 2 or CHOICES Group 3 Member who was receiving HCBS upon admission and who meets NF LOC and requires temporary placement in a NF—for example, due to the need for skilled or rehabilitative services upon hospital discharge or due to the temporary illness or absence of a primary caregiver—when such Member is reasonably expected to be discharged and to resume HCBS participation within no more than ninety (90) days.

(b) Such CHOICES Group 2 or CHOICES Group 3 Member must meet the NF LOC upon admission and in such case, while receiving Short-Term NF Care may continue enrollment in CHOICES Group 2 or CHOICES Group 3, pending discharge from the NF within no more than ninety (90) days or until such time it is determined that discharge within ninety (90) days from admission is not likely to occur, at which time the Member shall be transitioned to CHOICES Group 1, as appropriate.

(c) The Community PNA shall continue to apply during the provision of Short-Term NF care, up to the ninetieth (90th) day, in order to allow sufficient resources for the Member to maintain his community residence for transition back to the community.

(d) The PASRR process is required for CHOICES Group 2 and CHOICES Group 3 Members entering Short-Term NF Care.

(e) Persons receiving Short-Term NF Care are not eligible to receive any other HCBS, except as permitted in 1200-13-01-.05 to facilitate transition to the community.

(131~~138~~)Single Point of Entry (SPOE). The agency charged with screening, intake, and facilitated enrollment processes for non-~~Medicaid~~TennCare eligible individuals seeking enrollment into CHOICES.

(132) Skilled Nursing Facility (SNF). A Medicare-certified SNF.

(133~~139~~)Skilled Nursing Service. A Physician-ordered nursing service the complexity of which is such that it can only be safely and effectively provided directly by a registered nurse or licensed practical nurse.

(134~~140~~)Skilled Rehabilitative Service. A Physician-ordered rehabilitative service the complexity of which is such that it can only be safely and effectively provided by qualified health care personnel (e.g., registered physical therapist, licensed physical therapist assistant, registered occupational therapist, certified occupational therapy assistance, licensed respiratory therapist, licensed respiratory therapist assistant).

(135~~141~~)Specialized Services for Individuals with MI.

(a) The implementation of an individualized POC developed under and supervised by a Physician, provided by a Physician and other qualified mental health professionals that accomplishes the following;

1. Prescribes specific therapies and activities for the treatment of individuals who are experiencing an acute episode of severe MI, which necessitates continuous supervision by trained mental health personnel; and

2. Is directed toward diagnosing and reducing the individual's behavioral symptoms that necessitated institutionalization, improving his level of independent functioning, and achieving a functioning level that permits reduction in the intensity of mental health services to below the level of specialized services at the earliest possible convenience.

(b) Services to maintain generally independent individuals who are able to function with little supervision or in the absence of a continuous specialized services program are not included in this definition.

(136~~142~~)Specialized Services for Individuals with MR and Related Conditions.

(a) The implementation of an individualized POC specifying a continuous program for each individual, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services, and related services that is directed towards the acquisition of the behaviors necessary for the individual to function with as much self-determination and independence as possible; and the prevention or deceleration of regression or loss of current optimal functional status.

(b) Services to maintain generally independent individuals who are able to function with little supervision or in the absence of a continuous specialized services program are not included.

(137~~143~~)Specified CHOICES HCBS. The CHOICES HCBS that are available to persons who qualify for and are granted Immediate Eligibility by the Bureau. Specified CHOICES HCBS are limited to Adult Day Care, Attendant Care, Home-Delivered Meals, Personal Care Visits, and PERS.

~~(144) Statewide E/D Waiver. The Section 1915(c) HCBS Waiver project approved for Tennessee by CMS to provide services to a specified number of Medicaid-eligible adults who reside in Tennessee, who are aged or have physical disabilities, and who meet the medical eligibility (or LOC) criteria for reimbursement of Level 1 NF services.~~

(138~~145~~)Statewide IDMR Waiver. Tennessee's HCBS Waiver for the Mentally Retarded and Developmentally Disabled under Section 1915(c) of the Social Security Act.

~~(146) Subcontractor. For purposes of the Statewide E/D Waiver, an individual, organized partnership, professional corporation, or other legal association or entity that enters into a written contract with the ALA to provide Waiver services to an Enrollee.~~

(139~~147~~)Supports Broker. For purposes of CD:

(a) An individual assigned by the FEA to each CHOICES Member participating in CD who assists the Member/Representative in performing the Employer of Record functions, including, but not limited to: developing job descriptions; locating, recruiting, interviewing, scheduling, monitoring, and evaluating Workers.

(b) The Supports Broker collaborates with, but does not duplicate, the functions of the Member's Care Coordinator.

(c) The Supports Broker does not have authority or responsibility for CD. The Member or Member's Representative must retain authority and responsibility for CD.

(140~~148~~)TennCare. The program administered by the Single State Agency as designated by the State and CMS pursuant to Title XIX of the Social Security Act and the Section 1115 Research and Demonstration Waiver granted to the State of Tennessee.

(141~~149~~)TennCare CHOICES in Long-Term ~~Care~~ Services and Supports Program (CHOICES). The program in which NF services for TennCare eligibles of any age and HCBS for individuals aged sixty-five (65) and older and/or adults aged twenty-one (21) and older with ~~p~~Physical ~~d~~Disabilities are integrated into TennCare's Managed Care System.

(142) TennCare Eligible. For purposes of this Chapter, an individual who has been determined by DHS to be financially eligible to have TennCare reimbursement for covered LTSS.

(143~~150~~)Tennessee Pre-Admission Evaluation System (TPAES). A component of the State's Medicaid Management Information System and the system of record for all PreAdmission Evaluation ~~(i.e., level of care)~~ (LOC) submissions and ~~level of care~~ LOC determinations, as well as enrollments into and transitions between ~~LTC~~ LTSS programs, including CHOICES and the State's Money Follows the Person Rebalancing Demonstration (MFP), and which shall also be used to gather data required to comply with tracking and reporting requirements pertaining to MFP.

(144~~151~~)Third Party Liability (TPL). See "Third Party Liability" in Rule 1200-13-13-.01.

(145~~152~~)Tracheal Suctioning Reimbursement. The rate of ~~Medicaid~~ reimbursement provided for NF services, including enhanced respiratory care assistance, delivered by a NF that meets the requirements set forth in Rule 1200-13-01-.03(5), to residents determined by the Bureau to meet the medical eligibility criteria set forth in Rule 1200-13-01-.10(5)(e) or determined by an MCO to require short-term intensive respiratory intervention during the post-weaning period.

(146~~153~~)Transfer Form. For purposes of ICF/IID~~MR~~ services and HCBS ID waiver programs, a form approved by the Bureau which is used in lieu of a new PAE to document the transfer of an ICF/IID~~MR~~ eligible individual having an approved unexpired ICF/IID~~MR~~ PAE from one ICF/IID~~MR~~ to another ICF/IID~~MR~~, from an HCBS MR Waiver Program to an ICF/MR, from an ICF/IID~~MR~~ to an HCBS IDMR Waiver Program, or from one HCBS IDMR Waiver Program to another HCBS IDMR Waiver Program.

~~(154) Transfer Form. For purposes of the NF program and Statewide E/D Waiver prior to implementation of CHOICES, a form which is used in lieu of a new PAE to document the transfer of a NF eligible individual having an approved unexpired PAE from Level 1 in one NF to Level 1 in another such facility or to the HCBS E/D Waiver, from Level 2 in one NF to Level 2 in another such facility, or from the HCBS E/D Waiver to Level 1 in a NF.~~

(147~~155~~)Transition Allowance. For purposes of CHOICES.

(a) A per Member allotment not to exceed two thousand dollars ($2,000) per lifetime which may, at the sole discretion of an MCO, be provided as a CEA to continued institutional care for a CHOICES Member in order to facilitate transition from a NF to the community when such Member will, upon transition, receive more cost-effective non-residential HCBS or Companion Care.

(b) Items which may be purchased or reimbursed are only those items the Member has no other means to obtain and which are essential in order to establish a community residence when such residence is not already established and to facilitate the person's safe and timely transition, including rent and/or utility deposits, essential kitchen appliances, basic furniture, and essential basic household items, such as towels, linens, and dishes.

(c) Transition Allowance cannot be provided to CHOICES Members transitioning to a CBRA facility.

(148~~156~~)Ventilator Weaning Reimbursement. The rate of ~~Medicaid~~ reimbursement provided for ventilator weaning services delivered by a NF that meets the requirements set forth in Rule 1200-13-01-.03(5) to residents determined by an MCO to require such services based on medical necessity criteria.

(149~~157~~)Wait List. The list maintained by NFs of all individuals who have affirmatively expressed an intent to be considered for current or future admission to the NF or requested that their name be entered on any "wait list."

(150~~158~~)Waiting List. For purposes of CHOICES, the list maintained by the Bureau of individuals who have applied for CHOICES ~~Group 2~~ HCBS but who cannot be served because an Enrollment Target has been reached.

~~(159) Waiver Eligible. For purposes of the Statewide E/D Waiver, a resident of Tennessee determined by the Bureau to meet the criteria specified in Rule 1200-13-01-.17(5), and determined by DHS to qualify for Medicaid upon enrollment into a Section 1915(c) HCBS Waiver and receipt of HCBS. A Waiver Eligible is not necessarily enrolled into the Waiver.~~

(151~~160~~)Worker. See "Consumer-Directed Worker."

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

Rule 1200-13-01-.05 TennCare CHOICES Program

Paragraph (2) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Paragraph (2) which shall read as follows:

(2) Program components. The TennCare CHOICES Program is a managed ~~LTC~~ LTSS program that is administered by the TennCare MCOs under contract with the Bureau. The MCOs are responsible for coordinating all covered physical, behavioral, and ~~LTC services~~ LTSS for their ~~m~~Members who qualify for and are enrolled in CHOICES. The program consists of two components:

(a) NF services, as described in this Chapter.

(b) CHOICES HCBS, as described in this Chapter.

The introductory Emergency Rule Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a Rulemaking Hearing Rule introductory Subparagraph (a) which shall read as follows:

(a) There are three (3) groups in TennCare CHOICES:

Part 1. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Part 1. which shall read as follows:

1. CHOICES Group 1. Participation in CHOICES Group 1 is limited to TennCare Members of all ages who qualify for and are receiving TennCare-reimbursed NF services. Eligibility for TennCare-reimbursed LTSS is determined by DHS. Medical (or LOC) eligibility is determined by the Bureau as specified in Rule 1200-13-01-.10. Persons in CHOICES Group 1 must be enrolled in TennCare Medicaid or in the CHOICES 1 and 2 Carryover Group and qualify for TennCare reimbursement of LTSS. Persons who qualify in the CHOICES 1 and 2 Carryover Group are enrolled in TennCare Standard.

~~1. CHOICES Group 1. Participation in CHOICES Group 1 is limited to Medicaid Enrollees of all ages who qualify for and are receiving Medicaid-reimbursed NF services. Medicaid eligibility for LTC services is determined by DHS. Medical (or LOC) eligibility is determined by the Bureau as specified in Rule 1200-13-01-.10. Persons in CHOICES Group 1 must be enrolled in TennCare Medicaid and qualify for Medicaid reimbursement of LTC services.~~

Introductory Subpart (i) of Part 2. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new introductory Subpart (i) which shall read as follows:

(i) Participation in CHOICES Group 2 is limited to TennCare ~~Enrollees~~ Members who qualify for and are receiving TennCare-reimbursed CHOICES HCBS. To be eligible for CHOICES Group 2, ~~Enrollees~~ Applicants must meet the following criteria:

Subpart (iii) of Part 2. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "Enrollees" with the word "Members" so as amended Subpart (iii) shall read as follows:

(iii) Eligibility Categories Served in CHOICES Group 2. Participation in CHOICES Group 2 is limited to TennCare ~~Enrollees~~ Members who qualify in one of the following eligibility categories:

Subpart (iii) of Part 2. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by adding a new Item (III) which shall read as follows:

(III) The CHOICES 1 and 2 Carryover Group, as defined in Rule 1200-13-01-.02. Financial and categorical eligibility are determined by DHS. Persons who qualify in the CHOICES 1 and 2 Carryover Group are enrolled in TennCare Standard.

Emergency Rule Part 3. of Subparagraph (a) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 3. which shall read as follows:

3. CHOICES Group 3~~.~~, including Interim CHOICES Group 3.

(i) Participation in CHOICES Group 3 is limited to TennCare Enrollees who qualify for and are receiving TennCare-reimbursed CHOICES HCBS. To be eligible for CHOICES Group 3, Enrollees must meet the following criteria:

(I) Be in one of the defined target populations;

(II) Qualify in one of the specified eligibility categories;

(III) Be At Risk for Institutionalization as defined in Rule 1200-13-01-.02; and

(IV) Have needs that can be safely and appropriately met in the community and at a cost that does not exceed ~~the~~ their Expenditure Cap for CHOICES HCBS as defined in Rule 1200-13-01-.02.

(ii) Target Populations for CHOICES Group 3. Only persons in one of the target populations below may qualify to enroll in CHOICES Group 3:

(I) Persons age sixty-five (65) and older.

(II) Persons twenty-one (21) years of age and older who have one or more Pphysical Ddisabilities as defined in Rule 1200-13-01-.02.

(iii) Eligibility Categories served in CHOICES Group 3. Participation in CHOICES Group 3 is limited to TennCare Enrollees who qualify in one of the following eligibility categories:

(I) SSI eligibles, who are determined eligible for SSI by the Social Security Administration. SSI eligibles are enrolled in TennCare Medicaid.

(II) For Interim CHOICES Group 3 only, the CHOICES At-Risk Demonstration Group, as defined in Rule 1200-13-01-.02. Financial and categorical eligibility are determined by DHS. Persons who qualify in the CHOICES At-Risk Demonstration Group will be enrolled in TennCare Standard. This eligibility category is only open for enrollment between July 1, 2012 and December 31, 2013. Members enrolled in Interim CHOICES Group 3 on December 31, 2013 may continue to qualify in this group after December 31, 2013, so long as they continue to meet NF financial eligibility criteria and the LOC criteria in place at the time of enrollment into Interim CHOICES Group 3, and remain continuously enrolled in the CHOICES At-Risk Demonstration Group, Interim CHOICES Group 3, and TennCare.

Emergency Rule Subparagraph (b) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subparagraph (b) which shall read as follows:

(b) Level of Care (LOC). All Enrollees in TennCare CHOICES must meet the applicable LOC criteria, as determined by the Bureau in accordance with Rule 1200-13-01-.10. Physician certification of LOC shall be required only for NF services.

1. Persons shall meet NF LOC in order to enroll in CHOICES Group 1 or CHOICES Group 2.

2. Persons shall be At Risk for Institutionalization, as defined in Rule 1200-13-01-.02, in order to enroll in CHOICES Group 3, including Interim CHOICES Group 3.

3. Members enrolled in CHOICES Group 1 on June 30, 2012, may continue to qualify in this group after June 30, 2012, so long as they continue to meet NF financial eligibility, continue to meet the NF LOC criteria in place on June 30, 2012, and remain continuously enrolled in CHOICES Group 1 and in TennCare.

4. Members enrolled in CHOICES Group 1 on June 30, 2012, who wish to begin receiving HCBS and transition to CHOICES Group 2 shall, for purposes of LOC, be permitted to do so, so long as they continue to meet the NF LOC criteria in place on June 30, 2012, and have remained continuously enrolled in CHOICES Group 1 and in TennCare since June 30, 2012.

5. Members enrolled in CHOICES Group 2 on June 30, 2012, may continue to qualify in this group after June 30, 2012, so long as they continue to meet NF financial eligibility, continue to meet the NF LOC criteria in place on June 30, 2012, and remain continuously enrolled in CHOICES Group 2 and in TennCare.

6. Members enrolled in CHOICES Group 2 on June 30, 2012, who wish to be admitted to a NF and transition to CHOICES Group 1 shall be required to meet the NF LOC criteria in place at the time of enrollment into CHOICES Group 1 unless a determination has been made by TennCare that the Member's needs can no longer be safely met in the community within the Member's Individual Cost Neutrality Cap, in which case, the Member shall meet the NF LOC criteria in place on June 30, 2012, to qualify for enrollment into CHOICES Group 1.

~~(b) Level of Care (LOC).~~

~~All Enrollees in TennCare CHOICES must meet the applicable LOC criteria, as determined by the Bureau in accordance with Rule 1200-13-01-.10. Physician certification of LOC shall be required only for NF services.~~

~~1. Persons shall meet NF LOC in order to enroll in CHOICES Group 1 or CHOICES Group 2.~~

~~2. Persons shall meet At-Risk LOC in order to enroll in CHOICES Group 3, including Interim CHOICES Group 3.~~

~~3. Members enrolled in CHOICES Group 1 on June 30, 2012, may continue to qualify in this group after June 30, 2012, so long as they continue to meet NF financial eligibility, continue to meet the NF LOC criteria in place on June 30, 2012, and remain continuously enrolled in CHOICES Group 1 and in TennCare.~~

~~4. Members enrolled in CHOICES Group 1 on June 30, 2012, who wish to begin receiving HCBS and transition to CHOICES Group 2 shall, for purposes of LOC, be permitted to do so, so long as they continue to meet the NF LOC criteria in place on June 30, 2012, and have remained continuously enrolled in CHOICES Group 1 and in TennCare since June 30, 2012.~~

~~5. Members enrolled in CHOICES Group 2 on June 30, 2012, may continue to qualify in this group after June 30, 2012, so long as they continue to meet NF financial eligibility, continue to meet the NF LOC criteria in place on June 30, 2012, and remain continuously enrolled in CHOICES Group 2 and in TennCare.~~

~~6. Members enrolled in CHOICES Group 2 on June 30, 2012, who wish to be admitted to a NF and transition to CHOICES Group 1 shall be required to meet the NF LOC criteria in place at the time of enrollment into CHOICES Group 1 unless a determination has been made by TennCare that the member's needs can no longer be safely met in the community within the member's individual cost neutrality cap, in which case, the person shall meet the NF LOC criteria in place on June 30, 2012, to qualify for enrollment into CHOICES Group 1.~~

Part 1. of Subparagraph (c) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "Persons" with the word "Members" so as amended Part 1. shall read as follows:

1. ~~Persons~~ Members in CHOICES Group 1 must have been determined through the PASRR process described in Rules 1200-13-01.-10 and 1200-13-01-.23 to be appropriate for NF placement.

Emergency Rule Part 2. of Subparagraph (c) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 2. which shall read as follows:

2. ~~Persons~~ Members in CHOICES Group 2 or CHOICES Group 3 are not required to complete the PASRR process unless they are admitted to a NF for ~~the~~ Short-Term NF ~~benefit~~ Care described in Paragraph (8) of this Rule and defined in Rule 1200-13-01-.02. Completion of the PASRR process is not required for Members of CHOICES Group 2 or CHOICES Group 3 who have elected the Inpatient Respite Care benefit described in Paragraph (8) of this Rule, since

the service being provided is not NF services, but rather, Inpatient Respite Care, which is ~~an~~ CHOICES HCBS.

Emergency Rule Subparagraph (d) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subparagraph (d) which shall read as follows:

(d) All ~~Enrollees~~ Members in TennCare CHOICES must be admitted to a NF and require ~~Medicaid~~ TennCare reimbursement of NF services or be receiving CHOICES HCBS in CHOICES Group 2 or CHOICES Group 3.

Subparagraph (e) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Subparagraph (e) which shall read as follows:

(e) All ~~Enrollees~~ Members in TennCare CHOICES Group 2 must be determined by the MCO to be able to be served safely and appropriately in the community and within their ~~i~~Individual ~~c~~Cost ~~n~~Neutrality ~~c~~Cap, in accordance with this Rule. If a person can be served safely and appropriately in the community and within their ~~i~~Individual ~~c~~Cost-~~n~~Neutrality ~~c~~Cap only through receipt of Companion Care services, the person may not be enrolled into CHOICES Group 2 until a qualified companion has been identified, an adequate back-up plan has been developed, and the companion has completed all required paperwork and training and is ready to begin delivering Companion Care services immediately upon the person's enrollment into CHOICES. Reasons a person cannot be served safely and appropriately in the community may include, but are not limited to, the following:

1. The home or home environment of the ~~a~~Applicant is unsafe to the extent that it would reasonably be expected that HCBS could not be provided without significant risk of harm or injury to the Applicant or to individuals who provide covered services.

2. The Applicant refuses or fails to sign a Risk Agreement, or the Applicant's decision to receive services in the home or community poses an unacceptable level of risk.

~~2. The health, safety, and welfare of the individual cannot be assured due to the lack of a signed Risk Agreement, or the person's decision to receive services in the home or community poses an unacceptable level of risk.~~

3. The Applicant or his caregiver is unwilling to abide by the POC or Risk Agreement~~, resulting in the inability to ensure the person's health, safety and welfare~~.

Emergency Rule Subparagraph (f) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subparagraph (f) which shall read as follows:

(f) All ~~Enrollees~~ Members in TennCare CHOICES Group 3 must be determined by the MCO to be able to be served safely and appropriately in the community within the array of services and supports available in CHOICES Group 3, including CHOICES HCBS up to the ~~e~~Expenditure ~~c~~Cap of $15,000 (excluding the cost of minor home modifications), non-CHOICES HCBS available through TennCare (e.g., home health), services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers. Reasons a person cannot be served safely and appropriately in the community may include, but are not limited to, the following:

1. The home or home environment of the ~~a~~Applicant is unsafe to the extent that it would reasonably be expected that HCBS could not be provided without significant risk of harm or injury to the Applicant or to individuals who provide covered services.

2. The ~~a~~Applicant or his caregiver is unwilling to abide by the POC~~, resulting in the inability to ensure the person's health, safety and welfare~~.

Parts 2., 4., 5. and 6. of Subparagraph (g) of Paragraph (3) of Rule 1200-13-01-.05 TennCare CHOICES Program are deleted in their entirety and replaced with new Parts 2., 4., 5. and 6. which shall read as follows:

2. ~~Individuals~~ Members admitted to CHOICES Group 2 under the Immediate Eligibility option are ~~individuals~~ persons who are not already eligible for TennCare.

4. If eligibility in the CHOICES 217-Like Group is denied by DHS, the ~~individual~~ Applicant shall receive notice and the right to request a fair hearing regarding the DHS eligibility decision. Continuation of Specified CHOICES HCBS benefits or Immediate Eligibility shall not be granted during the fair hearing process once the forty-five (45) day Immediate Eligibility period has expired. A fair hearing shall not be granted regarding either of the following:

   (i) A decision by the Bureau to not grant the optional forty-five (45) day period of Immediate Eligibility; or

   (ii) The end of a forty-five (45) day period of Immediate Eligibility granted by the Bureau.

5. During a period of Immediate Eligibility, persons are eligible only for Specified CHOICES HCBS, as defined in Rule 1200-13-01-.02. They are not eligible for any other TennCare services, including other LTSS.

~~5. During the period of Immediate Eligibility, individuals are eligible only for the limited package of HCBS identified in Paragraph (8)(l). They are not eligible for any other TennCare services, including other LTC services.~~

6. During a period of Immediate Eligibility, ~~individuals~~ persons who are also Medicare beneficiaries are not entitled to Medicare crossover payments on their Medicare benefits. They cannot be considered "dual eligibles" since they are not yet Medicaid-eligible.

Introductory Subparagraph (a) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "individual" with the word "Applicant" so as amended introductory Subparagraph (a) shall read as follows:

(a) Enrollment into CHOICES Group 1. To qualify for enrollment into CHOICES Group 1, an ~~individual~~ Applicant must:

Emergency Rule Part 2. of Subparagraph (a) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 2. which shall read as follows:

2. Have an approved unexpired ~~CHOICES~~ PAE for NF LOC, including Level 1 reimbursement of NF services, Level 2 reimbursement of NF services, or Enhanced Respiratory Care Reimbursement for services in a NF. Eligibility for Enhanced Respiratory Care Reimbursement ~~may~~ shall be established ~~only with a CHOICES PAE~~ in accordance with Rule 1200-13-01-.10.

Part 3. of Subparagraph (a) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "Medicaid" with the word "TennCare" so as amended Part 3. shall read as follows:

3. Be approved by DHS for ~~Medicaid~~ TennCare reimbursement of NF services.

Part 4. of Subparagraph (a) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the acronym and word "LTC Services" with the acronym "LTSS" so as amended Part 4. shall read as follows:

4. Be admitted to a NF. The Bureau must have received notification from the NF that Medicaid reimbursement is requested for the effective date of CHOICES enrollment (i.e., the individual is no longer privately paying for NF services and Medicare payment of NF services is not available). Enrollment into CHOICES Group 1 (and payment of a capitation payment for ~~LTC services~~ LTSS) cannot begin until the Bureau or the MCO will be responsible for payment of NF services.

Subparagraph (b) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Subparagraph (b) which shall read as follows:

(b) Enrollment into CHOICES Group 2. To qualify for enrollment into CHOICES Group 2:

1. An Applicant must be in one of the target populations specified in this Rule;

2. An Applicant must have an approved unexpired PAE for NF LOC;

3. An Applicant must be approved by DHS for TennCare reimbursement of LTSS as an SSI recipient, in the CHOICES 217-Like Group, or in the CHOICES 1 and 2 Carryover Group. To be eligible in the CHOICES 217-Like Group, an Applicant must be approved by TennCare to enroll in CHOICES Group 2 or be approved by the Bureau for Immediate Eligibility for CHOICES Group 2, subject to determination of categorical and financial eligibility by DHS;

4. The Bureau must have received a determination by the MCO that the Applicant's needs can be safely and appropriately met in the community, and at a cost that does not exceed his Individual Cost Neutrality Cap, as described in this Rule, except in instances where the Applicant is not eligible for TennCare at the time of CHOICES application, in which case, such determination shall be made by the MCO upon enrollment into CHOICES Group 2; and

5. There must be capacity within the established Enrollment Target to enroll the Applicant in accordance with this Rule which may include satisfaction of criteria for Reserve Capacity, as applicable; or the Applicant must meet specified exceptions to enroll even when the Enrollment Target has been reached.

~~(b) Enrollment into CHOICES Group 2.~~

~~To qualify for enrollment into CHOICES Group 2:~~

~~1. An individual must be in one of the target populations specified in this Rule;~~

~~2. An individual must have an approved unexpired CHOICES PAE for NF LOC;~~

~~3. An individual must be approved by DHS for reimbursement of LTC services as an SSI recipient or in the CHOICES 217-Like Group. To be eligible in the CHOICES 217-Like Group, an individual must be approved by TennCare to enroll in CHOICES Group 2 or be approved by the Bureau for Immediate Eligibility for CHOICES Group 2, subject to categorical and financial eligibility by DHS;~~

~~4. The Bureau must have received a determination by the MCO that the individual's needs can be safely and appropriately met in the community, and at a cost that does not exceed his Individual Cost Neutrality Cap, as described in this Rule, except in instances where the person is not eligible for TennCare at the time of CHOICES application, in which case, such determination shall be made by the MCO upon enrollment into CHOICES Group 2; and~~

~~5. There must be capacity within the established Enrollment Target to enroll the individual in accordance with this Rule which may include satisfaction of criteria for reserve capacity, as applicable; or the individual must meet specified exceptions to enroll even when the Enrollment Target has been reached.~~

Emergency Rule Subpart (iii) of Part 1. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subpart (iii) which shall read as follows:

(iii) The total cost of CHOICES HCBS, HH Services, and PDN Services he can receive while enrolled in CHOICES Group 2. The Member's Individual Cost Neutrality Cap functions as a limit on the total cost of ~~CHOICES~~ HCBS that~~, when combined with the cost of HH Services and PDN Services the Member will receive, can be provided by the Member in the home or community setting~~ can be provided to the Member in the home or community setting, including CHOICES HCBS, HH Services and PDN Services.

Part 2. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the phrase "cost neutrality cap" in the first sentence with the phrase "Cost Neutrality Cap" so as amended Part 2. shall read as follows:

2. A Member is not entitled to receive services up to the amount of his ~~c~~Cost ~~n~~Neutrality ~~c~~Cap. A Member shall receive only those services that are medically necessary (i.e., required in order to

help ensure the Member's health, safety and welfare in the home or community setting and to delay or prevent the need for NF placement). Determination of the services that are needed shall be based on a comprehensive assessment of the Member's needs and the availability of Natural Supports and other (non-TennCare reimbursed) services to meet identified needs which shall be conducted by the Member's Care Coordinator.

Items (I), (II) and (III) of Subart (i) of Part 3. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program are deleted in their entirety and replaced with new Items (I), (II) and (III) which shall read as follows:

(I) A Member who would qualify only for Level 1 NF reimbursement shall have a ~~c~~Cost ~~n~~Neutrality ~~c~~Cap set at the average ~~cost of~~ Level 1 cost of NF care.

(II) A Member who would qualify for Level 2 NF reimbursement shall have a ~~c~~Cost ~~n~~Neutrality ~~c~~Cap set at the average ~~cost of~~ Level 2 ~~(or skilled)~~ cost of NF care.

(III) A Member who would qualify for the Enhanced Respiratory Care Reimbursement for persons who are chronically ventilator dependent, or for persons who have a functioning tracheostomy that requires frequent suctioning through the tracheostomy will have a ~~c~~Cost ~~n~~Neutrality ~~c~~Cap that reflects the higher payment that would be made to the NF for such care. There is no ~~c~~Cost ~~n~~Neutrality ~~c~~Cap for Ventilator Weaning Reimbursement, as such service is available only on a short-term basis in a SNF or acute care setting.

Subart (iii) of Part 3. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Subpart (iii) which shall read as follows:

(iii) A Member's Individual Cost Neutrality Cap shall be the average Level 1 cost of ~~Level 1~~ NF care unless a higher ~~c~~Cost ~~n~~Neutrality ~~c~~Cap is established based on information submitted in the PAE application.

Part 4. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Part 4. which shall read as follows:

4. Application of the Individual Cost Neutrality Cap.

(i) The annual ~~c~~Cost ~~n~~Neutrality ~~c~~Cap shall be applied on a calendar year basis. The Bureau and the MCOs will track utilization of CHOICES HCBS, HH services, and PDN services across each calendar year.

(ii) A Member's Individual Cost Neutrality Cap must also be applied prospectively on a twelve (12) month basis. This is to ensure that a Member's POC does not establish a threshold level of supports that cannot be sustained over the course of time. This means that, for purposes of care planning, the MCO will always project the total cost of all CHOICES HCBS (including one-time costs such as Minor Home Modifications, short-term services or short-term increases in services) and HH and PDN Services forward for twelve (12) months in order to determine whether the Member's needs can continue to be safely and cost-effectively met based on the most current POC that has been developed. The cost of one-time services such as Minor Home Modifications, short-term services or short-term increases in services must be counted as part of the total cost of ~~CHOICES~~ HCBS for a full twelve (12) month period following the date of service delivery.

(iii) If it can be reasonably anticipated, based on the CHOICES HCBS, HH and PDN services currently received or determined to be needed in order to safely meet the person's needs in the community, that the person will exceed his ~~c~~Cost ~~n~~Neutrality ~~c~~Cap, then the person does not qualify to enroll in or to remain enrolled in CHOICES Group 2.

Subpart (i) and introductory Subpart (ii) of Part 5. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program are amended by replacing the word "applicant" with the word "Applicant" so as amended Subpart (i) and introductory Subpart (ii) shall read as follows:

(i) A Member has a right to due process regarding his Individual Cost Neutrality Cap when services are denied or reduced, when a determination is made that an ~~a~~Applicant cannot be enrolled into CHOICES, or a currently enrolled CHOICES Member can no longer remain enrolled in CHOICES because his needs cannot be safely and effectively met in the home and community-based setting at a cost that does not exceed his Individual Cost Neutrality Cap.

(ii) When an adverse action is taken, notice of action shall be provided, and the ~~a~~Applicant or Member shall have the right to a fair hearing regarding any valid factual dispute pertaining to such action, which may include, but is not limited to, whether his Cost Neutrality Cap was calculated appropriately.

Emergency Rule Item (I) of Subpart (ii) of Part 5. of Subparagraph (c) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Item (I) which shall read as follows:

(I) Denial of or reductions in CHOICES HCBS based on a Member's Cost Neutrality Cap shall constitute an adverse action under the Grier Revised Consent Decree (Modified) ~~(See Rules 1200-13-13-.01(4) and 1200-13-14-.01(4))~~, as defined in Rules 1200-13-13-.01 and 1200-13-14-.01, and shall give rise to Grier notice of action and due process rights to request a fair hearing in accordance with Rules 1200-13-13-.11 and 1200-13-14-.11.

Subparagraph (d) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Subparagraph (d) which shall read as follows:

(d) Enrollment Target for CHOICES Group 2.

1. There shall be an Enrollment Target for CHOICES Group 2. The Enrollment Target functions as a cap on the total number of persons who can be enrolled into CHOICES Group 2 at any given time.

(i) Effective July 1, 2012, the Enrollment Target for CHOICES Group 2 will be twelve thousand five hundred (12,500).

(ii) Once the Enrollment Target (including Reserve Capacity as defined in 1200-13-01-.02 and as described in 1200-13-01-.05(d)(2)) is reached, qualified Applicants shall not be enrolled into CHOICES Group 2 or qualify in the CHOICES 217-Like eligibility category based on receipt of HCBS until such time that capacity within the Enrollment Target is available, with the following exceptions:

(I) NF-to-Community Transitions. A Member being served in CHOICES Group 1 who meets requirements to enroll in CHOICES Group 2 can enroll in CHOICES Group 2 even though the Enrollment Target has been met. This Member will be served in CHOICES Group 2 outside the Enrollment Target but shall be moved within the CHOICES Enrollment Target at such time that a slot becomes available. A request to transition a Member from CHOICES Group 1 to CHOICES Group 2 in excess of the CHOICES Group 2 Enrollment Target must specify the name of the NF where the Member currently resides, the date of admission and the planned date of transition.

(II) CEA Enrollment. An MCO with an SSI-eligible recipient who meets all other criteria for enrollment into CHOICES Group 2, but who cannot enroll in CHOICES Group 2 because the Enrollment Target for that group has been met, has the option, at its sole discretion, of offering HCBS as a CEA to the Member. Upon receipt of satisfactory documentation from the MCO of its CEA determination and assurance of provider capacity to meet the Member's needs, the Bureau will enroll the person into CHOICES Group 2, regardless of the Enrollment Target. The person will be served in CHOICES Group 2 outside the Enrollment Target, but shall be moved within the CHOICES Group 2 Enrollment Target at such time that a slot becomes

available. Satisfactory documentation of the MCO's CEA determination shall include an explanation of the Member's circumstances that warrant the immediate provision of NF services unless HCBS are immediately available. Documentation of adequate provider capacity to meet the Member's needs shall include a listing of providers for each HCBS in the Member's POC which the MCO has confirmed are willing and able to initiate HCBS within ten (10) business days of the Member's enrollment into CHOICES Group 2.

(III) If enrollment into CHOICES Group 2 is denied because the Enrollment Target has been reached, notice shall be provided to the Applicant, including the right to request a fair hearing regarding any valid factual dispute pertaining to the Bureau's decision. If the person otherwise qualifies for enrollment into CHOICES Group 2, but does not meet the exceptions specified in 1200-13-01-.05(4)(d)(1)(ii), the Applicant shall be placed on a Waiting List for CHOICES Group 2.

(IV) Once the CHOICES Group 2 Enrollment Target is reached, any persons enrolled in excess of the Enrollment Target in accordance with this Rule must receive the first available slots. Only after all persons enrolled in excess of the Enrollment Target have been moved under the Enrollment Target can additional persons be enrolled into CHOICES Group 2.

2. Reserve Capacity.

(i) The Bureau shall reserve three hundred (300) slots within the CHOICES Group 2 Enrollment Target. These slots are available only when the Enrollment Target has otherwise been reached, and only to the following:

(I) Applicants being discharged from a NF; and

(II) Applicants being discharged from an acute care setting who are at imminent risk of being placed in a NF setting absent the provision of HCBS.

(ii) Once all other available (i.e., unreserved) slots have been filled, Applicants who meet specified criteria (including new Applicants seeking to establish eligibility in the CHOICES 217-Like Group as well as current SSI-eligible individuals seeking enrollment into CHOICES Group 2) may be enrolled into reserved slots. TennCare may require confirmation of the NF or hospital discharge and in the case of hospital discharge, written explanation of the Applicant's circumstances that warrant the immediate provision of NF services unless HCBS are immediately available.

(iii) If enrollment into a Reserve Capacity slot is denied, notice shall be provided to the Applicant, including the right to request a fair hearing regarding any valid factual dispute pertaining to the Bureau's decision. If the person otherwise qualifies for enrollment into CHOICES Group 2, but does not meet the specified criteria for Reserve Capacity, the Applicant shall be placed on a Waiting List for CHOICES Group 2.

~~(d) Enrollment Target for CHOICES Group 2.~~

~~1. There shall be an Enrollment Target for CHOICES Group 2. The Enrollment Target functions as a cap on the total number of individuals who can be enrolled into CHOICES Group 2 at any given time.~~

~~(i) Effective March 1, 2010, the Enrollment Target for CHOICES Group 2 will be seven thousand five hundred (7,500).~~

~~(ii) Effective July 1, 2010, the Enrollment Target for CHOICES Group 2 will be nine thousand five hundred (9,500).~~

~~(iii) Effective September 30, 2011, the Enrollment Target for CHOICES Group 2 will be eleven thousand (11,000).~~

(iv) Effective July 1, 2012, the Enrollment Target for CHOICES Group 2 will be twelve thousand five hundred (12,500).

2. Reserve Capacity.

(i) The Bureau shall reserve three hundred (300) slots within the CHOICES Group 2 Enrollment Target. These slots are available only when the Enrollment Target has otherwise been reached, and only to the following:

(I) Individuals being discharged from a NF; and

(II) Individuals being discharged from an acute care setting who are at imminent risk of being placed in a NF setting absent the provision of HCBS.

(ii) Once all other available (i.e., unreserved) slots have been filled, individuals who meet specified criteria (including new applicants seeking to establish eligibility in the CHOICES 217-Like Group as well as current SSI-eligible individuals seeking enrollment into CHOICES Group 2) may be enrolled into reserved slots. TennCare may require confirmation of the NF or hospital discharge and in the case of hospital discharge, written explanation of the applicant's circumstances that warrant the immediate provision of NF services unless HCBS are immediately available.

(iii) If enrollment into a reserve capacity slot is denied, notice shall be provided to the applicant, including the right to request a fair hearing regarding any valid factual dispute pertaining to the Bureau's decision. If the person otherwise qualifies for enrollment into CHOICES Group 2, but does not meet the specified criteria for reserve capacity, the person shall be placed on a Waiting List for CHOICES Group 2.

(iv) Once the Enrollment Target is reached, qualified persons shall not be enrolled into CHOICES Group 2 or qualify in the CHOICES 217-Like eligibility category based on receipt of HCBS until such time that capacity within the Enrollment Target is available, with the following exceptions:

(I) NF-to-Community Transitions. A Member being served in CHOICES Group 1 who meets requirements to enroll in CHOICES Group 2 can enroll in CHOICES Group 2 even though the Enrollment Target has been met. This Member will be served in CHOICES Group 2 outside the Enrollment Target but shall be moved within the CHOICES Enrollment Target at such time that a slot becomes available. A request to transition a Member from CHOICES Group 1 to CHOICES Group 2 in excess of the CHOICES Group 2 Enrollment Target must specify the name of the NF where the Member currently resides, the date of admission and the planned date of transition.

(II) CEA Enrollment. An MCO with an SSI-eligible recipient who meets all other criteria for enrollment into CHOICES Group 2, but who cannot enroll in CHOICES Group 2 because the Enrollment Target for that group has been met, has the option, at its sole discretion, of offering HCBS as a CEA to the Member. Upon receipt of satisfactory documentation from the MCO of its CEA determination and assurance of provider capacity to meet the Member's needs, the Bureau will enroll the person into CHOICES Group 2, regardless of the Enrollment Target. The person will be served in CHOICES Group 2 outside the Enrollment Target, but shall be moved within the CHOICES Group 2 Enrollment Target at such time that a slot becomes available. Satisfactory documentation of the MCO's CEA determination shall include an explanation of the Member's circumstances that warrant the immediate provision of NF services unless HCBS are immediately available. Documentation of adequate provider capacity to meet the Member's needs shall include a listing of providers for each HCBS in the Member's POC which the MCO has confirmed are willing and able to initiate HCBS within five (5) days of the Member's enrollment into CHOICES.

~~(v) Once the CHOICES Group 2 Enrollment Target is reached, any persons enrolled in excess of the Enrollment Target in accordance with this Rule must receive the first available slots that become available. Only after all persons enrolled in excess of the Enrollment Target have been moved under the Enrollment Target can additional persons be enrolled into CHOICES Group 2.~~

Emergency Rules Subparagraphs (e), (f), and (g) of Paragraph (4) of Rule 1200-13-01-.05 TennCare CHOICES Program are deleted in their entirety and replaced with Rulemaking Hearing Rule Subparagraphs (e), (f), and (g) which shall read as follows:

(e) Enrollment into CHOICES Group 3. To qualify for enrollment into CHOICES Group 3 (including Interim CHOICES Group 3):

1. An individual must be in one of the target populations specified in this Rule;

2. An individual must be At Risk for Institutionalization, as defined in Rule 1200-13-01-.02;

~~2. An individual must have an approved unexpired PAE for At-Risk LOC;~~

3. An individual must be approved by DHS for reimbursement of ~~LTC services~~ LTSS as an SSI recipient or for Interim CHOICES Group 3 only, in the CHOICES At-Risk Demonstration Group, as defined in Rule 1200-13-01-.02. To be eligible in the CHOICES At-Risk Demonstration Group, an individual must be enrolled in Interim CHOICES Group 3, subject to determination of categorical and financial eligibility by DHS;

4. The Bureau must have received a determination by the MCO that the individual's needs can be safely and appropriately met in the community, and at a cost that does not exceed his Expenditure Cap, as described in this Rule, except in instances where the person is not eligible for TennCare at the time of CHOICES application, in which case, such determination shall be made by the MCO upon enrollment into CHOICES Group 3; and

5. There must be capacity within the established Enrollment Target, as applicable, to enroll the individual in accordance with this Rule.

(f) Expenditure Cap for CHOICES Group 3.

1. Each Member enrolling or enrolled in CHOICES Group 3 shall be subject to an Expenditure Cap on CHOICES HCBS. The Expenditure Cap shall be used to determine:

(i) Whether or not an ~~a~~Applicant qualifies to enroll in CHOICES Group 3;

(ii) Whether or not a ~~m~~Member qualifies to remain enrolled in CHOICES Group 3; and

(iii) The total cost of CHOICES HCBS a ~~m~~Member can receive while enrolled in CHOICES Group 3, excluding the cost of ~~m~~Minor ~~h~~Home ~~m~~Modifications. The Expenditure Cap functions as a limit on the total cost of CHOICES HCBS, excluding ~~m~~Minor ~~h~~Home ~~m~~Modifications, that can be provided by the MCO to the ~~m~~Member in the home or community setting.

2. A Member is not entitled to receive services up to the amount of the ~~e~~Expenditure ~~c~~Cap. A Member shall receive only those services that are medically necessary (i.e., required in order to help ensure the Member's health, safety and welfare in the home or community setting and to delay or prevent the need for NF placement). Determination of the services that are needed shall be based on a comprehensive assessment~~, conducted by the Member's Care Coordinator, of the Member's needs and the availability of Natural Supports and other (non-TennCare reimbursed) services to meet identified needs~~ of the Member's needs and the availability of Natural Supports and other (non-TennCare reimbursed) services to meet identified needs, which shall be conducted by the Member's Care Coordinator.

3. The Expenditure Cap for CHOICES HCBS provided to CHOICES Group 3 ~~m~~Members shall be $15,000 (fifteen thousand dollars) annually, excluding the cost of ~~m~~Minor ~~h~~Home ~~m~~Modifications.

4. Application of the Expenditure Cap.

(i) The annual ~~e~~Expenditure ~~c~~Cap shall be applied on a calendar year basis. The Bureau and the MCOs will track utilization of CHOICES HCBS excluding ~~m~~Minor ~~h~~Home ~~m~~Modifications, across each calendar year.

(ii) A Member's Expenditure Cap must also be applied prospectively on a twelve (12) month basis. This is to ensure that a Member's POC does not establish a threshold level of supports that cannot be sustained over the course of time. This means that, for purposes of care planning, the MCO will always project the total cost of CHOICES HCBS (excluding ~~m~~Minor ~~h~~Home ~~m~~Modifications) forward for twelve (12) months in order to determine whether the Member's needs can continue to be met based on the most current POC that has been developed. The cost of one-time services such as short-term services or short-term increases in services must be counted as part of the total cost of CHOICES HCBS for a full twelve (12) month period following the date of service delivery.

(iii) If it can be reasonably anticipated, based on the CHOICES HCBS currently received or determined to be needed (in addition to non-CHOICES HCBS available through TennCare, e.g., home health, services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers) in order to safely meet the person's needs in the community, that the person will exceed his Expenditure Cap, then the person does not qualify to enroll in or to remain enrolled in CHOICES Group 3.

(iv) Any ~~s~~Short-~~t~~Term NF ~~services~~ Care received by a ~~m~~Member enrolled in CHOICES Group 3 shall not be counted against his Expenditure Cap.

(g) Enrollment Target for CHOICES Group 3 (including Interim CHOICES Group 3).

1. The State may establish an Enrollment Target for CHOICES Group 3 which shall be at least ten (10) percent of the Enrollment Target established by the State for CHOICES Group 2.

2. Notwithstanding any Enrollment Target established for CHOICES Group 3 as described in this subparagraph, Interim CHOICES Group 3 which is open for enrollment between July 1, 2012, and December 31, 2013, shall not be subject to an Enrollment Target.

Paragraph (5) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Paragraph (5) which shall read as follows:

(5) Disenrollment from CHOICES. A Member may be disenrolled from CHOICES voluntarily or involuntarily.

(a) Voluntary disenrollment from CHOICES means the Member has chosen to disenroll, and no notice of action shall be issued regarding a Member's decision to voluntarily disenroll from CHOICES. However, notice shall be provided regarding any subsequent adverse action that may occur as a result of the Member's decision, including any change in benefits, cost-sharing responsibility, or continued eligibility for TennCare when the Member's eligibility was conditioned on receipt of LTSS. Voluntary disenrollment shall proceed only upon:

1. Discharge from a NF when the Member is not transitioning to CHOICES Group 2 or CHOICES Group 3, as described in these rules;

2. Election by the Member to receive hospice services in a NF, which is not a LTSS; or

3. Receipt of a statement signed by the Member or his authorized Representative voluntarily requesting disenrollment.

(b) A Member may be involuntarily disenrolled from CHOICES only by the Bureau, although such process may be initiated by a Member's MCO. Reasons for involuntary disenrollment include but are not limited to:

1. The Member no longer meets one or more criteria for eligibility and/or enrollment as specified in this Rule.

2. The Member's needs can no longer be safely met in the community. This may include but is not limited to the following instances:

(i) The home or home environment of the Member becomes unsafe to the extent that it would reasonably be expected that HCBS could not be provided without significant risk of harm or injury to the Member or to individuals who provide covered services to the Member.

(ii) The Member or his caregiver refuses to abide by the POC or Risk Agreement.

(iii) Even though an adequate provider network is in place, there are no providers who are willing to provide necessary services to the Member.

(iv) The Member refuses or fails to sign a Risk Agreement, or the Member's decision to continue receiving services in the home or community poses an unacceptable level of risk.

3. The Member's needs can no longer be safely met in the community at a cost that does not exceed the Member's Cost Neutrality Cap or Expenditure Cap, as applicable and as described in this Rule.

4. The Member no longer needs or is no longer receiving LTSS.

5. The Member has refused to pay his Patient Liability. The MCO and/or its participating providers are unwilling to serve the Member in CHOICES because he has not paid his Patient Liability, and/or no other MCO is willing to serve the Member in CHOICES.

~~(5) Disenrollment from CHOICES.~~

~~A Member may be disenrolled from CHOICES voluntarily or involuntarily.~~

~~(a) Voluntary disenrollment shall proceed only upon receipt of a statement signed by the Member or his authorized Representative. No notice of action shall be issued regarding a Member's decision to voluntarily disenroll from CHOICES. However, notice shall be provided regarding any subsequent adverse action that may occur as a result of the Member's decision, including any change in benefits, cost-sharing responsibility, or continued eligibility for TennCare when the Member's eligibility was conditioned on receipt of LTC services.~~

~~(b) A Member may be involuntarily disenrolled from CHOICES only by the Bureau, although such process may be initiated by a Member's MCO. Reasons for involuntary disenrollment include when the Member no longer meets one or more criteria for eligibility and/or enrollment as specified in this Rule. Such reasons include but are not limited to:~~

~~1. The Member's needs can no longer be safely met in the community. This may include, but is not limited to the following instances:~~

~~(i) The home or home environment of the Member becomes unsafe to the extent that it would reasonably be expected that HCBS could not be provided without significant risk of harm or injury to the Member or to individuals who provide covered services to the Member.~~

~~(ii) The Member or his caregiver refuses to abide by the POC or Risk Agreement, resulting in the inability to ensure the Member's health, safety and welfare.~~

~~(iii) Even though an adequate provider network is in place, there are no providers who are willing to provide necessary services to the Member.~~

~~(iv) The health, safety, and welfare of the Member cannot be assured due to the lack of a signed Risk Agreement, or the Member's decision to continue receiving services in the home or community poses an unacceptable level of risk.~~

~~2. The Member's needs can no longer be safely met in the community at a cost that does not exceed the Member's Cost Neutrality Cap or Expenditure Cap, as appropriate and as described in this Rule.~~

~~3. The Member no longer needs or is no longer receiving LTC services.~~

~~4. The Member has refused to pay his Patient Liability. The MCO and/or its participating providers are unwilling to serve the Member in CHOICES because he has not paid his Patient Liability, and/or no other MCO is willing to serve the Member in CHOICES.~~

Emergency Rule Paragraph (6) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Paragraph (6) which shall read as follows:

(6) Advance Determinations that an Applicant Would Not Qualify to Enroll in CHOICES Group 3 (including Interim CHOICES Group 3).

(a) For purposes of the Need for Inpatient Nursing Care, Effective July 1, 2012, as specified in TennCare Rule 1200-13-01-.10(4)(~~c~~b)(2)(i)(II) and 1200-13-01-.10(4)(~~c~~b)(2)(ii)(II), ~~a~~Advance ~~d~~Determination by TennCare that a CHOICES ~~a~~Applicant would not qualify for enrollment into CHOICES Group 3 shall be made only if all of the following criteria are met:

1. The ~~a~~Applicant has a total acuity score of at least six (6) but no more than eight (8);

2. The ~~a~~Applicant has an individual acuity score of at least three (3) for the Orientation measure;

3. The ~~a~~Applicant has an individual acuity score of at least two (2) for the Behavior measure;

4. The absence of intervention and supervision for dementia-related behaviors at the frequency specified in the PAE would result in imminent and serious risk of harm to the ~~a~~Applicant and/or others (documentation of the specific behaviors, the frequency of such behaviors, and the imminence and seriousness of risk shall be required); and

5. There is sufficient evidence, as required and determined by TennCare, to demonstrate that the necessary intervention and supervision needed by the person cannot be safely provided within the array of services and supports that would be available if the ~~a~~Applicant was enrolled in CHOICES Group 3, including CHOICES HCBS up to the ~~e~~Expenditure ~~c~~Cap of $15,000, non-CHOICES HCBS available through TennCare (e.g., home health), services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers.

(b) Documentation required to support an ~~a~~Advance ~~d~~Determination for ~~Medicaid eligible members~~ Applicants enrolled in TennCare shall include all of the following:

1. A comprehensive needs assessment performed by an MCO Care Coordinator pursuant to requirements set forth in the MCO's Contractor Risk Agreement, including:

(i) An assessment of the ~~m~~Member's physical, behavioral, functional, and psychosocial needs;

(ii) An assessment of the ~~m~~Member's home environment in order to identify any modifications that may be needed, and to identify and address any issues that may affect the Member's ability to be safely served in the community;

(iii) An assessment of the ~~m~~Member's ~~n~~Natural ~~s~~Supports, including care being provided by family members and/or other caregivers, and ~~long-term care services~~ LTSS the ~~m~~Member is currently receiving (regardless of payer), and whether there is any anticipated change in the ~~m~~Member's need for such care or services or the availability of such care or services from the current caregiver or payer; and

(iv) An assessment of the physical health, behavioral health, and ~~long-term care services~~ LTSS and other social support services and assistance (e.g., housing or income assistance) that are needed~~, as applicable,~~ to ensure the ~~m~~Member's health, safety and welfare in the community and to prevent the need for institutional placement. Such assessment shall specify the specific tasks and functions for which assistance is needed by the ~~m~~Member, the frequency with which such tasks must be performed, and the amount of paid assistance necessary to perform these tasks;

2. A person-centered plan of care developed by the MCO Care Coordinator which specifies the CHOICES HCBS that would be necessary and that would be approved by the MCO to safely support the person in the community, as well as non-CHOICES HCBS available through TennCare (e.g., home health), services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers (or attestation that the person could not be safely supported in the community with *any* combination of services and supports, as applicable);

3. An explanation regarding why an array of covered services and supports, including CHOICES HCBS ~~within the $15,000 expenditure cap for CHOICES 3~~ up to the Expenditure Cap of $15,000 and non-CHOICES HCBS (e.g., home health), services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers would not be sufficient to safely meet the person's needs in the community;

4. A detailed explanation of:

(i) ~~t~~The ~~m~~Member's living arrangements and the services and supports the ~~m~~Member has received for the six (6) months prior to application for CHOICES, including non-CHOICES HCBS available through TennCare (e.g., home health), services available through Medicare, private insurance or other funding sources, and unpaid supports provided by family members and other caregivers; and

(ii) ~~a~~Any recent significant event(s) or circumstances that have impacted the ~~a~~Applicant's need for services and supports, including how such event(s) or circumstances would impact the person's ability to be safely supported within the array of covered services and supports that would be available if the person were enrolled in CHOICES Group 3.

(c) Documentation required to support an ~~a~~Advance ~~d~~Determination for ~~a~~Applicants not enrolled in TennCare at the time the PAE is submitted shall include all of the items specified in Subparagraph (b) above, except as follows:

1. A comprehensive assessment, including an assessment of the ~~a~~Applicant's home environment, performed by the AAAD, or the most recent MDS assessment performed by a Nursing Facility contracted with one or more TennCare MCOs may be submitted in lieu of the MCO comprehensive needs assessment specified in Part (b)1. above.

2. The person-centered plan of care as described in Part (b)2. above shall not be required.

Emergency Rule Paragraph (7) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Paragraph (7) which shall read as follows:

(7) Transitioning Between CHOICES Groups.

(a) Transition from Group 1 to Group 2.

1. An MCO may request to transition a Member from Group 1 to Group 2 only when the Member chooses to transition from the NF to an HCBS setting. Members shall not be required to transition from Group 1 to Group 2. Only an MCO may submit to TennCare a request to transition a Member from Group 1 to Group 2.

2. A Member that has already been discharged from the NF shall not be transitioned to CHOICES Group 2. Once a Member has discharged from the NF, he has voluntarily disenrolled from CHOICES Group 1 and must be newly enrolled into CHOICES Group 2. A new PAE shall be required for enrollment into CHOICES Group 2.

~~2~~3. When Members move from Group 1 to Group 2, DHS must recalculate the Member's Patient Liability based on the Community PNA.

(b) Transition from Group 2 to Group 1. ~~1.~~ An MCO may request to transition a Member from Group 2 to Group 1 only under the following circumstances:

~~(i)~~1. Except as provided in TennCare Rule 1200-13-01-.05(3)(b)6.~~(6)~~, the ~~m~~Member meets the NF LOC criteria in place at the time of enrollment into CHOICES Group 1, and at least one (1) of the following is true;

~~(I)~~(i) The Member chooses to transition from HCBS to NF, for example, due to a decline in the Member's health or functional status, or a change in the Member's natural caregiving supports; or

~~(II)~~(ii) The MCO has made a determination that the Member's needs can no longer be safely met in the community and at a cost that does not exceed the average cost of NF services for which the Member would qualify, and the Member chooses to transition to the more appropriate institutional setting in order to safely meet his needs.

~~(ii)~~2. When Members move from Group 2 to Group 1, DHS must recalculate the Member's Patient Liability based on the Institutional PNA.

(c) At such time as a transition between CHOICES Groups 1 and 2 is made, the MCO shall issue notice of transition to the Member. Because the Member has elected the transition and remains enrolled in CHOICES, such transition between CHOICES groups shall not constitute an adverse action. Thus, the notice will not include the right to appeal or request a fair hearing regarding the Member's decision.

(d) Transition from ~~CHOICES~~ Group 1 or ~~CHOICES~~ Group 2 to ~~CHOICES~~ Group 3.

1. The ~~State~~ Bureau or the MCO shall, subject to eligibility and enrollment criteria set forth in TennCare Rule 1200-13-01-.05(3) and (4), initiate a transition from Group 1 or from Group 2 to Group 3 when a ~~m~~Member who was enrolled in CHOICES Group 1 or Group 2 on or after July 1, 2012, no longer meets NF LOC, but is At Risk for Institutionalization as defined in Rule 1200-13-01-.02.

2. A Member that has already been discharged from the NF shall not be transitioned from CHOICES Group 1 to CHOICES Group 3. Once a Member has discharged from the NF, he has voluntarily disenrolled from CHOICES Group 1 and must be newly enrolled into CHOICES Group 3. A new PAE shall be required for enrollment into CHOICES Group 3.

~~2.~~3. When a Member transitions from CHOICES Group 1 to Group 3, DHS must recalculate the Member's Patient Liability based on the Community PNA.

(e) Transition from ~~CHOICES~~ Group 3 to ~~CHOICES~~ Group 1 or ~~CHOICES~~ Group 2.

1. The ~~State~~ Bureau or the MCO shall initiate a transition from Group 3 to Group 1 or Group 2, as appropriate, when the Member meets NF LOC in place at the time of the transition request and satisfies all requirements for enrollment into the requested Group.

2. When a member transitions from Group 3 to Group 1, DHS must recalculate the Member's Patient Liability based on the Institutional PNA.

Paragraph (8) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Paragraph (8) which shall read as follows:

(8) Benefits in the TennCare CHOICES Program.

(a) CHOICES includes NF care and CHOICES HCBS benefits, as described in this Chapter. Pursuant to federal regulations, NF services must be ordered by the treating physician. A physician's order is not required for CHOICES HCBS.

(b) Members of CHOICES Group 1 who are Medicaid eligible receive NF care, in addition to all of the medically necessary covered benefits available for Medicaid recipients, as specified in Rule 1200-13-13-.04. While receiving NF care, Members are not eligible for HCBS.

(c) Members of CHOICES Group 1 who are eligible for TennCare Standard in the CHOICES 1 and 2 Carryover Group receive NF care, in addition to all of the medically necessary covered benefits available for TennCare Standard recipients, as specified in Rule 1200-13-14-.04. While receiving NF care, Members are not eligible for HCBS.

(~~c~~d) Members of CHOICES Group 2 who are Medicaid eligible receive CHOICES HCBS as specified in an approved POC, in addition to medically necessary covered benefits available for TennCare Medicaid recipients, as specified in Rule 1200-13-13-.04. While receiving HCBS, Members are not eligible for NF care, except for Short-Term NF care, as described in this Chapter.

(~~d~~e) Members of CHOICES Group 2 who are eligible for TennCare Standard in the CHOICES 217-Like Group or in the CHOICES 1 and 2 Carryover Group receive CHOICES HCBS as specified in an approved POC, in addition to medically necessary covered benefits available for TennCare Standard recipients, as specified in Rule 1200-13-14-.04. While receiving HCBS, Members are not eligible for NF care, except for Short-Term NF care, as described in this Chapter.

(~~e~~f) Members of CHOICES Group 3 who are SSI Eligible receive CHOICES HCBS as specified in an approved POC, in addition to medically necessary covered benefits available for TennCare Medicaid recipients, as specified in Rule 1200-13-13-.04. While receiving HCBS, Members are not eligible for NF care, except for Short-Term NF care, as described in this Chapter.

(~~f~~g) Members of CHOICES Group 3 who are eligible for TennCare Standard in the CHOICES At-Risk Demonstration Group receive CHOICES HCBS as specified in an approved POC, in addition to medically necessary covered benefits available for TennCare Standard recipients, as specified in Rule 1200-13-14-.04. While receiving HCBS, Members are not eligible for NF care, except for Short-Term NF care, as described in this Chapter.

(~~g~~h) Members are not eligible to receive any other HCBS during the time that Short-Term NF services are provided. CHOICES HCBS such as Minor Home Modifications or installation of a PERS which are required to facilitate transition from the NF back to the home or community may be provided during the NF stay and billed with date of service being on or after discharge from the NF.

(~~h~~i) Members receiving CBRA services, other than Companion Care, are eligible to receive only Assistive Technology services, since other types of support and assistance are within the defined scope of the 24-hour CBRA benefit and are the responsibility of the CBRA provider.

(ij) Members receiving Companion Care are eligible to receive only Assistive Technology, Minor Home Modifications, and Pest Control, since all needed assistance with ADLs and IADLs are within the defined scope of the 24-hour CBRA benefit.

(j~~k~~) All ~~LTC services~~ LTSS, NF services as well as CHOICES HCBS, must be authorized by the MCO in order for MCO payment to be made for the services. An MCO may elect to accept the Bureau's PAE determination as its prior authorization for NF services. NF care may sometimes start before authorization is obtained, but payment will not be made until the MCO has authorized the service.

CHOICES HCBS must be specified in an approved POC and authorized by the MCO prior to delivery of the service in order for MCO payment to be made for the service.

(kl) CHOICES HCBS covered under TennCare CHOICES and applicable limits are specified below. The benefit limits are applied across all services received by the Member regardless of whether the services are received through CD and/or a traditional provider agency. Corresponding limitations regarding the scope of each service are defined in Rule 1200-13-01-.02 and in Subparagraphs (a) through (jk) above.

Service	Benefits for CHOICES 2 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
1. Adult Day Care	Covered with a limit of 2080 hours per calendar year, per CHOICES Member.	No	Yes
2. Assistive Technology	Covered with a limit of $900 per calendar year, per Member.	No	No
3. Attendant Care	Covered only for persons who require hands-on assistance with ADLs when needed for more than 4 hours per occasion or visits at intervals of less than 4 hours between visits. For Members who do not require ~~h~~Homemaker ~~s~~Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, covered with a limit of 1080 hours per calendar year, per Member. For Members who require Homemaker Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, covered with a limit of 1240 hours for calendar year 2012, per Member. For Members who require ~~h~~Homemaker ~~s~~Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, beginning January 1, 2013, covered with a limit of 1400 hours per calendar year, per Member. ~~Not covered when the Member is receiving any of the following HCBS: Adult Day Care, CBRA facility services, Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving any of the following HCBS: Adult Day Care, CBRA facility services, or Short-Term NF Care.	Yes	Yes

Service	Benefits for CHOICES 2 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
4. CBRA	Companion Care. ~~Not covered when the Member is receiving any of the following HCBS: Adult Day Care, CBRA facility services, Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving any of the following HCBS: Adult Day Care, CBRA facility services, or Short-Term NF Care.	Yes	No
	CBRA facility services (e.g., ACLFs, Adult Care Homes).	No	No
5. Home-Delivered Meals	Covered with a limit of 1 meal per day, per Member. ~~Not covered when the Member is receiving CBRA services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	Yes
6. Homemaker Services	*Covered only for ~~m~~Members who also need hands-on assistance with ADLs and as a component of Attendant Care or Personal Care Visits as defined in these rules. Not covered as a stand-alone benefit. Not covered for persons who do not require hands-on assistance with ADLs. ~~Not covered when the Member is receiving CBRA services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	*	*

Service	Benefits for CHOICES 2 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
7. In-Home Respite Care	Covered with a limit of 216 hours per calendar year, per Member. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care~~. Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	Yes	No
8. Inpatient Respite Care	Covered with a limit of 9 days per calendar year, per Member. ~~PAE and~~ PASRR approval not required. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	No
9. Minor Home Modifications	Covered with a limit of $6,000 per project, $10,000 per calendar year, and $20,000 per lifetime. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care, except when provided as a CEA to facilitate transition from a NF to the community. See Rule 1200-13-01-.05(8)(o).~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting. Not covered when the Member is receiving Short-Term NF Care, except when provided to facilitate transition from a NF to the community. See Rule 1200-13-01-.05(8)(h).	No	~~N/A~~No

Service	Benefits for CHOICES 2 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
10. Personal Care Visits	Covered with a limit of 2 intermittent visits per day, per Member; visits limited to a maximum of 4 hours per visit and there shall be at least four (4) hours between intermittent visits. ~~Not covered when the Member is receiving any of the following HCBS: Adult Day Care, CBRA facility services, Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving any of the following HCBS: Adult Day Care, CBRA services (including Companion Care),or Short-Term NF Care.	Yes	Yes
11. PERS	~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care~~. Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	Yes
12. Pest Control	Covered with a limit of 9 treatment visits per calendar year, per Member. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving Short-Term NF Care.	No	No
13. Short-Term NF Care	Covered with a limit of 90 days per stay, per Member. Approved ~~PAE and~~ PASRR required. Members receiving Short-Term NF Care are not eligible to receive any other HCBS except when permitted ~~as a CEA~~ to facilitate transition to the community. See Rule 1200-13-01-.05(8)(~~e~~h).	No	~~N/A~~No

Service	Benefits for CHOICES 3 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
1. Adult Day Care	Covered with a limit of 2080 hours per calendar year, per CHOICES Member.	No	N/A
2. Assistive Technology	Covered with a limit of $900 per calendar year, per Member.	No	N/A
3. Attendant Care	Covered only for persons who require hands-on assistance with ADLs when needed for more than 4 hours per occasion or visits at intervals of less than 4 hours between visits. For Members who do not require ~~h~~Homemaker ~~s~~Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, covered with a limit of 1080 hours per calendar year, per Member. For Members who require ~~h~~Homemaker ~~s~~Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, covered with a limit of 1240 hours for calendar year 2012, per Member. For Members who require ~~h~~Homemaker ~~s~~Services as defined in Rule 1200-13-01-.02 in addition to hands on assistance with ADLs, beginning January 1, 2013, covered with a limit of 1400 hours per calendar year, per Member. ~~Not covered when the Member is receiving any of the following HCBS: Adult Day Care, CBRA facility services, Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving any of the following HCBS: Adult Day Care, CBRA services (including Companion Care), or Short-Term NF Care.	Yes	N/A
4. Home-Delivered Meals	Covered with a limit of 1 meal per day, per Member. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care~~. Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	N/A

Service	Benefits for CHOICES 3 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
5. Homemaker Services	*Covered only for ~~m~~Members who also need hands-on assistance with ADLs and as a component of Attendant Care or Personal Care Visits as defined in these rules. Not covered as a stand-alone benefit. Not covered for persons who do not require hands-on assistance with ADLs. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	*	*
6. In-Home Respite Care	Covered with a limit of 216 hours per calendar year, per Member. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	Yes	N/A
7. Inpatient Respite Care	Covered with a limit of 9 days per calendar year, per Member. ~~PAE and~~ PASRR approval not required. NF LOC not required. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	N/A

Service	Benefits for CHOICES 3 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
8. Minor Home Modifications	Covered with a limit of $6,000 per project, $10,000 per calendar year, and $20,000 per lifetime. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care, except when provided as a CEA to facilitate transition from a NF to the community. See Rule 1200-13-01-.05(8)(o).~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting. Not covered when the Member is receiving Short-Term NF Care, except when provided to facilitate transition from a NF to the community. See Rule 1200-13-01-.05(8)(h).	No	N/A
9. Personal Care Visits	Covered with a limit of 2 intermittent visits per day, per Member; visits limited to a maximum of 4 hours per visit and there shall be at least four (4) hours between intermittent visits. ~~Not covered when the Member is receiving any of the following HCBS: Adult Day Care, CBRA facility services, Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving any of the following HCBS: Adult Day Care, CBRA services (including Companion Care), or Short-Term NF Care.	Yes	N/A
10. PERS	~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care~~. Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving CBRA services (including Companion Care) or Short-Term NF Care.	No	N/A

Service	Benefits for CHOICES 3 Members	Benefits for Consumer Direction ("Eligible HCBS")	Benefits for Immediate Eligibles ("Specified HCBS")
11. Pest Control	Covered with a limit of 9 treatment visits per calendar year, per Member. ~~Not covered when the Member is receiving CBRA facility services or Short-Term NF Care.~~ Not covered (regardless of payer), when the Member is living in an ACLF, Adult Care Home, Residential Home for the Aged or other group residential setting, or receiving Short-Term NF Care.	No	N/A
12. Short-Term NF Care	Covered with a limit of 90 days per stay, per Member. Approved ~~PAE and~~ PASRR required. Member must meet NF LOC. Members receiving Short-Term NF Care are not eligible to receive any other HCBS except when permitted ~~as a CEA~~ to facilitate transition to the community. See Rule 1200-13-01-.05(8)(~~e~~h).	No	N/A

(~~l~~m) Applicants who qualify as "Immediate Eligibles" are eligible only for Specified CHOICES HCBS, as defined in these rules. Immediate Eligibles are not eligible for any other TennCare benefits, including other CHOICES benefits. The benefit limits are the same as those specified in Subparagraph (l) above. When the limit is an annual limit, the services used in the Immediate Eligibility period count against the annual limit if the Applicant should become eligible for TennCare. These Specified CHOICES HCBS, are listed below.

~~Applicants who qualify as "Immediate Eligibles" are eligible only for certain HCBS covered under CHOICES. They are not eligible for any other TennCare benefits, including other CHOICES benefits. These HCBS, called Specified HCBS, are listed below. The limits are the same as those specified in Subparagraph (k) above. When the limit is an annual limit, the services used in the Immediate Eligibility period count against the annual limit if the applicant should become eligible for TennCare.~~

1. Personal Care Visits.
2. Attendant Care.
3. Home-Delivered Meals.
4. PERS.
5. Adult Day Care.

(~~m~~n) Transportation.

1. Emergency and non-emergency transportation for TennCare covered services other than CHOICES services is provided by the MCOs in accordance with Rules 1200-13-13-.04 and 1200-13-14-.04.
2. Transportation is not provided to HCBS covered by CHOICES, except in the circumstance where a Member requires Adult Day Care that is not available within 30 miles of the Member's residence.

For CHOICES Members not participating in CD, provider agencies delivering CHOICES HCBS may permit staff to accompany a Member outside the home~~, but not to personally transport the Member~~. In circumstances where the Member is unable to drive, assistance by provider agency staff in performing IADLs (e.g., grocery shopping, picking up prescriptions, banking) specified in the POC may include transporting the Member when such assistance would otherwise be performed for the Member by the provider staff, and subject to the provider agency's agreement and responsibility to ensure that the Worker has a valid driver's license and proof of insurance prior to transporting a Member. The decision of whether or not to accompany the Member outside the home (and in the circumstances described above, to transport the Member) is at the discretion of the agency/Worker, taking into account such issues as the ability to safely provide services outside the home setting ~~and~~ , the cost involved, and the provider's willingness to accept and manage potential risk and/or liability. In no case will additional hours of service and/or an increased rate of reimbursement be provided as a result of an agency/Worker decision to accompany or transport a Member outside the home.

3. For CHOICES Members participating in CD, the Member may elect to have his Consumer-Directed Workers (including Companion Care workers) to accompany and/or transport the Member if such an arrangement is agreed to by both the Member and the Workers and specified in the Service Agreement; however, no additional hours or reimbursement will be available. Consumer-Directed Worker(s) must provide to the FEA a valid driver's license and proof of insurance prior to transporting a Member.

(~~n~~o) Freedom of Choice.

1. CHOICES Members who meet NF LOC as defined in Rule 1200-13-01-.10 shall be given freedom of choice of NF care or CHOICES HCBS, so long as the Member meets all criteria for enrollment into CHOICES Group 2, as specified in this Chapter and the Member may be enrolled into CHOICES Group 2 in accordance with requirements pertaining to the CHOICES Group 2 Enrollment Target as described in this Chapter.

2. CHOICES Members shall also be permitted to choose providers for CHOICES HCBS specified in the POC from the MCO's list of participating providers, if the participating provider selected is available and willing to initiate services timely and to deliver services in accordance with the POC. The Member is not entitled to receive services from a particular provider. A Member is not entitled to a fair hearing if he is not able to receive services from the provider of his choice.

(~~o~~p) Transition Allowance. For CHOICES Members moving from CHOICES 1 to CHOICES 2 or CHOICES 3, the MCO may, at its sole discretion, provide a Transition Allowance not to exceed two thousand dollars ($2,000) per lifetime as a CEA to facilitate transition of the Member from the NF to the community. An MCO shall not be required to provide a Transition Allowance, and Members transitioning out of a NF are not entitled to receive a Transition Allowance, which is not a covered benefit. Items that an MCO may ~~be~~ elect to purchase~~d~~ or reimburse~~d~~ are limited to the following:

1. Those items which the Member has no other means to obtain and which are essential in order to establish a community residence when such residence is not already established and to facilitate the person's safe and timely transition;

2. Rent and/or utility deposits; and

3. Essential kitchen appliances, basic furniture, and essential basic household items, such as towels, linens, and dishes.

Subparagraph (a) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Subparagraph (a) which shall read as follows:

(a) CD is a model of service delivery that affords CHOICES Group 2 and CHOICES Group 3 Members the opportunity to have more choice and control with respect ~~to certain types of~~ to Eligible CHOICES HCBS that are needed by the Member, in accordance with this Rule. CD is not a service or set of services.

1. The model of CD that will be implemented in CHOICES is ~~a prior authorization model~~ an employer authority model.

2. The determination regarding the services a Member will receive shall be based on a comprehensive needs assessment performed by a Care Coordinator that identifies the Member's needs, the availability of family and other caregivers to meet those needs, and the gaps in care for which paid services may be authorized.

3. Upon completion of the comprehensive needs assessment, CHOICES Members determined to need Eligible CHOICES HCBS may elect to receive one or more of the Eligible CHOICES HCBS through a Contract Provider, or they may participate in CD. Companion Care is available only through CD.

4. CHOICES Members who do not need Eligible CHOICES HCBS shall not be offered the opportunity to enroll in CD.

Subparagraph (b) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Subparagraph (b) which shall read as follows:

(b) CHOICES HCBS eligible for CD (Eligible CHOICES HCBS).

1. CD is limited to the following HCBS:

(i) Attendant Care.

(ii) Companion Care (available only to Members electing CD and in CHOICES Group 2; not available to CHOICES Group 3 Members).

(iii) In-Home Respite Care.

(iv) Personal Care Visits.

2. CHOICES Members do not have budget authority. The amount of a covered benefit available to the Member shall not increase as a result of his decision to participate in CD, even if the rate of reimbursement for the service is lower in CD. The amount of each covered benefit to be provided to the Member is specified in the approved POC.

3. HH Services, PDN Services, and CHOICES HCBS other than those specified above shall not be available through CD.

Introductory Subparagraph (c) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "Members" with the word "Member" so as amended the introductory Subparagraph (c) shall read as follows:

(c) Eligibility for CD. To be eligible for CD, a CHOICES Members must meet all of the following criteria:

Part 1. of Subparagraph (c) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 1. which shall read as follows:

1. Be a Member of CHOICES Group 2 or CHOICES Group 3.

Part 2. of Subparagraph (c) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Part 2. which shall read as follows:

2. Be determined by a Care Coordinator, based on a comprehensive needs assessment, to need one or more ~~of the HCBS eligible for CD~~ Eligible CHOICES HCBS.

Part 4. of Su0.bparagraph (c) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by adding the phrase "as applicable" after the word and comma "Agreement," so as amended Part 4. shall read as follows:

4. Any additional risks associated with a Member's decision to participate in CD must be identified and addressed in a signed Risk Agreement, as applicable, and the MCO must determine that the Member's needs can be safely and appropriately met in the community while participating in CD.

Emergency Rule Part 1. of Subparagraph (d) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 1. which shall read as follows:

1. A CHOICES Group 2 or CHOICES Group 3 Member assessed to need one or more Eligible CHOICES HCBS may elect to participate in CD at any time.

Emergency Rule Subpart (i) of Part 1. of Subparagraph (f) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subpart (i) which shall read as follows:

(i) The person is not enrolled in TennCare or in CHOICES Group 2 or CHOICES Group 3.

Subpart (iv) of Part 1. of Subparagraph (f) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by replacing the word "members" with the word "Members" after the words "with the" in the third line so as amended Subpart (iv) shall read as follows:

(iv) The Member is unwilling to sign a Risk Agreement which identifies and addresses any additional risks associated with the Member's decision to participate in CD, or the risks associated with the ~~m~~Member's decision to participate in CD pose too great a threat to the Member's health, safety and welfare.

Part 7. of Subparagraph (h) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by adding the word "CHOICES" after the words "of eligible" so as amended Part 7. shall read as follows:

7. The Back-up Plan shall be reviewed and updated at least annually, and as frequently as necessary if there are changes in the type, amount, duration, scope of eligible CHOICES HCBS or the schedule at which such services are needed, changes in Workers (when such Workers also serve as a back-up to other Workers) and changes in the availability of paid or unpaid back-up Workers to deliver needed care.

Subparagraph (h) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by adding a new Part 8. which shall read as follows:

8. A Member may use Contract Providers to serve as back-up to Consumer Directed Workers only upon prior arrangement by the Member (or Representative for CD) with the Contract Provider, inclusion in the Member's back-up plan, verification by the Supports Broker, prior approval by the MCO and subject to the Member's Individual Cost Neutrality Cap as described in Rule 1200-13-01-.05(4)(c). If the higher cost of services delivered by a Contract Provider would result in a Member's Cost Neutrality Cap being exceeded, a Member shall not be permitted to use Contract Providers to provide back-up workers. A Member's MCO shall not be required to maintain Contract Providers on "stand-by" to provide back-up for services delivered through Consumer Direction.

Subpart (ii) of Part 1. of Subparagraph (i) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Subpart (ii) which shall read as follows:

(ii) Members may hire family members, excluding spouses, to serve as Workers. However, a family member shall not be reimbursed for a service that he would have otherwise provided without pay. A ~~m~~Member shall not be permitted to employ any person who resides with the ~~m~~Member to deliver Personal Care Visits, Attendant Care, or In-Home Respite Care. A Member or his Representative for CD shall not be permitted to employ either of the following to deliver Companion Care services:

(I) An ~~i~~Immediate Family Member as defined in Rule 1200-13-01-.02.

(II) Any person with whom the ~~m~~Member currently resides, or with whom the ~~m~~Member has resided in the last five (5) years.

Emergency Rule Part 1. of Subparagraph (j) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 1. which shall read as follows:

1. A Competent Adult, as defined in this Chapter, with a functional disability living in his own home, enrolled in CHOICES Group 2 or CHOICES Group 3, and participating in CD, or his Representative for CD, may choose to direct and supervise a Consumer-Directed Worker in the performance of a Health Care Task as defined in this Chapter.

Emergency Rule Part 3. of Subparagraph (j) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 3. which shall read as follows:

3. A Member shall not receive additional amounts of any service as a result of his decision to self-direct health care tasks. Rather, the Health Care Tasks shall be performed by the Worker in the course of delivering Eligible CHOICES HCBS already determined to be needed, as specified in the POC.

Emergency Rule Part 7. of Subparagraph (j) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Part 7. which shall read as follows:

7. The Member or his Representative for CD will identify one or more Consumer-Directed Workers who will perform the task in the course of delivery of ~~e~~Eligible CHOICES HCBS. If a Worker agrees to perform the Health Care Tasks, the tasks to be performed must be specified in the Service Agreement. The Member or his Representative for CD is solely responsible for identifying a Worker who is willing to perform Health Care Tasks, and for instructing the paid personal aide on the task(s) to be performed.

Subpart (ii) of Part 1. of Subparagraph (k) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Subpart (ii) which shall read as follows:

(ii) Voluntary or involuntary withdrawal of a Member from CD of Eligible CHOICES HCBS shall not affect a Member's eligibility for ~~LTC services~~ LTSS or enrollment in CHOICES, provided the Member continues to meet all requirements for enrollment in CHOICES as defined in this Chapter.

Emergency Rule Subpart (iii) of Part 1. of Subparagraph (k) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subpart (iii) which shall read as follows:

(iii) If a Member voluntarily withdraws or is involuntarily withdrawn from CD, any Eligible CHOICES HCBS he receives, with the exception of Companion Care, shall be provided through Contract Providers, subject to the requirements in this Chapter. Companion Care is only available through CD.

Emergency Rule Item (II) of Subpart (i) of Part 2. of Subparagraph (k) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Item (II) which shall read as follows:

(II) The person is no longer enrolled in either CHOICES Group 2 or CHOICES Group 3.

Item (III) of Subpart (i) of Part 2. of Subparagraph (k) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new Item (III) which shall read as follows:

(III) The Member no longer needs any of the Eligible CHOICES HCBS ~~eligible for CD~~, as specified in the POC.

Item (V) of Subpart (i) of Part 2. of Subparagraph (k) of Paragraph (9) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by adding ",as applicable," after the word "Agreement" so as amended Item (V) shall read as follows:

(V) The Member is unwilling to sign a Risk Agreement, as applicable, which identifies and addresses any additional risks associated with the Member's decision to participate in CD, or the risks associated with the Member's decision to participate in CD pose too great a threat to the Member's health, safety and welfare.

Subparagraphs (b), (c) and (d) of Paragraph (10) of Rule 1200-13-01-.05 TennCare CHOICES Program are deleted in their entirety and replaced with new Subparagraphs (b), (c) and (d) which shall read as follows:

(b) ~~Reimbursement methodology for Level I care~~ Level 1 reimbursement methodology for NF care: See Rule 1200-13-01-.03(6).

(c) ~~Reimbursement methodology for Level 2 care~~ Level 2 reimbursement methodology for NF care: See Rule 1200-13-01-.03(7).

(d) ~~Reimbursement methodology for Level 2 care at an Enhanced Respiratory Care rate~~ Enhanced Respiratory Care reimbursement methodology for NF care: See Rule 1200-13-01-.03(8).

Part 3. of Subparagraph (e) of Paragraph (10) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with new Part 3. which shall read as follows:

3. Non-participating NF providers will be reimbursed eighty percent (80%) of the lowest rate paid to any participating NF provider in Tennessee for the applicable level of NF services ~~except that for the first thirty (30) days following CHOICES implementation in the Grand Division, reimbursement shall be made at the NF's rate as established by the Office of the Comptroller~~.

Subparagraph (b) of Paragraph (11) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and current Subparagraph (c) re-lettered as (b).

~~(b) During the Continuity of Care period, both participating and non-participating HCBS providers will be reimbursed by the Member's MCO in accordance with the contract rates for providers of similar services.~~

Subparagraph (c) re-lettered as (b) of Paragraph (11) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with a new re-lettered Subparagraph (b) which shall read as follows:

(~~c~~b) ~~After the Continuity of Care period has ended, n~~Non-participating HCBS providers will be reimbursed by the Member's MCO at eighty percent (80%) of the lowest rate paid to any HCBS provider in the state for that service.

Emergency Rule Subparagraph (c) of Paragraph (12) of Rule 1200-13-01-.05 TennCare CHOICES Program is deleted in its entirety and replaced with Rulemaking Hearing Rule Subparagraph (c) which shall read as follows:

(c) Appeals related to the PAE process (including decisions pertaining to the PASRR process) are processed by the Bureau's Division of Long-Term ~~Care~~ Services and Supports in accordance with Rule 1200-13-01-.10(7).

Introductory language of Subparagraph (d) of Paragraph (12) of Rule 1200-13-01-.05 TennCare CHOICES Program is amended by deleting the word "Care" after the phrase "Long-Term" and adding the words "Services and Supports" so as amended introductory language of Subparagraph (d) shall read as follows:

(d) Appeals related to the enrollment or disenrollment of an individual in CHOICES or to denial or involuntary withdrawal from participation in CD are processed by the Division of Long-Term ~~Care~~ Services and Supports in the Bureau, in accordance with the following procedures:

Part 3. of Subparagraph (d) of Paragraph (12) of rule 1200-13-01-.05 TennCare CHOICES Program is amended by deleting the word "Care" after the phrase "Long-Term" in the first sentence and adding the words "Services and Supports" so as amended Part 3. shall read as follows:

3. Appeals regarding denial of enrollment into CHOICES, involuntary disenrollment from CHOICES, or denial or involuntary withdrawal from participation in CD must be filed in writing

with the TennCare Division of Long-Term ~~Care~~ Services and Supports within thirty-five (35) days of issuance of the written notice if the appeal is filed with the Bureau by fax, and within forty (40) days of issuance of the written notice if the appeal is mailed to the Bureau. This allows five (5) days mail time for receipt of the written notice and when applicable, five (5) days mail time for receipt of the written appeal.

Statutory Authority: T.C.A. §§ 4-5-202, 4-5-203, 71-5-105 and 71-5-109.

Emergency Rule 1200-13-01-.08 Personal Needs Allowance (PNA), Patient Liability, Third Party Insurance and Estate Recovery for Persons Receiving LTC is deleted in its entirety and replaced with Rulemaking Hearing Rule 1200-13-01-.08 which shall read as follows:

1200-13-01-.08 PERSONAL NEEDS ALLOWANCE (PNA), PATIENT LIABILITY, THIRD PARTY INSURANCE AND ESTATE RECOVERY FOR PERSONS RECEIVING ~~LTC~~ LTSS.

(1) Personal Needs Allowance (PNA). The PNA is established for each Enrollee receiving ~~LTC services~~ LTSS in accordance with the Tennessee Medicaid State Plan, approved Section 1915(c) Waiver applications, and these rules. It is deducted from the Enrollee's monthly income in calculating Patient Liability for ~~LTC services~~ LTSS.

(a) The PNA for each person receiving ~~Medicaid-funded~~ TennCare-reimbursed services in a NF or an ICF/IID~~MR~~ is $50. Persons with no income have no PNA. Persons with incomes that are less than $50 per month (including institutionalized persons receiving SSI payments) may keep the entire amount of their income as their PNA.

(b) The maximum PNA for persons participating in CHOICES Group 2 or CHOICES Group 3 is 300% of the SSI FBR.

(c) The maximum PNA for persons participating in one of the State's Section 1915(c) HCBS Waivers is as follows:

~~1. The Statewide HCBS E/D Waiver: 200% of the SSI FBR, as defined in Rule 1200-13-01-.02.~~

~~2.~~1. The Statewide ID~~MR~~ Waiver: 200% of the SSI FBR.

~~3.~~2. The Arlington ID~~MR~~ Waiver: 200% of the SSI FBR.

~~4.~~3. The Self-Determination ID~~MR~~ Waiver: 300% of the SSI FBR.

(2) Patient Liability.

(a) Enrollees receiving ~~LTC services~~ LTSS are required to contribute to the cost of their ~~LTC~~ LTSS if their incomes are at certain levels. They are subject to the post-eligibility treatment of income rules set forth in Section 1924 of the Social Security Act (42 U.S.C.A. § 1396r-5), and 42 C.F.R. § 435.725.

(b) For Enrollees being served in HCBS Waivers, the State must also use institutional eligibility and post-eligibility rules for determining Patient Liability.

(c) For Members of the CHOICES 217-Like Group and the CHOICES At-Risk Demonstration Group, the State uses institutional eligibility and post-eligibility rules for determining Patient Liability in the same manner as specified under 42 C.F.R. §§ 435.217, 435.236, and 435.726 and Section 1924 of the Social Security Act (42 U.S.C.A. § 1396r-5), if the HCBS were provided under a Section 1915(c) Waiver.

(d) For a Member of CHOICES Group 2 or CHOICES Group 3 receiving the Short-Term NF Care benefit (for up to 90 days) or an Enrollee in one of the State's Section 1915(c) Waiver programs who is temporarily placed in a medical institution, i.e., a hospital, NF or ICF/IID~~MR~~ (for up to 90 days), the post-eligibility calculation shall be performed as if the individual is continuing to receive HCBS. The purpose is to ensure that the individual can maintain a community residence for transition back to the community. After 90 days, or as soon as it appears that the inpatient stay will not be a short-term

stay, whichever comes first, a CHOICES Group 2 or CHOICES Group 3 Member will be transitioned to CHOICES Group 1, or a waiver participant must be disenrolled from the waiver, and the institutional post-eligibility calculation shall apply.

(e) Patient Liability shall be collected as follows:

1. If the Enrollee resides in a NF, ICF/IIDMR, or CBRA facility (i.e., an ACLF or Critical Adult Care Home), the Enrollee must pay his Patient Liability to the residential facility. The facility shall reduce the amount billed to the Bureau or the MCO, as applicable, by the amount of the Enrollee's Patient Liability obligation, regardless of whether such amount is actually collected by the facility.

2. If a CHOICES Group 2 Member does not reside in a CBRA facility, i.e., the Member is receiving HCBS (including Companion Care) in his own home, and for all CHOICES Group 3 members (who are not eligible to receive CBRA services), the Member must pay his Patient Liability to the MCO. The amount of Patient Liability collected will be used to offset the cost of CHOICES Group 2 or CHOICES Group 3 benefits or CEA services provided as an alternative to covered CHOICES Group 2 or CHOICES Group 3 benefits that were reimbursed by the MCO for that month. The amount of Patient Liability collected by the MCO cannot exceed the cost of CHOICES Group 2 or CHOICES Group 3 benefits (or CEA services provided as an alternative to CHOICES Group 2 or CHOICES Group 3 benefits) reimbursed by the MCO for that month.

(f) A CHOICES provider, including an MCO, may decline to continue to provide ~~LTC services~~ LTSS to a CHOICES Member who fails to pay his Patient Liability. If other Contract Providers or the other TennCare MCO(s) operating in the Grand Division are unwilling to provide ~~LTC services~~ LTSS to a CHOICES Member who has failed to pay his Patient Liability, the Member may be disenrolled from the CHOICES program in accordance with the procedures set out in this Chapter.

(3) TPL for ~~LTC~~ LTSS.

(a) LTC insurance policies are considered TPL and ~~are treated like all other TPL policies, as described in Rule 1200-13-01-.04~~ the Bureau is subrogated to all rights of recovery.

(b) Applicants for the CHOICES program who have LTC insurance policies must report these policies to DHS upon enrollment in the CHOICES program. Applicants may be subject to criminal prosecution for knowingly providing incorrect information.

(c) Obligations of CHOICES Members receiving NF or CBRA services (other than Companion Care) having insurance that will pay for care in a NF or other residential facility (including cash benefits to the Member for the cost of such services):

1. If the benefits are assignable, the Member must assign them to the NF or residential facility. These benefits will be used to reduce the amounts that the MCO would otherwise be required to pay the NF or the residential facility for ~~LTC services~~ LTSS.

2. If the benefits are not assignable, the Member must provide payment to the NF or the residential facility immediately upon receipt of the benefits. These benefits will be used to reduce the amounts that the MCO would otherwise be required to pay the NF or the residential facility for ~~LTC services~~ LTSS.

(d) Obligations of CHOICES Members receiving non-residential CHOICES HCBS or Companion Care services having insurance that will pay for CHOICES HCBS (including cash benefits to the Member for the cost of such services):

1. If the benefits are assignable, the Member must assign them to the MCO. These benefits will be used to reduce the amounts that the MCO would otherwise be required to pay for CHOICES HCBS for the Member.

2. If the benefits are not assignable, the Member must make payment to the MCO immediately upon receipt of the benefits. These benefits will be used to reduce the amounts that the MCO would otherwise be required to pay for CHOICES HCBS for the Member.

~~(e) TPL payments do not reduce the amount of Patient Liability a Member is obligated to contribute toward the cost of LTC Services.~~

(e) TPL payments do not reduce the amount of Patient Liability an Enrollee is obligated to contribute toward the cost of LTSS, except in instances where the total cost of LTSS for the month is less than the combined total of TPL payments and the member's Patient Liability amount, in which case, TPL shall be collected first. The NF shall then collect Patient Liability up to the total cost of LTSS provided for the month.

(f) If benefits received by the policyholder are not paid to the facility or MCO, as applicable, such benefits shall be considered income, and may render the person ineligible for TennCare (including ~~LTC~~ LTSS) benefits.

(4) Estate Recovery. Persons enrolled in TennCare ~~LTC~~ LTSS programs are subject to the requirements of the FERP as set forth under Section 1917(b) of the Social Security Act, 42 U.S.C.A. § 1396p(b).

(a) The State is required to seek adjustment or recovery for certain types of medical assistance from the estates of individuals as follows:

1. For persons age fifty-five (55) and older, the State is obligated to seek adjustment or recovery for NF (including ICF/IID~~MR~~) services, HCBS, and related hospital and prescription drug services.

2. For permanently institutionalized persons under age fifty-five (55), the State is obligated to seek adjustment or recovery for the institutional services.

(b) Estate recovery shall apply to the estates of individuals under age fifty-five (55) who are inpatients in a NF, ICF/IID~~MR~~, or other medical institution and who cannot reasonably be expected to be discharged home.

(c) A determination that an individual cannot reasonably be expected to be discharged to return home shall be made in accordance with the following.

1. The PAE for LOC that is certified by the physician shall specify whether discharge is expected and the anticipated length of stay in the institution.

2. The following shall be deemed sufficient evidence that a person cannot reasonably be expected to be discharged to return home and is thus permanently institutionalized:

(i) An approved PAE certified by the physician indicating that discharge is not expected; or,

(ii) The continued stay of a resident of a medical institution at the end of a temporary stay predicted by his physician at the time of admission to be no longer than six (6) months in duration.

(d) Written notice of the determination that the individual residing in a medical institution cannot reasonably be expected to be discharged to return home shall be issued to the individual or his Designated Correspondent. The notice shall explain the right to request a reconsideration review. Such request must be submitted in writing to the Bureau, Long-Term ~~Care~~ Services and Supports Division, within thirty (30) days of receipt of the written notice. The reconsideration review shall be conducted as a Commissioner's Administrative Hearing in the manner set out in Rule 1200-13-01-.10~~(6)~~(f)(7).

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

Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for Medicaid Reimbursement of Care in Nursing Facilities as amended by Emergency Rule 1200-13-01-.10 Medical (Level of Care) Eligibility Criteria for Medicaid Reimbursement of Care in Nursing Facilities is deleted in its entirety and replaced with Rulemaking Hearing Rule 1200-13-01-.10 which shall read as follows:

1200-13-01-.10 MEDICAL (LEVEL OF CARE) ELIGIBILITY CRITERIA FOR ~~MEDICAID~~ TENNCARE REIMBURSEMENT OF CARE IN NURSING FACILITIES, CHOICES HCBS AND PACE.

(1) Definitions. See Rule 1200-13-01-.02.

(2) PreAdmission Evaluations and Discharge/Transfer/Hospice Forms.

(a) A PAE is required in the following circumstances:

1. When a ~~Medicaid~~ TennCare Eligible is admitted to a NF for receipt of ~~Medicaid~~ TennCare-reimbursed NF Services.

2. When a private-paying resident of a NF attains ~~Medicaid~~ TennCare Eligible status.

3. When Medicare reimbursement for SNF services has ended and ~~Medicaid~~ TennCare Level 2 reimbursement for NF services is requested.

4. When a NF Eligible is changed from ~~Medicaid~~ TennCare Level 1 to ~~Medicaid~~ TennCare Level 2 reimbursement, or from ~~Medicaid~~ TennCare Level 1 or Level 2 reimbursement to a Chronic Ventilator or Tracheal Suctioning Enhanced Respiratory Care rate, except as specified in Rule 1200-13-01-.10(5)(f).

5. When a NF Eligible is changed from ~~Medicaid~~ TennCare Level 2 reimbursement or an Enhanced Respiratory Care rate to ~~Medicaid~~ TennCare Level 1 reimbursement, unless the ~~individual~~ person has an approved unexpired Level 1 PAE.

6. When a NF Eligible is changed from an Enhanced Respiratory Care rate to ~~Medicaid~~ TennCare Level 2 reimbursement, unless the ~~individual~~ person has an approved unexpired Level 2 PAE.

7. When a NF Eligible requires continuation of the same LOC beyond the expiration date assigned by the Bureau.

8. When a NF Eligible no longer requires the specific skilled nursing or rehabilitative services for which a Level 2 PAE was approved but requires other ~~Level 2 care in a NF~~ skilled nursing or rehabilitative services for which Level 2 reimbursement may be authorized in a NF.

9. When a Member enrolled in CHOICES Group 1 or Group 2 on or after July 1, 2012, no longer meets NF LOC and wants to enroll in CHOICES Group 3 for HCBS.

10. When a Member enrolled in CHOICES Group 3 (including Interim CHOICES Group 3) on or after July 1, 2012, wants to enroll in CHOICES Group 1 or 2.

(b) NFs are required to complete and submit to the ~~m~~Member's MCO a Discharge/Transfer/Hospice Form any time a Member discharges from the facility or stops receiving NF services in the facility, which shall include but is not limited to the following circumstances:

1. When a CHOICES ~~m~~Member transfers from one ~~Nursing Facility~~ NF to another such facility.

2. When a CHOICES ~~m~~Member discharges to the hospital (even when readmission to the NF is expected following the hospital stay).

3. When a CHOICES ~~m~~Member elects to receive hospice services (even if Medicare will be responsible for payment of the hospice benefit).

4. When a CHOICES ~~m~~Member discharges home, with or without HCBS. In this case, the NF is obligated to notify the MCO before the ~~m~~Member is discharged from the facility and to coordinate with the MCO in discharge planning in order to ensure that any home and community based

services needed by the ~~m~~Member will be available upon discharge, and to avoid a lapse in CHOICES and/or TennCare eligibility.

5. Upon the death of a CHOICES ~~m~~Member.

(c) A PreAdmission Evaluation is not required in the following circumstances:

1. When a ~~Medicaid~~ NF Eligible with an approved unexpired Level 1 ~~PreAdmission Evaluation~~ PAE returns to the ~~Nursing Facility~~ NF after being hospitalized.

2. When a ~~Medicaid~~ NF Eligible with an approved unexpired Level 2 ~~PreAdmission Evaluation~~ PAE returns to the ~~Nursing Facility~~ NF after being hospitalized, if there has been no change in the skilled nursing or rehabilitative service for which the ~~PreAdmission Evaluation~~ PAE was approved.

3. When a ~~Medicaid~~ NF Eligible changes from Level 2 to Level 1 NF reimbursement and has an approved unexpired Level 1 ~~PreAdmission Evaluation~~ PAE.

4. To receive Medicaid co-payment when Medicare is the primary payer of ~~Skilled Nursing Facility~~ SNF care.

5. When a Discharge/Transfer/Hospice Form is appropriate in accordance with (2)(b).

6. For authorization by an MCO of Ventilator Weaning services or short-term payment at the Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention. Medical necessity determinations and authorization of Ventilator Weaning services and short-term payment at the Tracheal Suctioning Enhanced Respiratory Care rate during the post-weaning period will be managed by the ~~Enrollee's~~ person's MCO.

7. When a person will be receiving hospice services in the NF.

(d) If a NF admits or allows continued stay of a TennCare Eligible without an approved PAE, it does so at its own risk and in such event the NF shall give the ~~individual~~ Applicant a plain language written notice, in a format approved by the Bureau, that Medicaid reimbursement will not be paid unless the PAE is approved and if it is not finally approved the ~~individual~~ Applicant can be held financially liable for services provided, including services delivered prior to the effective date of the PAE and enrollment in CHOICES Group 1, unless a third party is liable.

(e) Except as specified in 1200-13-01-.10(2)(e)2., an approved ~~PreAmission Evaluation~~ PAE is valid for ninety (90) calendar days beginning with the PAE Approval Date, unless an earlier expiration date has been established by TennCare (see 1200-13-01-.10(2)(h)). A valid approved ~~PreAmission Evaluation~~ PAE that has not been used within ninety (90) calendar days of the PAE Approval Date must be updated before it can be used. For purposes of Medicaid-reimbursed NF services, such update may be completed only upon submission of a confirmed Medicaid Only Payer Date. To update the PAE, the physician (in the case of NF services) or a Qualified Assessor (in the case of HCBS) shall certify that the ~~a~~Applicant's medical condition on the revised PAE Request Date is consistent with that described in the initial certification and/or assessment and that ~~Nursing Facility~~ NF services, or alternative HCBS, as applicable, are medically necessary for the ~~a~~Applicant. If the ~~individual's~~ Applicant's medical condition has significantly changed such that the previously approved ~~PreAdmission Evaluation~~ PAE does not reasonably reflect the ~~individual's~~ Applicant's current medical condition and functional capabilities, a new ~~PreAdmission Evaluation~~ PAE shall be required.

1. A PAE that is not used within 365 days of the PAE Approval Date shall expire and shall not be updated.

2. A PAE shall also expire upon the person's discharge from a NF, unless:

(i) The person transfers to another NF.

(ii) The person is discharged to the hospital and returns directly to the NF or to another NF.

(iii) The person is discharged home for therapeutic leave and returns to the NF within no more than ten (10) days.

(iv) The person is discharged home and a request to transition to CHOICES Group 2 is submitted by the MCO ~~to~~ and approved by TennCare prior to the person's discharge from the NF.

3. For persons electing hospice:

(i) If a person receiving NF services elects to receive hospice, is disenrolled from CHOICES Group 1, and subsequently withdraws the hospice election and wishes to re-enroll in CHOICES Group 1, the approved PAE may be used so long as:

(I) the person has remained in the NF;

(II) the person's condition has not changed;

(III) no more than thirty (30) days have lapsed since the person's disenrollment from CHOICES Group 1; and

(IV) NF LOC criteria have not changed.

(ii) If the person's condition has changed or if more than thirty (30) days have lapsed since the person's disenrollment from CHOICES Group 1, a new PAE shall be required.

(iii) If the PAE effective date was prior to July 1, 2012, a new PAE must be submitted and the person must qualify based on the new NF LOC criteria in place as of July 1, 2012.

(f) A PAE must include a recent history and physical or current medical records that support the ~~a~~Applicant's functional and/or skilled nursing or rehabilitative needs, as reflected in the PAE. A history and physical performed within 365 calendar days of the PAE Request Date may be used if the ~~patient's~~ Applicant's condition has not significantly changed. Medical records (progress notes, office records, discharge summaries, etc.) may be used to supplement a history and physical and provide current medical information if changes have occurred since the history and physical was performed, or may be used in lieu of a history and physical, so long as the records provide medical evidence sufficient to support the functional and/or skilled or rehabilitative needs reflected in the PAE.

(g) A PAE must be certified as follows:

1. Physician certification shall be required for reimbursement of NF services and enrollment into CHOICES Group 1. Consistent with requirements pertaining to certification of the need for SNF care set forth at 42 CFR § 424.20 and in Section 3108 of the Affordable Care Act, certification of the need for NF care may be performed by a nurse practitioner, ~~or~~ clinical nurse specialist, or physician assistant, ~~neither~~ none of whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a physician.

2. Certification of the level of care assessment by a Qualified Assessor shall be required for all PAEs.

(h) A PAE may be approved by the Bureau for a fixed period of time with an expiration date based on an assessment by the Bureau of the ~~individual's~~ Applicant's medical condition and anticipated continuing need for inpatient nursing care. Notice of appeal rights shall be provided when a PAE is approved with an expiration date.

(i) PASRR.

1. All ~~individuals~~ Applicants who reside in or seek admission to a Medicaid-certified ~~Nursing facility~~ NF must have a PASRR Level I screen for mental illness and mental retardation. The initial Level I screen must be completed prior to admission to the ~~Nursing Facility~~ NF and submitted to TennCare regardless of:

(i) payer source;

(ii) whether the PASRR screening is positive or negative (including specified exemptions); and

(iii) the level of ~~nursing facility~~ NF reimbursement requested.

2. If the Level I screen indicates the need for a PASRR Level II evaluation of need for specialized services for mental illness and/or mental retardation, the ~~individual~~ Applicant must undergo the PASRR Level II evaluation prior to admission to the ~~Nursing Facility~~ NF.

(j) Medicaid payment will not be available for any dates of ~~Nursing Facility~~ NF services rendered prior to the date the PASRR process is complete and the ~~individual~~ Applicant has been determined appropriate for nursing home placement. The PASRR process is complete when either:

1. TennCare has received a negative Level I PASRR screen form and no contradictory information is subsequently received; or

2. For ~~persons~~ Applicants with a positive Level I PASRR screen (as submitted or upon review and determination by the Bureau), the Bureau has received a certified exemption or advance categorical determination signed by the physician; or a determination by DMH and/or DIDD, as applicable, that the ~~person~~ Applicant is appropriate for NF placement. Determination by the Bureau that a Level II PASRR evaluation must be performed may be made:

(i) Upon receipt of a positive PASRR screen from the NF or other submitting entity;

(ii) Based on TennCare review of a negative PASRR screening form or history and physical submitted by a NF or other entity; or

(iii) Upon review of any contradictory information submitted in the PAE application or supporting documentation at any time prior to disposition of the PAE.

(k) A NF that has entered into a provider agreement with a TennCare MCO shall assist a NF resident or ~~a~~Applicant as follows:

1. The ~~Nursing Facility~~ NF shall assist a ~~Nursing Facility~~ NF resident or an ~~a~~Applicant for admission in applying for Medicaid eligibility and in applying for Medicaid-reimbursed ~~Nursing Facility~~ NF care. This shall include assistance in properly completing all necessary paperwork and in providing relevant ~~Nursing Facility~~ NF documentation to support the ~~PreAdmission Evaluation~~ PAE. For Applicants not currently eligible for Medicaid, the NF may request assistance from the AAAD in completing the Medicaid application process in order to expedite the eligibility determination by DHS. Reasonable accommodations shall be made for an ~~individual~~ Applicant with disabilities or, alternatively, for a ~~d~~Designated Correspondent with disabilities when assistance is needed with the proper completion and submission of a ~~PreAdmission Evaluation~~ PAE.

2. The ~~Nursing Facility~~ NF shall request a Notice of Disposition or Change from the Department of Human Services upon learning that a resident or ~~a~~Applicant has, or is likely to have, applied for Medicaid eligibility.

(l) The Bureau shall process PAEs independently of determinations of Medicaid eligibility by DHS; however, Medicaid reimbursement for NF care shall not be available until the PASRR process has been completed, and both the PAE and financial eligibility have been approved.

(3) Medicaid Reimbursement.

(a) A NF that has entered into a provider agreement with a TennCare MCO is entitled to receive Medicaid reimbursement for covered services provided to a NF Eligible if:

1. The NF has completed the PASRR process as ~~defined~~ described in 1200-13-01-.10(2)(i) above and pursuant to 1200-13-01-.23.

2. The Bureau has received an approvable PAE for the ~~individual~~ person within ten (10) calendar days of the PAE Request Date or the physician certification date, whichever is earlier. The PAE Approval Date shall not be more than ten (10) days prior to date of submission of an approvable PAE. An approvable PAE is one in which any deficiencies in the submitted application are cured prior to disposition of the PAE.

3. The NF has entered into the TennCare PreAdmission Evaluation System (TPAES) a Medicaid Only Payer Date.

4. The person has been enrolled into CHOICES Group 1.

5. For a retroactive eligibility determination, the Bureau has received a Notice of Disposition or Change and has received an approvable request to update an approved, unexpired PAE within thirty (30) calendar days of the mailing date of the Notice of Disposition or Change, so long as the person has remained in a NF since the PAE was completed (except for short-term hospitalization). The effective date of payment for NF services shall not be earlier than the PAE Approval Date of the original approved, unexpired PAE that has been updated.

6. If the NF participates in the Enrollee's MCO, reimbursement will be made by the MCO to the NF as a Network Provider. If the NF does not participate in the Enrollee's MCO, reimbursement will be made by the MCO to the NF as a non-participating provider, in accordance with Rule 1200-13-01-.05(10).

(b) Any deficiencies in a submitted PAE application must be cured prior to disposition of the PAE to preserve the PAE submission date for payment purposes.

1. Deficiencies cured after the PAE is denied but within thirty (30) days of the original PAE submission date will be processed as a new application, with reconsideration of the earlier denial based on the record as a whole (including both the original denied application and the additional information submitted). If approved, the effective date of PAE approval can be no more than ten (10) days prior to the date of receipt of the information which cured the original deficiencies in the denied PAE. Payment will not be retroactive back to the date the deficient application was received or to the date requested in the deficient application.

2. Once a PAE has been denied, the original denied PAE application must be resubmitted along with any additional information which cures the deficiencies of the original application. Failure to include the original denied application may delay the availability of Medicaid reimbursement for ~~nursing facility~~ NF services.

(c) The earliest date of Medicaid reimbursement for care provided in a ~~Nursing Facility~~ NF shall be the date that all of the following criteria are met:

1. Completion of the PASRR process, as ~~defined~~ described in 1200-13-01-.10(2)(i) above and pursuant to 1200-13-01-.23;

2. The effective date of level of care eligibility as reflected by the PAE Approval Date;

3. The effective date of Medicaid eligibility;

4. The date of admission to the ~~Nursing Facility~~ NF; and

5. The effective date of enrollment into CHOICES Group 1.

(d) PAE Effective Dates ~~P~~pertaining to Advance Determinations for ~~P~~persons ~~N~~not ~~E~~enrolled in TennCare when the PAE is ~~S~~submitted:

1. An Advance ~~d~~Determination by TennCare that an ~~person~~ Applicant not enrolled in TennCare at the time the PAE is submitted cannot be safely supported within the array of services and supports that would be available if the ~~person~~ Applicant were enrolled in CHOICES Group 3, and approval of NF LOC, shall be effective for no more than thirty (30) days, pending a

comprehensive assessment and ~~plan of care~~ POC developed by the MCO Care Coordinator once the ~~person~~ Applicant is eligible for TennCare and enrolled in CHOICES Group 1 or 2.

2. If TennCare determines that an ~~a~~Advance ~~d~~Determination cannot be approved for an ~~a~~Applicant already admitted to a NF who is not enrolled in TennCare at the time the PAE is submitted, but ~~subsequently~~ upon enrollment into CHOICES Group 3 and receipt of comprehensive documentation submitted by the MCO, determines that the ~~a~~Applicant's needs cannot be safely and appropriately met in the community with the array of services and supports available in CHOICES Group 3, enrollment in CHOICES Group 3 will be terminated pursuant to 1200-13-01-.05(5)(b), and NF LOC will be approved. In such case, the effective date of NF LOC and, subject to requirements set forth in TennCare Rule 1200-13-01-.05(4)(a), enrollment into CHOICES Group 1 will be the date that NF LOC would have been effective had an ~~a~~Advance ~~d~~Determination been ~~made~~ approved.

(e) Application of new LOC criteria. The new LOC criteria set forth in 1200-13-01-.10(4) shall be applied to all ~~persons~~ Applicants enrolled into CHOICES on or after July 1, 2012, based on their effective date of enrollment into the CHOICES program.

1. It is the date of enrollment into CHOICES and not the date of PAE submission, approval, or the PAE effective date which determines the LOC criteria that must be applied.

2. TennCare may~~, at its discretion,~~ review a PAE that had been reviewed and approved based on the NF LOC criteria in place as of June 30, 2012, to determine whether an ~~person~~ Applicant who will be enrolled into CHOICES on or after July 1, 2012, meets the new LOC criteria. However, all ~~persons~~ Applicants enrolled into CHOICES with an effective date of enrollment on or after July 1, 2012, shall meet the criteria in place at the time of enrollment, and in accordance with these rules.

(f) A NF that has entered into a provider agreement with a TennCare MCO and that admits a ~~Medicaid~~ TennCare Eligible without completion of the PASRR process~~,~~ and without an approved PAE does so without the assurance of Medicaid reimbursement.

(g) ~~Medicaid~~ TennCare reimbursement will only be made to a ~~Nursing Facility~~ NF on behalf of the ~~Nursing Facility~~ NF Eligible and not directly to the ~~Nursing Facility~~ NF Eligible.

(h) A NF that has entered into a provider agreement with a TennCare MCO shall admit ~~individuals~~ persons on a first come, first served basis, except as otherwise permitted by State and federal laws and regulations.

(4) ~~Criteria for Reimbursement of Medicaid Level 1~~ Level of Care Criteria for Medicaid Level 1 Reimbursement of Care in a Nursing Facility, CHOICES HCBS and PACE.

(a) The NF must have completed the PASRR process, as applicable and as described in 1200-13-01-.10(2)(i) above and pursuant to 1200-13-01-.23.

~~(a) The Nursing Facility must have completed the PASRR process as defined in 1200-13-01-.10(2)(i) above.~~

~~(b) The individual must be determined by DHS to be eligible for Medicaid reimbursement for NF care.~~

(~~c~~b) An ~~individual~~ Applicant must meet both of the following LOC criteria in order to be approved for TennCare-reimbursed care in a NF, CHOICES HCBS or PACE, as applicable:

1. Medical Necessity of Care:

(i) ~~Persons~~ Applicants requesting ~~Medicaid~~ TennCare-reimbursed NF care. Care in a ~~Nursing Facility~~ NF must be expected to improve or ameliorate the ~~individual's~~ Applicant's physical or mental condition, to prevent a deterioration in health status, or to delay progression of a disease or disability, and such care must be ordered and supervised by a physician on an ongoing basis.

(ii) ~~Persons~~ Applicants requesting HCBS in CHOICES or PACE. HCBS must be required in order to allow the ~~person~~ Applicant to continue living safely in the home or community-based setting and to prevent or delay placement in a ~~nursing facility~~ NF, and such HCBS must be specified in an approved plan of care and needed on an ongoing basis.

(I) The need for one-time CHOICES HCBS is not sufficient to meet medical necessity of care for HCBS.

(II) If a ~~m~~Member's ongoing need for assistance with activities of daily living and/or instrumental activities of daily living can be met, as determined through the needs assessment and care planning processes, through the provision of assistance by family members and/or other caregivers, or through the receipt of services available to the ~~m~~Member through community resources (e.g., Meals on Wheels) or other payer sources (e.g., Medicare), the ~~m~~Member does not require HCBS in order to continue living safely in the home and community-based setting and to prevent or delay placement in a ~~nursing facility~~ NF.

2. Need for Inpatient Nursing Care:

(i) ~~Persons requesting care in a Nursing Facility~~ Applicants requesting TennCare-reimbursed NF care.

The ~~individual~~ Applicant must have a physical or mental condition, disability, or impairment that, as a practical matter, requires daily inpatient nursing care. The ~~individual~~ Applicant must be unable to self-perform needed nursing care and must meet one (1) or more of the following criteria on an ongoing basis:

(I) Have a total score of at least nine (9) on the TennCare NF LOC Acuity Scale; or

(II) Meet one or more of the ADL or related criteria specified in 1200-13-01-.10(4)(~~c~~b)(2)(iii) on an ongoing basis and be determined by TennCare to not qualify for enrollment in CHOICES Group 3 (see TennCare Rule 1200-13-01-.05).

(ii) ~~Persons~~ Applicants eligible to receive care in a NF, but requesting HCBS in CHOICES Group 2 or PACE.

The ~~individual~~ Applicant must have a physical or mental condition, disability, or impairment that requires ongoing supervision and/or assistance with activities of daily living in the home or community setting. In the absence of ongoing CHOICES HCBS or PACE, the ~~person~~ Applicant would require and must qualify to receive NF services in order to remain eligible for HCBS. The ~~individual~~ Applicant must be unable to self-perform needed nursing care and must meet one (1) or more of the following criteria on an ongoing basis:

(I) Have a total score of at least nine (9) on the TennCare NF LOC Acuity Scale; or

(II) Meet one (1) or more of the ADL or related criteria specified in 1200-13-01-.10(4)(~~c~~b)(2)(iii) on an ongoing basis and be determined by TennCare to not qualify for enrollment in CHOICES Group 3 (see TennCare Rule 1200-13-01-.05).

(iii) ~~Persons~~ Applicants not eligible to receive care in a NF, but at risk of NF placement and requesting HCBS in CHOICES Group 3, including Interim CHOICES Group 3. The ~~individual~~ Applicant must have a physical or mental condition, disability, or impairment that requires ongoing supervision and/or assistance with activities of daily living in the home or community setting. In the absence of ongoing CHOICES HCBS, the ~~person~~ Applicant would not be able to live safely in the community and would be at risk of NF placement. The following criteria shall reflect the ~~individual's~~ Applicant's capabilities on an ongoing basis and not isolated, exceptional, or infrequent limitations of function in a generally independent ~~individual~~ person who is able to function with minimal supervision or assistance. The Applicant must be unable to self-perform needed nursing care and must

meet one (1) or more of the following criteria on an ongoing basis:

(I) Transfer. The ~~individual~~ Applicant is incapable of transfer to and from bed, chair, or toilet unless physical assistance is provided by others on an ongoing basis (daily or at least four days per week).

(II) Mobility. The ~~individual~~ Applicant requires physical assistance from another person for mobility on an ongoing basis (daily or at least four days per week). Mobility is defined as the ability to walk, using mobility aids such as a walker, crutch, or cane if required, or the ability to use a wheelchair if walking is not feasible. The need for a wheelchair, walker, crutch, cane, or other mobility aid shall not by itself be considered to meet this requirement.

(III) Eating. The ~~individual~~ Applicant requires gastrostomy tube feedings or physical assistance from another person to place food/drink into the mouth (daily or at least four days per week). Food preparation, tray set-up, and assistance in cutting up foods shall not be considered to meet this requirement.

(IV) Toileting. The ~~individual~~ Applicant requires physical assistance from another person to use the toilet or to perform incontinence care, ostomy care, or indwelling catheter care on an ongoing basis (daily or at least four days per week).

(V) Expressive and Receptive Communication. The ~~individual~~ Applicant is incapable of reliably communicating basic needs and wants (e.g., need for assistance with toileting; presence of pain) using verbal or written language; or the ~~individual~~ Applicant is incapable of understanding and following very simple instructions and commands (e.g., how to perform or complete basic activities of daily living such as dressing or bathing) without continual intervention (daily or at least four days per week).

(VI) Orientation. The ~~individual~~ Applicant is disoriented to person (e.g., fails to remember own name, or recognize immediate family members) or is disoriented to place (e.g., does not know residence is a ~~Nursing Facility~~ NF) daily or at least four days per week.

(VII) Medication Administration. The ~~individual~~ Applicant is not mentally or physically capable of self-administering prescribed medications (daily or at least four days per week) despite the availability of limited assistance from another person. Limited assistance includes, but is not limited to, reminding when to take medications, encouragement to take, reading medication labels, opening bottles, handing to ~~individual~~ Applicant, and reassurance of the correct dose.

(VIII) Behavior. The ~~individual~~ Applicant requires persistent intervention (daily or at least four days per week) due to an established and persistent pattern of dementia-related behavioral problems (e.g., aggressive physical behavior, disrobing, or repetitive elopement).

(IX) Skilled Nursing or Rehabilitative Services. The ~~individual~~ Applicant requires daily skilled nursing or rehabilitative services at a greater frequency, duration, or intensity than, for practical purposes, would be provided through a daily home health visit.

(~~d~~c) For continued ~~Medicaid~~ TennCare reimbursement of care in a ~~Nursing Facility~~ NF, ~~an individual~~ Member must continue to be financially eligible for ~~Medicaid~~ TennCare reimbursement ~~for Nursing Facility~~ NF ~~C~~care and must continue to meet NF LOC (including medical necessity of care and the need for inpatient care) in place at the time of enrollment into CHOICES Group 1.

(~~e~~d) A ~~Nursing Facility~~ NF Eligible admitted to a ~~Nursing Facility~~ NF and ~~to~~ enrolled in CHOICES Group 1 prior to July 1, 2012, who continues to meet the LOC criteria in place at the time of enrollment into CHOICES Group 1 shall continue to meet NF LOC for purposes of enrolling in CHOICES Group 2, subject to requirements set forth in 1200-13-01-.05(3) and 1200-13-01-.05(4).

(~~f~~e) A ~~Nursing Facility~~ NF Eligible receiving HCBS in CHOICES Group 2 prior to July 1, 2012, shall be required to meet the NF LOC in place as of July 1, 2012, in order to qualify for Medicaid-reimbursed NF care unless TennCare determines that the ~~person's~~ Member's needs can no longer be safely and cost-effectively met in CHOICES Group 2.

(5) Criteria for Medicaid Level 2 and Enhanced Respiratory Care Reimbursement of Care in a ~~Nursing Facility~~ NF.

(a) The ~~Nursing Facility~~ NF must have completed the PASRR process as ~~defined~~ described in 1200-13-01-.10(2)(i) above and pursuant to 1200-13-01-.23.

~~(b) The individual must be determined by DHS to be eligible for Medicaid reimbursement for NF care.~~

(~~c~~b) An ~~individual~~ Applicant must meet both of the following criteria in order to be approved for Medicaid Level 2 reimbursement of care in a ~~Nursing Facility~~ NF:

1. The ~~individual~~ Applicant must meet NF LOC as defined in 1200-13-01-.10(4) above.

2. Need for Inpatient Skilled Nursing or Rehabilitative Services on a Daily Basis: The ~~individual~~ Applicant must have a physical or mental condition, disability, or impairment that requires skilled nursing or rehabilitative services on a daily basis or skilled rehabilitative services at least five days per week when skilled rehabilitative services constitute the primary basis for the approval of the ~~PreAdmission Evaluation~~ PAE. The ~~individual~~ Applicant must require such services at a greater frequency, duration, or intensity than, for practical purposes, would be provided through a daily home health visit. In addition, the ~~individual~~ Applicant must be mentally or physically unable to perform the needed skilled services or the ~~individual~~ Applicant must require skilled services which, in accordance with accepted medical practice, are not usually and customarily self-performed. For interpretation of this rule, the following shall apply:

(i) Administration of oral medications, ophthalmics, otics, inhalers, subcutaneous injections (e.g., fixed-dose insulin, subtherapeutic heparin, and calcitonin), topicals, suppositories, nebulizer treatments, oxygen administration, shall not, in and of itself, be considered sufficient to meet the requirement of (5)(~~c~~b)2.

(ii) Nursing observation and assessment, in and of itself, shall not be considered sufficient to meet the requirement of (5)(~~c~~b)2. Examples of nursing services for which Level 2 reimbursement might be provided include, but are not limited to, the following:

(I) Gastrostomy tube feeding

(II) Sterile dressings for Stage 3 or 4 pressure sores

(III) Total parenteral nutrition

(IV) Intravenous fluid administration

(V) Nasopharyngeal and tracheostomy suctioning

(VI) Ventilator services

(iii) A skilled rehabilitative service must be expected to improve the ~~individual's~~ Applicant's condition. Restorative and maintenance nursing procedures (e.g., routine range of motion exercises; stand-by assistance during ambulation; applications of splints/braces by nurses and nurses aides) shall not be considered sufficient to fulfill the requirement of (5)(b)2. Factors to be considered in the decision as to whether a rehabilitative service meets, or continues to meet, the requirement of (5)(~~c~~b)2. shall include, but not be limited to, an assessment of the type of therapy and its frequency, the remoteness of the injury or impairment, and the reasonable potential for improvement in the ~~individual's~~ Applicant's functional capabilities or medical condition.

(iv) Effective July 1, 2012, level 2 NF reimbursement for sliding scale insulin may be authorized for an initial period of no more than two (2) weeks for ~~residents~~ Applicants with unstable blood glucose levels that require daily monitoring and administration of sliding scale insulin. Approval of such reimbursement will require a physician's order and supporting documentation including a plan of care for stabilizing the ~~a~~Applicant's blood sugar and transitioning to fixed dosing during the approval period. Additional periods of no more than two (2) weeks per period, not to exceed a maximum total of sixty (60) days, may be authorized upon submission of a new PAE and only with a physician's order and detailed explanation regarding why previous efforts to stabilize and transition to fixed dosing were not successful.

(c) In order to be approved for ~~Medicaid~~ TennCare-reimbursed care in a NF at the Chronic Ventilator rate of reimbursement, an ~~individual~~ Applicant must be ventilator dependent for at least 12 hours each day with an invasive patient end of the circuit (i.e., tracheostomy cannula).

(d) In order to be approved by the Bureau for ~~Medicaid~~ TennCare-reimbursed care in a NF at the Tracheal Suctioning rate of reimbursement, an ~~individual~~ Applicant must have a functioning tracheostomy and require suctioning through the tracheostomy, at a minimum, multiple times per eight (8) hour shift. The suctioning must be required to remove excess secretions and/or aspirate from the trachea, which cannot be removed by the ~~patient's~~ Applicant's spontaneous effort. Suctioning of the nasal or oral cavity does not qualify for this higher level of reimbursement. An MCO may authorize, based on medical necessity, short-term payment at the Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention during the post-weaning period.

(e) Determination of medical necessity and authorization for ~~Medicaid~~ TennCare reimbursement of Ventilator Weaning services, or short-term payment at the Tracheal Suctioning Enhanced Respiratory Care rate for a person who has just been weaned from the ventilator, but who still requires short-term intensive respiratory intervention shall be managed by the Enrollee's MCO.

(6) TennCare Nursing Facility Level of Care Acuity Scale.

(a) Effective July 1, 2012, for all new enrollments into CHOICES Groups 1 and 2, level of care (LOC) eligibility for TennCare-reimbursement of NF services shall be based on an assessment of the following measures:

1. The ~~a~~Applicant's need for assistance with the following Activities of Daily Living (ADLs):

(i) Transfer;

(ii) Mobility;

(iii) Eating; and

(iv) Toileting.

2. The ~~a~~Applicant's level of independence (or deficiency) in the following ADL-related functions:

(i) Communication (expressive and receptive);

(ii) Orientation (to person and place);

(iii) Dementia-related behaviors; and

(iv) Self-administration of medications~~; and~~.

3. The ~~a~~Applicant's need for certain skilled and/or rehabilitative services.

(b) One or more questions on the PAE for NF LOC shall be used to assess each of the ADL or related measures specified above. There are four (4) possible responses to each question.

(c) Weighted Values.

1. Interpretation of possible responses for all measures except behavior:

   (i) "Always" shall mean that the ~~a~~Applicant is always independent with that ADL or related activity.

   (ii) "Usually" shall mean that the ~~person~~ Applicant is usually independent (requiring assistance fewer than 4 days per week).

   (iii) "Usually not" shall mean that the ~~a~~Applicant is usually not independent (requiring assistance 4 or more days per week).

   (iv) "Never" means that the ~~a~~Applicant is never independent with that ADL or related activity.

2. Interpretation of possible responses for the behavior measure:

   (i) "Always" shall mean that the ~~a~~Applicant always requires intervention for dementia-related behaviors.

   (ii) "Usually" shall mean that the ~~a~~Applicant requires intervention for dementia-related behaviors 4 or more days per week.

   (iii) "Usually not" shall mean that the ~~a~~Applicant requires intervention for dementia-related behaviors, but fewer than 4 days per week.

   (iv) "Never" shall mean that the ~~a~~Applicant does not have dementia-related behaviors that require intervention.

3. The weighted value of each of the potential responses to a question regarding the ADL or related functions specified above when supported by the medical evidence submitted with the PAE shall be as follows:

ADL (or related) question	Condition	Always	Usually	Usually not	Never	Maximum Individual Acuity Score	Maximum Acuity Score for the Measure(s)
Transfer	Highest value of two measures	0	1	3	4	4	
Mobility		0	1	2	3	3	4
Eating		0	1	3	4	4	4
Toileting	Highest value of three questions for the toileting measure	0	0	1	2	2	3
Incontinence care		0	1	2	3	3	
Catheter/ ostomy care		0	1	2	3	3	
Orientation		0	1	3	4	4	4
Expressive communication	Highest value of two questions for the communication measure	0	0	0	1	1	1
Receptive communication		0	0	0	1	1	
Self-administration of medication	First question only; excludes SS insulin	0	0	1	2	2	2
Behavior		3	2	1	0	3	3
Maximum possible ADL (or related) Acuity Score							21

4. The weighted value for each of the skilled and/or rehabilitative services for which level 2 or enhanced respiratory care NF reimbursement could be authorized when determined by TennCare to be needed by the ~~a~~Applicant on a daily basis or at least five days per week for rehabilitative

services, based on the medical evidence submitted with the PAE shall be as follows:

Skilled or rehabilitative service	Maximum Individual Acuity Score
Ventilator	5
Frequent tracheal suctioning	4
New tracheostomy or old tracheostomy requiring suctioning through the tracheostomy multiple times per day at less frequent intervals, i.e., < every 4 hours	3
Total Perenteral Nutrition (TPN)	3
Complex wound care (i.e., infected or dehisced wounds)	3
Wound care for stage 3 or 4 decubitus	2
Peritoneal dialysis	2
Tube feeding, enteral	2
Intravenous fluid administration	1
Injections, sliding scale insulin	1
Injections, other IV, IM	1
Isolation precautions	1
PCA pump	1
Occupational Therapy by OT or OT assistant	1
Physical Therapy by PT or PT assistant	1
Teaching catheter/ostomy care	0
Teaching self-injection	0
Other	0
Maximum Possible Skilled Services Acuity Score	5

5. Conditions.

(i) Maximum Acuity Score for Transfer and Mobility:

(I) Assessment of the need for assistance with transfer and the need for assistance with mobility are separate but overlapping measures of an ~~a~~Applicant's physical independence (or dependence) with movement.

(II) The maximum individual acuity score for transfer shall be four (4).

(III) The maximum individual acuity score for mobility shall be three (3).

(IV) The highest individual acuity score among the transfer and mobility measures shall be the ~~a~~Applicant's total acuity score across both measures.

(V) The maximum acuity score across both of the transfer and mobility measures shall be four (4).

(ii) Maximum Acuity Score for Toileting:

(I) Assessment of the need for assistance with toileting shall include the following:

I. An assessment of the ~~a~~Applicant's need for assistance with toileting;

II. Whether the ~~a~~Applicant is incontinent, and if so, the degree to which the ~~a~~Applicant is independent in incontinence care; and

III. Whether the ~~a~~Applicant requires a catheter and/or ostomy, and if so, the degree

to which the ~~a~~Applicant is independent with catheter and/or ostomy care.

(II) The highest individual acuity score among each of the three (3) toileting questions shall be the ~~a~~Applicant's total acuity score for the toileting measure.

(III) The maximum acuity score for toileting shall be two (2).

(iii) Maximum Acuity Score for Communication:

(I) Assessment of the ~~a~~Applicant's level of independence (or deficiency) with communication shall include an assessment of expressive as well as receptive communication.

(II) The highest individual acuity score across each of the two (2) communication questions shall be the ~~a~~Applicant's total score for the communication measure.

(III) The maximum possible acuity score for communication shall be one (1).

(iv) Maximum Acuity Score for Self-Administration of Medication:

(I) Assessment of the ~~a~~Applicant's level of independence (or deficiency) with self-administration of medications as an ADL-related function shall not take into consideration whether the ~~a~~Applicant requires sliding scale insulin and the ~~a~~Applicant's level of independence in self-administering sliding scale insulin.

(II) Sliding scale insulin shall be considered along with other skilled and/or rehabilitative services for which TennCare could authorize level 2 NF reimbursement .

(III) The maximum individual acuity score for self-administration of medication shall be two (2).

(IV) The maximum individual acuity score for sliding scale insulin shall be one (1).

(v) Maximum Skilled Services Acuity Score

(I) The highest individual acuity score across all of the skilled and/or rehabilitative services shall be the Applicant's total acuity score for skilled and/or rehabilitative services.

(II) The maximum possible acuity score for skilled and/or rehabilitative services shall be five (5).

(d) Maximum Acuity Score

1. The maximum possible acuity score for Activities of Daily Living (ADL) or related deficiencies shall be twenty-one (21).

2. The maximum possible acuity score for skilled and/or rehabilitative services shall be five (5).

3. The maximum possible total NF LOC acuity score shall be twenty-six (26).

(e) Calculating an Applicant's Total Acuity Score

1. Subject to the conditions set forth in 1200-13-01-.10(6)(c)5.~~(5)~~, an ~~a~~Applicant's acuity score for each functional measure (i.e., eating, toileting, orientation, communication, self-administration of medication, or behavior), or in the case of transfer and mobility, the ~~a~~Applicant's acuity score across both measures shall be added in order to determine the ~~a~~Applicant's total ADL or related acuity score (up to a maximum of 21).

2. The ~~a~~Applicant's total ADL or related acuity score shall then be added to the ~~a~~Applicant's skilled services acuity score (up to a maximum of 5) in order to determine the ~~a~~Applicant's total acuity

score (up to a maximum of 26).

(7) PreAdmission Evaluation Denials and Appeal Rights.

(a) A ~~Medicaid~~ TennCare Eligible or the legal representative of the ~~Medicaid~~ TennCare Eligible has the right to appeal the denial of a ~~PreAdmission Evaluation~~ PAE and to request an Administrative Hearing by submitting a written letter of appeal to the Bureau of TennCare, Division of Long-Term ~~Care~~ Services and Supports, within thirty (30) calendar days of receipt of the notice of denial.

(b) If the Bureau denies a PAE, the ~~individual~~ Applicant will be notified in the following manner:

1. A written ~~n~~Notice of denial shall be sent to the ~~individual~~ Applicant and, where applicable, to the ~~d~~Designated ~~c~~Correspondent. A ~~n~~Notice of denial shall also be provided to the ~~Nursing Facility~~ NF. This notice shall advise the ~~individual~~ Applicant of the right to appeal the denial decision within thirty (30) calendar days. The notice shall also advise the ~~individual~~ Applicant of the right to submit within thirty (30) calendar days either the original ~~PreAdmission Evaluation~~ PAE with additional information for review or a new ~~PreAdmission Evaluation~~ PAE. The ~~n~~Notice shall be mailed to the ~~Individual's~~ Applicant's address as it appears upon the ~~PreAdmission Evaluation~~ PAE. If no address appears on the ~~PreAdmission Evaluation~~ PAE and supporting documentation, the ~~n~~Notice will be mailed to the ~~Nursing Facility~~ NF for forwarding to the ~~individual~~ Applicant.

2. If the PAE is resubmitted with additional information for review or if a new PAE is submitted, and the Bureau continues to deny the PAE, another written notice of denial shall be sent as described in (7)(b)1.

(c) The ~~individual~~ Applicant has the right to be represented at the hearing by anyone of his/her choice. The hearing will be conducted according to the provisions of the Tennessee Uniform Administrative Procedures Act.

(d) Reasonable accommodations shall be made for ~~individuals~~ Applicants with disabilities who require assistance with an appeal.

(e) Any ~~n~~Notice required pursuant to this section shall be a plain language written ~~n~~Notice.

(f) When a PAE is approved for a fixed period of time with an Expiration Date determined by the Bureau, the ~~individual~~ Applicant shall be provided with a ~~n~~Notice of appeal rights, including the opportunity to submit an appeal within thirty (30) calendar days of receipt of the notice of denial. Nothing in this section shall preclude the right of the ~~individual~~ Applicant to submit a new PAE establishing medical necessity of care when the Expiration Date has been reached.

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

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Tennessee Dept of Finance and Administration (board/commission/ other authority) on 9/14/12 (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: 07/16/12

Rulemaking Hearing(s) Conducted on: (add more dates). 09/07/12

Date: 9/14/12

Signature: Patti Killingsworth

Name of Officer: Patti Killingsworth

Title of Officer: Chief, Long-Term Services and Support, Bureau of TennCare
Tennessee Department of Finance and Administration

Subscribed and sworn to before me on: 9/14/2012

Notary Public Signature: Patricia A. Thompson

My commission expires on: 9/20/2015

PATRICIA A. THOMPSON STATE OF TENNESSEE NOTARY PUBLIC RUTHERFORD COUNTY

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

Robert E. Cooper, Jr.
Attorney General and Reporter

9-25-12
Date

Department of State Use Only

Filed with the Department of State on: 09/26/12

Effective on: 12/25/12

Tre Hargett
Secretary of State

RECEIVED
2012 SEP 26 AM 11:21
SECRETARY OF STATE
PUBLICATIONS