



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/30/2024 1:33:16 PM

Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Office of the Inspector General

TITLE-SERIES: 71-25

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: Yes

RULE NAME: Behavioral Health Centers Licensure

CITE STATUTORY AUTHORITY: W. Va. Code 27-9-1, 27-17-3

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 08/29/2024 5 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: Jessica Y. Whitmore

ADDRESS: State Capitol Complex

Building 6, Suite 817

EMAIL: jessica.y.whitmore@wv.gov

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

Minimum requirements to be licensed as a Behavioral Health Center.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Changes made pursuant to HB113 passed during the 2024 First Special Session. Addition of appeal of consumer grievances to the Mental Health Ombudsman. Other technical amendments to references were made.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

None

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

None

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2024 Increase/Decrease (use "-")	2025 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Jessica Y Whitmore -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE ~~64~~ 71
LEGISLATIVE RULE
~~DEPARTMENT OF HEALTH~~ OFFICE OF INSPECTOR GENERAL

SERIES ~~11~~ 25
BEHAVIORAL HEALTH CENTERS LICENSURE

~~§64-11-1~~ 71-25-1. General.

1.1. Scope. -- This rule establishes general standards and procedures for the licensure of behavioral health services and supports under the provisions of W. Va. Code §27-1A-7, §27-9-1, *et seq.*, and related federal and state codes.

1.2. Authority. -- W. Va. Code §27-9-1, ~~*et seq.*~~; ~~§27-17-1, *et seq.*~~; ~~§27-1A-4(g); §27-1A-6(6); and §27-1A-7 and §27-17-3.~~

1.3. Filing Date. -- ~~May 1, 2024.~~

1.4. Effective Date. -- ~~May 1, 2024.~~

1.5. Sunset Date -- ~~This rule shall terminate and have no further force or effect on August 1, 2029~~
This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

1.6. Purpose -- These standards are the basis for the licensing and approval of behavioral health centers providing services and supports in the state of West Virginia. Licenses are issued if the standards and applicable rules and regulations are met. The purpose is to protect the health, safety, and wellbeing of consumers receiving care from behavioral health centers; to regulate the behavioral health centers through the formulation, application, and enforcement of licensing requirements; and to ensure the provision of services and supports that are individualized and person-centered.

~~§64-11-2~~ 71-25-2. Application and Enforcement.

2.1. Application. -- The core requirements of sections 1 through 13 of this rule apply to all behavioral health centers, both public and private. Each behavioral health center included in this rule shall comply with core requirements in addition to specialized modules as applicable to each program.

2.2. This rule contains the requirements to obtain a license to operate as a behavioral health center providing behavioral health services and supports for consumers in West Virginia.

2.3. This rule applies equally to profit, nonprofit, publicly-funded, and privately-funded facilities.

2.4. Enforcement. This rule is enforced by the Office of Inspector General ~~housed within the West Virginia Department of Health~~ or his or her designee. ~~For the purposes of this rule, the~~ The Inspector General designates the Director of the Office of Health Facility Licensure and Certification to enforce the provisions of this rule, except where otherwise stated.

2.5. Exemptions. -- The following programs or services are exempt from the requirements of this rule:

2.5.1. A program not providing behavioral health services;

2.5.2. Services provided through a Medicaid self-directed, community-based waiver;

2.5.3. Outpatient services approved by the Centers for Medicare and Medicaid Services (CMS) at federally designated locations;

2.5.4. Hospitals operating within the scope of their license under W. Va. Code ~~§16-5B-1, et seq.~~ 16B-3-1, et seq.;

2.5.5. Individuals or groups of behavioral health or health practitioners functioning within the scope of their license under chapter 30 of the West Virginia Code; and

2.5.6. Specialized Family Care providers providing only services to individuals in Specialized Family Care settings, or Natural Family or Adoptive Family Homes providing Intellectual/Developmental Disabilities Waiver (IDDW) services.

2.6. The ~~Inspector General~~ Director will deem the license of all facilities operating as Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) serving only children that are in compliance with federal certification standards and of residential children's programs functioning within the scope of their license as described in 78CSR3.

2.7. In the event a facility otherwise exempt under subsection 2.5.3. of this rule wants to be licensed as a behavioral health center, that facility must follow the application procedures in this rule and must comply with all provisions of this rule. While licensed, the exemption in subsection 2.5.3. no longer applies.

~~§64-11-3~~ 71-25-3. **Definitions.**

3.1. Abuse. -- The willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain, or mental anguish. Abuse also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial wellbeing. Instances of abuse of all residents, irrespective of any mental or physical condition, cause physical harm, pain, or mental anguish. It includes verbal abuse, sexual abuse, physical abuse, and mental abuse, including abuse facilitated or enabled through the use of technology. *Willful*, as used in this definition of abuse, means the individual must have acted deliberately, not that the individual must have intended to inflict injury or harm.

3.2. Addiction. -- A disease characterized by the individual's pursuing reward, relief, or both, by substance use or other behaviors. Addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one's behaviors and interpersonal relationships; likely to involve cycles of relapse and remission.

3.3. Adult Basic Skills Coaching. -- Coaching or prompting of individuals in their home or group home environment in areas including, but not limited to, money management, safety, housekeeping, personal care, nutrition, cooking, and medication education. This is a supportive service.

3.4. Advocate. -- A person or agency that acts on behalf of a consumer to establish, expand, protect, and enforce his or her human, legal, and civil rights in a consumer's best interest.

3.5. Alteration. -- A change to a provider location that affects the usability of the building or facility or any part thereof. Alterations include, but are not limited to, remodeling, renovation, rehabilitation, reconstruction, historic restoration, changes or rearrangement in structural parts or elements, and changes or rearrangements in the plan configuration of walls and full-height partitions. Normal maintenance, reroofing, painting, wallpapering, carpeting, flooring, or changes to mechanical and electrical systems are not alterations unless they affect the usability of the building or facility. Administrative offices and buildings are not included.

3.6. Assessment. -- An evaluation of a consumer by a qualified person working within his or her scope of practice using skills of examination including appraisal and analysis of data collected to provide care and services.

3.7. Aversive Procedures. -- Restrictive procedures that impose consequences a consumer finds undesirable in a treatment program to decrease inappropriate behaviors. What is undesirable varies with each consumer but generally includes such measures as fines or loss of privileges. Aversive procedures include, but are not limited to, physical and chemical restraint, time-out, and seclusion.

3.8. Behavioral Health Center. -- A provider, entity, or facility that provides behavioral health services, supports, or both.

3.9. Behavioral Health Services. -- A direct service provided as an inpatient, residential or outpatient service to an individual with mental health, addictive, behavioral, or adaptive challenges that is intended to improve or maintain functioning in the community. The service is designed to provide treatment, habilitation, or rehabilitation.

3.10. Behavioral Intervention. -- A written behavior support plan approved by the service planning team, the consumer, and the designated legal representative if applicable. A behavioral intervention must be based on a functional assessment of the targeted behavior and must be specific and measurable.

3.11. Case Management. -- A skilled, non-clinical service that links appropriate services and supports to a specific population. Case management is a collaborative process of assessment, planning, facilitation, evaluation, and advocating of available services to meet a consumer's assessed need promoting consumer safety, quality of care, and cost-effective outcomes. The case manager is a trained professional who coordinates a team process which assesses the needs of the consumer and consumer's family, when appropriate, and arranges, coordinates, monitors, evaluates, and advocates for a package of multiple services in collaboration with appropriate and available provider agencies to meet the specific consumer's complex needs. This service may involve, but is not limited to, assistance with completion of applications and forms; transportation; assistance with making appointments for medical, other care, or both; telephone calls; and other linkage activities to meet the consumer's specific needs. This service involves the preparation of a detailed, person-centered service plan with specific person-centered goals and objectives and designated outcomes and timeframes. Case management is not a behavioral health or supportive service requiring licensure as a behavioral health center if that is the only service being provided.

3.12. Chemical Restraint. -- A medication used to control behavior or to restrict the consumer's freedom of movement when the medication is not a standard treatment for the consumer's medical or

psychological condition. Doses of any medication prescribed at levels beyond that recommended for normal clinical use shall also be evaluated for inclusion as a chemical restraint.

3.13. Chief Executive Officer. -- The individual designated by the governing body to be responsible for the provider's daily operations. The chief executive officer may also be referred to as the provider's president, executive director, or chief administrative officer. The chief executive officer may designate requirements within this rule but will retain the responsibility that the designated requirements are met.

3.14. Civil Rights. -- The rights of personal liberty guaranteed by the Constitutions of the United States and the state of West Virginia, by federal and state law.

3.15. Comprehensive Plans of Services. -- A written description of the behavioral health services and supports provided to the consumer accompanied by a description of the measurable goals of the supports the consumer is receiving. These services may be provided by more than one agency acting in coordination. The comprehensive plan is utilized for consumers receiving both behavioral health services and supports.

3.16. Consumer. -- An individual who receives services, supports, or both, from a provider licensed under this rule.

3.17. Critical Incident. -- The alleged, suspected, or actual occurrence of any of the following involving a consumer:

3.17.1. Abuse;

3.17.2. Neglect;

3.17.3. Death due to any cause;

3.17.4. Attempted suicide;

3.17.5. Behavior that will likely lead to serious injury or significant property damage;

3.17.6. Fire resulting in injury, relocation, or an interruption of services;

3.17.7. Any incident with law enforcement authorities;

3.17.8. Injury that requires hospitalization or results in permanent physical damage;

3.17.9. Life-threatening reaction because of a drug or food;

3.17.10. A serious consequence resulting from an apparent error in medication or dietary administration;

3.17.11. Extended and unauthorized absence of a consumer that exceeds his or her treatment plan provision for community access; or

3.17.12. Removal of a consumer from either residential or program services without the consent of a consumer or his or her legal representative.

3.18. Critical Treatment Juncture. -- The occurrence of an unusual or significant event which may have an impact on the process of treatment. A critical treatment juncture will result in a documented meeting between the provider and the consumer, Designated Legal Representative (~~DLR~~), or both, and may cause a revision of the plan of services.

3.19. Designated Legal Representative (~~DLR~~) or Legal Representative. -- Parent of a minor child, conservator, full or limited legal guardian, health care surrogate, medical power of attorney, power of attorney, or other individual authorized to make certain decisions on behalf of a consumer and operating within the scope of his or her authority.

3.20. Director. -- The Director of the Office of Health Facility Licensure and Certification, or his or her designee.

~~3.20.~~ 3.21. Emergency. -- A situation or set of circumstances which presents immediate risk of death or serious injury to a consumer.

~~3.21.~~ 3.22. Employee. -- All persons who work or provide services at or for the provider. Employees include owners, associates, and contracted agents.

~~3.22.~~ 3.23. Expanded Plan of Service. -- A description of the treatment, habilitation, or rehabilitation goal or goals of the behavioral health services provided to the consumer stated in measurable terms, accompanied by a brief description of any supportive services to be provided. The expanded plan of service is developed at the conclusion of the assessment process and may be preceded by an initial plan of service.

~~3.23.~~ 3.24. Governing Body. -- A clearly identified group of persons or partnership, when applicable, which ensures accountability, exercises authority over, and has responsibility for the provider's operation and approval and review of policies and practices. The provider shall designate the governing body at the time of licensure. If an entity is a corporation with an out-of-state ownership or management structure, the provider shall identify the governing body in conjunction with the Inspector General.

~~3.24.~~ 3.25. Habilitation. -- A direct service to enhance the functional level of individuals by promoting the acquisition of skills or emotional or behavioral self-management abilities that the person did not develop at an appropriate developmental phase.

~~3.25.~~ 3.26. Human Rights Committee. -- A committee or committees whose primary function is to assist the provider in the promotion and protection of a consumer's rights, and to review, approve, and monitor individual programs designed to manage inappropriate behaviors and other programs that are intrusive or involve risks to a consumer's protection and rights.

~~3.26.~~ 3.27. Inappropriate Behavior. -- A behavior that is disruptive or increases the risk of harm to a consumer or individuals in his or her environment; a maladaptive behavior that interferes in the ability of the consumer to lead an integrated life in the community to an optimally independent degree.

~~3.27.~~ 3.28. Incapacitated Adult. -- Any person who, by documented reason of physical, mental, or other infirmity, is unable to independently carry on the daily activities of life necessary to sustaining life and reasonable health.

~~3.28.~~ 3.29. Initial Plan of Service. -- The plan developed during the admissions process that describes the services, supports, or both the consumer is to receive until the assessment process is complete and the expanded plan of service is developed.

3.30. Inspector General. -- The Inspector General of the Office of Inspector General as described in W. Va. Code §16B-2-1, or his or her designee.

~~3.29.~~ 3.31. Interdisciplinary Team. -- A group including a consumer, his or her legal representative, or both, and representatives from the disciplines and services that design a consumer's treatment plan.

~~3.30.~~ 3.32. Linkage. -- Establishment of a relationship between a committed individual and appropriate mental health resources while the consumer is still in the hospital; subsequent case management and provision of services designed to prevent rehospitalization and promote stabilization and maintenance of function.

~~3.31.~~ 3.33. Medication Error. -- Failure to follow the six rights of medication administration, as follows:

~~3.31.1.~~ 3.33.1. Right client;

~~3.31.2.~~ 3.33.2. Right route;

~~3.31.3.~~ 3.33.3. Right drug;

~~3.31.4.~~ 3.33.4. Right dose;

~~3.31.5.~~ 3.33.5. Right time; and

~~3.31.6.~~ 3.33.6. Right documentation.

3.34. Mental Health Ombudsman. -- The West Virginia Office of the Mental Health Ombudsman within the Office of the Inspector General as described in W. Va. Code §16B-12-2.

~~3.32.~~ 3.35. Neglect. -- The failure of the facility, its employees, or service providers to provide goods and services to a resident that are necessary to avoid physical harm, pain, mental anguish, or emotional distress.

~~3.33.~~ 3.36. Non-Critical Incident. -- Any unusual event or injury of unknown origin involving a consumer that needs to be recorded and investigated for risk management or quality improvement purposes but does not meet the definition of abuse, neglect, or critical incident.

3.37. Office of Health Facility Licensure and Certification. -- The West Virginia Office of Health Facility Licensure and Certification within the Office of the Inspector General.

~~3.34.~~ 3.38. Personal Attendant. -- A supportive service in which a provider assists a consumer with the activities of daily living, which may include prompting. The service may assist the individual to maintain his or her skills and abilities but does not carry the expectation of habilitation or rehabilitation as the result of the receipt of the service.

~~3.35.~~ 3.39. Physician Extender. -- A medical professional including an advanced practice registered nurse or a physician assistant functioning within his or her legal scope of practice.

~~3.36.~~ 3.40. Plan of Service. -- A written description of the behavioral health services, supports, or both that the consumer is to receive.

~~3.37.~~ 3.41. Provider. -- An entity, including, but not limited to, staff and individuals employed or contracted to provide consumer services on behalf of the entity, that provides behavioral health services, supportive services, or both under this rule for a licensed behavioral health center location.

~~3.38.~~ 3.42. Rehabilitation. -- A direct service that promotes re-acquisition of skills or emotional or behavioral self-management abilities that the person has lost due to mental illness, traumatic brain injury, institutionalization, or long-term addiction.

~~3.39.~~ 3.43. Respite. -- A supportive service designed to provide temporary substitute care for an individual whose primary care is normally provided by the family of a consumer. The services are to be used on a short-term basis due to the absence of or need for relief of the primary caregiver, consumer, or both. Respite consists of temporary care services and supervision for an individual who cannot provide for all of his or her own needs and may be provided in the consumer's home location, in the community, or in a location owned, rented, or leased by the respite provider.

~~3.40.~~ 3.44. Restraint. -- Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a consumer to move his or her arms, legs, body, or head freely, or a drug or medication that is used as a restriction to manage the consumer's behavior or restrict the consumer's freedom of movement and is not a standard treatment or dosage for the consumer's condition. A restraint does not include devices used to treat a medical condition.

~~3.41.~~ 3.45. Seclusion. -- The involuntary confinement of a consumer alone in a room or area from which the consumer is physically prevented from leaving.

~~3.42.~~ 3.46. Student. -- A student of a community or technical college, college, or university; health services intern; medical student; or medical intern or resident for the purposes of this rule.

~~3.43.~~ 3.47. Supportive Service. -- A service provided exclusively to individuals with intellectual disabilities, developmental disabilities, ongoing mental health or addictive challenged, or traumatic brain injury. This service is designed to assist the individual to live in the community in a manner that is socially inclusive, optimally independent, and self-directed while preserving his or her health, safety, and quality of life. These services are not designed to change behavior or emotional functioning to support the individual in his or her community-based settings. Supportive services may include coaching or prompting of age appropriate living skills.

~~3.44.~~ 3.48. Treatment. -- A direct medical, behavioral, or psychotherapeutic service designed to ameliorate the effects of a mental illness, addiction, or behavioral disorder or sustain the positive effects of interventions.

~~3.45.~~ 3.49. Variance. -- A declaration that compliance with a rule may be accomplished in a manner different from the manner set forth in the rule.

~~3.46.~~ 3.50. Volunteer. An individual who offers to provide assistance and support for consumers without pay. Natural support systems such as friends, neighbors, and family members are not to be considered volunteers.

~~3.47.~~ 3.51. Waiver. -- A declaration that a certain rule is inapplicable in a particular circumstance.

~~§64-11-4~~ 71-25-4. State Administrative Procedures.

4.1. General Licensure Provisions.

4.1.1. Before establishing, operating, maintaining, or advertising within the State of West Virginia as a behavioral health center as defined in this rule, a provider shall first obtain from the ~~Secretary~~ Director a license authorizing the operation.

4.1.2. A license is valid for the provider named and location or locations listed in the application and is not transferable.

4.1.3. The provider shall surrender an invalid license to the ~~Inspector General~~ Director upon written demand.

4.1.4. The provider shall notify the ~~Inspector General~~ Director prior to the sale or merger of the entity if the ownership of a provider changes. The Inspector General will require that a new license be obtained.

4.1.5. The ~~Inspector General~~ Director will make a decision on each complete application within 60 days of its receipt, provided a positive recommendation has been received from the Fire Marshal, and will provide to unsuccessful applicants written reason for the decision.

4.1.6. The ~~Inspector General~~ Director will perform an onsite inspection prior to issuing initial, renewal, amended if applicable, or provisional licenses. Such inspection will be performed within 60 days of receipt of a complete application, provided a positive recommendation has been received from the Fire Marshal.

4.1.7. The ~~Inspector General~~ Director may enter the premises of any practice, office, or facility if the ~~Inspector General~~ Director has reasonable belief that it is being operated or maintained as a behavioral health center without first obtaining a license.

4.1.8. If the owner or person in charge of a licensed behavioral health center or of any other unlicensed practice, office, or facility, which the ~~Inspector General~~ Director has reasonable belief is being operated or maintained as a behavioral health center refuses entry pursuant to this rule, the Director, in consultation with the Inspector General shall petition the Circuit Court of Kanawha County or the county in which the facility is located for an inspection warrant.

4.1.9. If the ~~Inspector General~~ Director finds, based on an inspection, that any person, partnership, association, or corporation is operating as a behavioral health center without a license, the behavioral health center shall apply for a license within 10 days.

4.1.10. A behavioral health center that fails to apply for a license is subject to the penalties established by section 13 of this rule.

4.2. License Application.

4.2.1. The provider shall submit an application for licensure, along with the required fee, when establishing a new location for service provision, relocating an existing program, renewing an expiring license, or a change of ownership occurs. Providers shall submit an application at least 60 days in advance of the need for or expiration of licensure. All applications are available online in the Behavioral Health Center portion of the OHFLAC website at ohflac.wvdhhr.org.

4.2.2. The provider shall notify the ~~Inspector General~~ Director 60 days in advance of the following:

- 4.2.2.a. A change in location of administrative offices;
- 4.2.2.b. A change in location of a behavioral health center service location;
- 4.2.2.c. A change in ownership;
- 4.2.2.d. A significant change in the population served or type of service provided; or
- 4.2.2.e. Termination of operation.

4.2.3. An amended license application shall be submitted to the ~~Inspector General~~ Director for a change in the geographic location of a service or facility, a change in the services to be provided, or a change in the bed capacity of a residential service location.

4.2.4. The provider shall submit all required information at the time of application or the application is invalid.

4.2.5. The application shall be signed by a member of the governing body, the chief executive officer, or both.

4.3. Issuance. If an applicant meets all provisions of this rule, the ~~Inspector General~~ Director shall issue a license in accordance with this section.

4.4. Types of Licenses. -- Following application and review, the ~~Inspector General~~ Director will issue a license in one of three categories:

4.4.1. Initial License. -- The ~~Inspector General~~ Director will issue an initial license to providers establishing a new behavioral health center found to be in compliance with regard to policy, procedure, provider, record keeping, and service environment rules. An initial license shall expire not more than six months from date of issuance and will not be re-issued. After a complete application for a regular license with required fee has been received, the existing initial license shall not expire until the regular license has been issued or denied.

4.4.2. Regular license. -- The ~~Inspector General~~ Director will issue a regular license to providers complying with this rule. It expires not more than two years from the date of issuance. The ~~Inspector General~~ Director may issue a regular license of shorter duration than two years to a provider.

4.4.2.a. A regular license may be amended by the ~~Inspector General~~ Director at any time during the cycle to reflect changes in the behavioral health center's service classification, programs, structure, or population.

4.4.2.b. A valid regular license shall be considered in effect until the ~~Inspector General~~ Director temporarily extends or denies in writing renewal of the license or until the ~~Inspector General~~ Director initiates formal action to terminate or otherwise modify the license and all due process actions have been resolved.

4.4.3. Provisional license. -- The Director, in consultation with the ~~Inspector General~~ may place a behavioral health center on provisional license status if the provider is not in substantial compliance with this rule but does not pose a significant risk to the rights or health and safety of a consumer.

4.4.3.a. Such status shall expire not more than six months from date of issuance and will not be consecutively re-issued unless the provisional recommendation is that of the state fire marshal.

4.4.3.b. If a behavioral health center is issued provisional license status, notification of that provisional status shall be publicly posted in the location of the behavioral health center receiving provisional status for the duration of the provisional status.

4.4.3.c. The ~~Inspector General~~ Director will re-evaluate a behavioral health center operating under a provisional status before or near the end of the provisional period.

4.4.3.d. Once the behavioral health center is deemed to be in substantial compliance with this rule, the provisional status of the behavioral health center will be lifted.

4.4.3.e. If the behavioral health center does not regain substantial compliance with this rule within the provisional period, the license for the behavioral health center will be terminated: *Provided*, That if the review has not yet been completed by the ~~Inspector General~~ Director within the designated time frame, the program or service may continue to operate until such time as the review has been completed and due process options, if any, are pursued to completion.

4.5. Construction and Alteration.

4.5.1. Before new construction begins, a provider shall submit to the ~~Inspector General~~ Director for approval a copy of the site drawings and specifications for the architectural structure and mechanical work.

4.5.2. Before alteration begins, the provider shall consult with the ~~Inspector General~~ Director regarding construction objectives. If the alteration does not affect consumer care or does not have an effect upon areas of a building or buildings in which consumer care is provided, the alteration will not be reviewable.

4.5.3. New construction and alterations shall use the most current Guidelines for Design and Construction of Residential Care Facilities as recognized by the American Institute of Architects, Academy of Architecture for Health with assistance from the U. S. Department of Health and Human Services shall be used as planning and building standards.

4.5.4. The ~~Inspector General~~ Director may require site drawings or other materials depending on the extent and type of alteration, provided that normal maintenance, reroofing, painting, wallpapering, asbestos removal, or changes to mechanical and electrical systems are not alterations unless they affect the usability of the building or facility to provide consumer care.

4.5.5. All altered structures, depending on the extent and type of alterations, and new structures owned or leased by the provider shall conform to the Americans with Disabilities Act (~~ADA~~) as amended.

4.5.6. All plumbing shall meet the requirements of local plumbing codes or, in the absence thereof, the National Plumbing Code and be maintained and repaired in a state to conform with its intended purpose.

4.5.7. The ~~Inspector General~~ Director will provide consultation and technical assistance in obtaining compliance with this rule.

4.6. Inspections and Records.

4.6.1. The provider shall comply with any reasonable requests from the ~~Inspector General~~ Director to have access to the service, staff, consumers, and relevant records of the agency. Consumers, their DLRs designated legal representatives, or both may be interviewed with his or her permission.

4.6.2. The provider may maintain files in an electronic medium.

4.6.3. The provider shall provide upon request all records required by the ~~Inspector General~~ Director to determine compliance with this rule.

4.6.4. Current consumer records necessary to provide care shall be maintained at the location in which the consumer services are provided. Consumer records not necessary to provide care shall be maintained at the location in which the consumer services are provided, or a central administrative office.

4.6.5. The provider shall establish a process for maintaining current, easily accessible consumer records from intake through discharge.

4.6.6. The ~~Inspector General~~ Director may conduct announced and unannounced inspections of all aspects of the provider's operation and premises. A consumer may deny access to his or her place of residence unless it is owned or leased by the provider or unless there is evidence of a clear and immediate danger to the health of a consumer.

4.6.7. A provider shall permit review and, upon request, provide a copy of a consumer's medical records, personnel records, and other relevant records as requested by the ~~Inspector General~~ Director. The ~~Inspector General~~ Director will ensure the confidentiality of such information, including consumer or employee protected health information.

4.6.8. The Director will inspect a licensed behavioral health center 30-to-90 days prior to the expiration of its license.

4.6.9. The ~~Inspector General~~ Director will issue a report within 10 working days of completion of an inspection.

4.6.10. The report may result in a citation. The ~~Inspector General~~ Director will describe the provider's non-compliance with the standard in detail and the provider shall be expected to supply the ~~Inspector General~~ Director with a plan of correction as described in the provisions of this rule.

4.6.11. An ~~ICF/IID~~ Intermediate Care Facilities for Individuals with Intellectual Disabilities for adults, also licensed as a behavioral health center, must submit a renewal application but will be exempt from an on-site renewal inspection only. An ~~ICF/IID~~ Intermediate Care Facilities for Individuals with Intellectual Disabilities will not be exempt from complaint investigations, enforcement, or any other provisions of this rule.

4.7. Complaint Investigation.

4.7.1. Any person may file a complaint with the ~~Inspector General~~ Director alleging violation of applicable laws or rules by a provider. Incidents reported to the ~~Inspector General~~ Director may be considered complaints at the discretion of the ~~Inspector General~~ Director but are not required to be considered complaints. A complaint shall state the nature of the complaint and the provider or behavioral health center by name.

4.7.2. The ~~Inspector General~~ Director may conduct unannounced inspections of behavioral health centers involved in a complaint and any other investigations necessary to determine the validity of a complaint.

4.7.3. At the time of the investigation, the investigator will present state identification and request to speak to the person in charge of the location. The investigator will instruct that person to contact the chief executive officer.

4.7.4. The ~~Inspector General~~ Director will give the provider a written report of the results of the investigation along with specific findings, detailed analysis of licensure regulations implicated, a report of any violations, and a notice describing the provider's due process rights. The written report will be issued by the ~~Secretary~~ Director within 10 working days of completing the investigation. The complaint investigation may result in a citation, recommendation, both, or neither.

4.7.5. The ~~Inspector General~~ Director will inform the complainant that an investigation was conducted and whether it was substantiated. The ~~Inspector General~~ Director will keep the names of a complainant and of any consumer or ~~DLR~~ designated legal representative involved in the complaint or investigation, and any information that could reasonably lead to the identification of the complainant, and any consumer or ~~DLR~~ designated legal representative, confidential, but will disclose the general nature of the complaint to the provider upon determining that a violation has occurred.

4.7.6. If a complaint becomes the subject of a judicial proceeding, nothing in this rule prohibits the disclosure of information that would otherwise be disclosed in judicial proceedings.

4.7.7. The provider shall not discharge or discriminate in any way against any individual or group of individuals who has been a complainant, on whose behalf a complaint has been submitted, or who has participated in an investigation process by reason of that complaint.

4.8. Reports of Investigations and Inspections.

4.8.1. All investigations and inspections will result in a written report by the ~~Inspector General~~ Director, even if no violation has been identified.

4.8.2. The report will specify the areas of non-compliance with the rule it violates and describe the precise data, observation, or interview to support the deficiency.

4.8.3. Information in reports or records is available to the public except:

4.8.3.a. As specified in this section regarding complaint investigations;

4.8.3.b. Information of a personal nature from a consumer or personnel record; and

4.8.3.c. Information required to be kept confidential by state or federal law.

4.8.4. The ~~Inspector General~~ Director will not make a report or complaint public until the provider has the opportunity to review the report, submit a plan of correction, have that plan of correction approved, and obtain an approved plan of correction, if necessary.

4.9. Plans of Correction.

4.9.1. Within 10 working days after receipt of the inspection report, the provider shall submit to the ~~Inspector General~~ Director for approval a written plan to correct all deficiencies that are in violation of this rule and described by citation. Citations being appealed through the identified methods of due process and not involving harm may not require a plan of correction until after due process. The plan shall specify:

4.9.1.a. Action taken or procedures proposed to correct the areas of non-compliance and prevent their reoccurrence;

4.9.1.b. Date of completion of each action taken or to be taken; and

4.9.1.c. Signature of the chief executive officer or his or her designee.

4.9.2. The ~~Inspector General~~ Director will approve, modify, or reject the proposed plan of correction in writing within 10 working days of receipt. The provider shall make modifications to the plan as requested by the ~~Inspector General~~ Director.

4.9.3. The ~~Inspector General~~ Director will state the reasons for rejection or modification of any plan of correction.

4.9.4. The provider shall submit a revised plan of correction within 10 working days whenever the ~~Inspector General~~ Director rejects a plan of correction. If the ~~Inspector General~~ Director cannot approve the second submitted plan of correction, he or she shall supply a directed plan of correction. The final report shall denote that the plan of correction was directed.

4.9.5. The provider shall immediately correct an area of non-compliance that clearly results in an immediate risk to the health or safety of a consumer or other persons.

4.9.6. The ~~Inspector General~~ Director may release a report to the public no less than 10 days after receipt of an approved plan of correction or a directed plan of correction unless the provider has elected to pursue due process appeals and has notified the ~~Secretary~~ Director of the intent to do so. Such report will not be releasable until the completion of the due process appeals have been exhausted by the provider.

4.10. A forensic group home shall not be located within one mile of a residential area; a public or private day care center; or a public or private k-12 school, learning pod, or micro-school. The Director, in consultation with the Inspector General may grant a variance to a forensic group home in existence prior to March 6, 2023, if the forensic group home demonstrates that it has adequate patient population controls and that otherwise meets the requirements set forth in this rule.

4.11. Waivers or Variances -- A provider shall comply with all relevant requirements unless a waiver or variance for a specific requirement has been granted through a prior written agreement. This agreement shall specify the specific requirement to be waived or varied, the duration of the waiver or variance, and the terms under which the waiver or variance is granted.

4.11.1. Waiver or variance of specific requirements will be granted only when the provider has documented and demonstrated that it complies with the intent of the particular requirement in a manner not permitted by the requirement.

4.11.2. The waiver or variance shall contain provisions for a review of the waiver or variance if necessary.

4.11.3. When a provider fails to comply with the waiver or variance agreement, the agreement is subject to immediate cancellation, provided that such cancellation shall allow sufficient time to make alternative arrangements for consumers. The Director, in consultation with the Inspector General will immediately inform the provider in writing of cancellation of a waiver or variance.

4.12. For the purposes of substance use disorder services, if a provider is enrolled to accept West Virginia Medicaid and is authorized to provide behavioral health services in its state, the Office of Health Facility Licensure and Certification may through reciprocity authorize it as a West Virginia Behavioral Health Center under this rule.

~~§64-11-5~~ 71-25-5. Consumer Rights.

5.1. Basic Rights.

5.1.1. A consumer shall have rights including, but not limited to:

5.1.1.a. The right to treatment and services that support a consumer's liberty and result in positive outcomes to the maximum extent possible;

5.1.1.b. The right to an individualized, written treatment plan to be developed promptly after admission; treatment based on the plan; periodic review and reassessment of needs; and appropriate revisions of the plan.

5.1.1.c. The right to treatment and services in the least restrictive, most appropriate, and potentially most effective setting;

5.1.1.d. The right to ongoing informed participation in the treatment plan process;

5.1.1.e. The right to refuse treatment at any time;

5.1.1.f. The right to a legal representative when unable to act on his or her own behalf;

5.1.1.g. The right to be free from involuntary experimentation;

5.1.1.h. The right to freedom from restraint or seclusion. Restraint and seclusion shall only be used in situations where there is imminent danger to the consumer or others and all less restrictive methods of control have been used;

5.1.1.i. The right to a humane treatment environment in which personal dignity and self-esteem are promoted;

5.1.1.j. The right to confidentiality of records, as provided in this rule;

5.1.1.k. The right to access his or her own consumer records in accordance with state law;

5.1.1.l. The right to assert grievances, orally or in writing, with respect to the infringement of all rights, including the right to have all grievances considered in a fair, timely, and impartial procedure. In the event the consumer is not satisfied with the determination by the provider, the consumer may appeal the determination by submitting a copy of the original grievance and determination to the Office of the Mental Health Ombudsman;

5.1.1.m. The right of access to an available advocate in order to understand, exercise, and protect his or her rights;

5.1.1.n. The right to be informed in advance of any charges for services;

5.1.1.o. The right to all available services without discrimination because of race, religion, color, sex, sexual orientation, disability, age, national origin, or marital status;

5.1.1.p. The right to exercise his or her civil rights;

5.1.1.q. The right to referral, as appropriate, to other providers of behavioral health services;

5.1.1.r. The right to be free from physical, verbal, sexual, or psychological abuse or punishment;

5.1.1.s. The right to be free from unnecessary or excessive medication;

5.1.1.t. The right to medication that is not used as punishment, for the convenience of staff, as a substitute for programming, or in quantities that interfere with the treatment program;

5.1.1.u. The right to be free from uncompensated labor, except for consumers in residential facilities who perform housekeeping tasks;

5.1.1.v. The right to be informed orally and in writing, in appropriate language and terms, of the rights described in this section; and

5.1.1.w. A residential consumer shall have:

5.1.1.w.1. The right to be housed with consumers of the same approximate ages, developmental levels, and social needs;

5.1.1.w.2. The right to unimpeded access to his or her attorney or religious advisor;

5.1.1.w.3. The right to constant access to his or her personal possessions unless contraindicated by treatment plan; and

5.1.1.w.4. The right to private communication with others by mail, electronic mail, text messaging, in person, and by telephone.

5.1.2. Rights and personal liberties may be limited by established policies and procedures when the limitation of the right is clinically appropriate and clearly justified in writing.

5.1.3. A consumer's rights and responsibilities shall devolve only to a legal representative as defined in this rule and to the extent that the legal representative's acts are not hostile or adverse to the best interests of a consumer. This provision does not relieve the provider of the responsibility of informing a consumer as required by this rule, to the extent that a consumer is capable of understanding the matter, nor does it in any way deprive a consumer of his or her legal rights granted under state or federal law.

5.2. Violation of Consumer Rights.

5.2.1. A consumer, an employee, or any other individual may make a complaint to the provider. A supervisor shall report to the chief executive officer or designee within 24 hours regarding all violations, or suspected violations, of a consumer's rights, except in the case of physical abuse for which immediate notification shall be made to all appropriate and required state and law enforcement agencies.

5.2.2. The provider must have evidence that all violations, or suspected violations, of a consumer's rights are thoroughly investigated within a reasonable time period not to exceed 14 days. The chief executive officer or designee shall provide a written report to the human rights committee of his findings and of the actions taken to prevent further occurrences. A consumer or consumers shall be identified by case number only.

5.2.3. The provider shall make a notation of the incident and the effect of the incident on a consumer's illness or treatment in a consumer's record.

5.2.4. If the chief executive officer or designee findings and actions on behalf of a consumer regarding a violation of the consumer's rights is unfavorable, insufficient, or not forthcoming within a reasonable time, the consumer, or his or her legal representative, may appeal to the governing body of the provider, the state licensure body, the West Virginia advocate, or other appropriate resource.

5.3. Human Rights Committee.

5.3.1. The provider shall maintain a human rights committee to:

5.3.1.a. Hold meetings and keep written minutes of all meetings, including, at a minimum, the names and titles of all members and guests present and members absent. However, a provider may choose to maintain additional information;

5.3.1.b. Report activities and recommendations, if any, at least annually to the governing body, or a standing committee of the governing body;

5.3.1.c. Review, approve prior to implementation, and monitor individual consumer behavior plans that include aversive procedures, such as restraint and seclusion, for the control of inappropriate behaviors;

5.3.1.d. Review internal and external investigations of complaints and consumer grievances, including alleged abuse, mistreatment, or neglect;

5.3.1.e. Review and approve prior to implementation research activities and monitor them every three months, or when changes are contemplated; and

5.3.1.f. Ensure that aversive procedures are used only with the written consent of a consumer or his or her legal representative.

5.3.2. A provider with fewer than 30 consumers shall have a minimum of three members on the human rights committee, and a provider with more than 30 consumers shall have a minimum of five members.

5.3.3. At least one-third of the committee members shall be consumers, and no more than one-third shall be staff of the provider.

5.3.4. Ensure that the members have training in confidentiality in order to review consumer records.

5.4. Provider and Behavioral Health Center Responsibility. Providers shall develop and implement a code of conduct that includes, but is not limited to, provisions regarding the following:

5.4.1. How informed consent and participation of a consumer in decisions about services, care, and treatment are to be honored and implemented;

5.4.2. That the right of a consumer to refuse participation in clinical studies or other remedies are to be respected and followed; and

5.4.3. Decisions made about care are to be based solely on the assessment and treatment needs, including consideration of the consumer's wants and desires and other clinical documentation of the consumer's health and behavioral health status.

~~§64-11-6~~ 71-25-6. Risk Management and Quality Assurance.

6.1. Insurance and Bonding.

6.1.1. The provider shall purchase or self-fund appropriate types of insurance including as appropriate, but not limited to, general liability, fire and theft, professional liability, officer's or director's liability, and automobile liability for vehicles owned or leased by the provider.

6.1.2. The provider shall ensure that all staff who handle or manage consumer funds are bonded at the provider's expense or that the provider maintains appropriate insurance coverage to cover potential losses unless the aggregate amount of consumer funds is less than \$500.

6.1.3. Parents acting in their legal capacity as conservators for their children or protected adults, even if employed by the provider, are not included in the requirement for bonding.

6.1.4. The provider may elect to self-insure but must guarantee replacement of losses of consumer funds.

6.1.5. All bonding policies shall be adequate to replace the aggregate of consumer funds managed by the provider or if the provider elects to self-insure, there must be evidence of sufficient financial capacity to replace consumer funds.

6.2. Transportation.

6.2.1. A provider that provides transportation in vehicles owned or leased by the provider for use with consumers as part of a service shall have procedures for ensuring:

6.2.1.a. The use of age-appropriate passenger restraint systems and adequate vehicle modifications including lifts;

6.2.1.b. Adequate passenger supervision relative to the ages, genders, behavioral challenges, and disabilities of the consumers being transported;

6.2.1.c. Proper and timely licensure and inspection of the vehicles;

6.2.1.d. First aid kits in each vehicle;

6.2.1.e. Proper and timely maintenance of vehicles;

6.2.1.f. That the number of persons in any vehicle used to transport consumers shall not exceed the number of available safety restraint systems;

6.2.1.g. Sufficient liability insurance;

6.2.1.h. Secure anchoring for wheelchairs; and

6.2.1.i. Annual validation of driver licenses of individuals driving vehicles that transport consumers.

6.2.2. The provider shall maintain evidence that staff or contracted individuals transporting consumers in their own vehicles as part of their duties are properly insured either personally or through the provider's insurance in case of automobile accident, have a valid state inspection sticker, and are

legally registered. No firearm may be present in any vehicle while the vehicle is used to transport a consumer.

6.3. Quality Assurance.

6.3.1. The provider shall have and implement a systems review of the appropriateness and effectiveness of consumer services which includes an analysis of the results of treatment plan reviews and of reports by the human rights committee.

6.3.2. The protection of civil rights for consumers with disabilities is of extreme importance. Special attention and efforts are essential to ensure that a consumer's human and civil rights are promoted, exercised, and protected.

~~§64-11-7~~ 71-25-7. Legal Compliance.

7.1. The provider shall comply with all applicable federal, state, and local laws, rules, and regulations associated with all aspects of service delivery and operations and shall possess all necessary licenses.

7.2. Current licenses or certificates shall be prominently displayed in an area visible to the public.

7.3. The provider shall maintain in the administrative file reports and certifications as applicable regarding:

7.3.1. Certification of occupancy requirements;

7.3.2. Delineation of zoning and building codes;

7.3.3. Compliance with occupational safety and health administration codes;

7.3.4. Records of maintenance and safety inspections performed internally, e.g., by the Safety Committee, Officer, or other; and

7.3.5. Any and all plans of correction or citations for the previous five years.

7.4. Governing Body.

7.4.1. The behavioral health center shall have a governing body that approves and reviews policies and procedures, has input into the provider's mission statement, assists the provider in guiding development, and ensures the accountability of the behavioral health center and provider.

7.4.2. The governing body shall evaluate implementation of policies and procedures.

7.4.3. The governing body shall develop, maintain, and implement a conflicts of interest policy and procedures for managing a conflict and the criteria for determining whether board members have conflicting interests. The conflicts of interest policy shall, at a minimum, require:

7.4.3.a. Those with a conflict, or who think they may have a conflict, to disclose the conflict or potential conflict; and

7.4.3.b. Prohibit interested board members from voting on any matter in which there is a conflict.

7.5. Security of Information and Consumer Records.

7.5.1. The provider shall have policies and procedures regulating access to records of staff and consumers that are in compliance with all federal and state requirements. Regulatory agencies shall be allowed access to relevant service and employment information, clinical records, incident reports, and other documents to fulfill their statutory and regulatory duties.

7.5.2. The provider shall ensure that service records, whether paper or electronic, are made available for inspection. The behavioral health center shall ensure that employment records, whether paper or electronic, are made available for inspection during normal business hours.

7.5.3. The provider shall have procedures to protect service and employment records by reasonable efforts, whether in electronic or paper form, from destruction by fire, water, loss, or other damage and from unauthorized access.

7.5.4. Written procedures shall govern the retention, maintenance, and destruction of consumer records.

7.5.5. At a minimum, the provider shall retain consumer records for a minimum of five years from date of last service and for five years following a child's 18th birthday if service ends prior to that time. Conversion of paper records to an electronic copy and destruction of paper is acceptable.

7.5.6. The provider shall have a policy regarding disposal of records which respects confidentiality and security of consumer information and in compliance with all applicable state and federal laws.

7.5.7. The provider shall have a policy that all computer and data systems owned by the provider will have up to date anti-virus protection and provide protections which safeguard consumer data and privacy. Systems will be consistent with federal and state privacy laws and regulations.

7.5.8. The format of electronically transmitted data shall comply with legal standards and requirements.

7.5.9. Release of consumer information and records.

7.5.9.a. The behavioral health center or provider will release consumer information and records only according to its written policies and procedures and in compliance with all applicable federal and state laws, rules, and regulations.

7.5.9.b. Except as required by law, before releasing information about a consumer, the behavioral health center or provider shall obtain consent from the consumer or his or her legal representative that includes at a minimum the following:

7.5.9.b.1. Specific consumer information to be released;

7.5.9.b.2. The time period for which the consent is valid and in effect;

7.5.9.b.3. The recipient that will receive the consumer information and records; and

7.5.9.b.4. The purpose of the release of consumer information and records.

7.5.9.c. Consumer records shall be released without written consent in the following situations:

7.5.9.c.1. In a proceeding under W. Va. Code §27-5-4 to disclose the results of an involuntary civil commitment;

7.5.9.c.2. In a proceeding under W. Va. Code §27-6A-1, *et seq.*, to disclose the results of an involuntary examination;

7.5.9.c.3. Pursuant to a court order based upon a finding that information in the consumer record is sufficiently relevant to a proceeding before the court to outweigh the importance of maintaining the confidentiality established by this rule;

7.5.9.c.4. To protect against a clear and substantial danger of imminent injury by a consumer to self or another;

7.5.9.c.5. To staff of the behavioral health center for treatment, internal review purposes, internal investigations, or a combination of the foregoing; and

7.5.9.c.6. The ~~Inspector-General~~ Director shall have full access to a consumer's records as needed in administering state and federal requirements.

7.5.10. Consumer Record Maintenance.

7.5.10.a. The provider shall establish a process for maintaining current, easily accessible consumer records from intake through discharge in accordance with applicable federal and state laws, rules, and regulations including the provisions of this rule.

7.5.10.b. The consumer record shall contain information essential to the services or treatment including, but not limited to, the following:

7.5.10.b.1. Consumer identification data;

7.5.10.b.2. Applicable social and medical information;

7.5.10.b.3. A summary of the assessment process;

7.5.10.b.4. A record of all evaluations;

7.5.10.b.5. Treatment plans, treatment strategies, and special treatment procedures;

7.5.10.b.6. Documentation of ongoing services provided;

7.5.10.b.7. Legal representative documents;

7.5.10.b.8. Court orders; and

7.5.10.b.9. A record of any signed and dated physician's or other healthcare provider's order.

7.6. Contractual relationships.

7.6.1. If the provider arranges externally or contractually for the provision of consumer services, the provider shall have a written agreement which specifies:

7.6.1.a. Roles and responsibilities of the provider and the subordinate service provider;

7.6.1.b. A guarantee that the subcontracting provider shall obtain and provide copies of information regarding employees to demonstrate that the employees are in compliance with the regulatory and risk management needs of the provider;

7.6.1.c. Clinical documentation required of the subordinate service provider with time lines for provision of the documentation;

7.6.1.d. Services to be provided;

7.6.1.e. Provision of appropriate liability or malpractice insurance either by the contractor or subordinate provider;

7.6.1.f. A general definition of the consumers to be served; and

7.6.1.g. That the subordinate provider shall adhere to state and federal requirements of confidentiality.

7.6.2. The provider shall maintain a file on each contracted subordinate provider, including:

7.6.2.a. Evidence of appropriate training, licensure, or certification; and

7.6.2.b. Evidence of malpractice or liability insurance as specified in the contract.

~~§64-11-8~~ 71-25-8. **Financial Management.**

8.1. The provider shall have a written budget, approved by the governing body, that shall serve as a plan for managing its financial resources for the fiscal year.

8.2. The provider shall have established financial management policies and procedures that follow generally accepted accounting principles (GAAP).

8.3. Financial accountability for consumer funds. -- A provider that assumes fiduciary responsibility for consumer funds shall have written operational procedures that ensure:

8.3.1. Separate individual accounting of funds with monthly statements to the consumer and his or her ~~DLR~~ designated legal representative, if any. Funds managed on behalf of consumers shall not be commingled with provider funds. Consumer funds may be maintained in one account for all consumer

funds. However, an individual accounting for each consumer must be maintained and one consumer's funds may not be used for the expenses of another consumer; and

8.3.2. Compliance with applicable legislative, judicial, and governmental requirements, including those applying to payment of benefits allotted by the state or federal government.

8.4. The chief executive officer, governing body, or both shall ensure adequate resources to support the provider's services. Sufficient operating funds shall consist of cash, liquid capital, or an irrevocable letter of credit.

8.5. All money earned by a consumer shall be used for the sole benefit of that consumer.

8.6. Providers shall allow a consumer or his or her ~~DLR~~ designated legal representative to use his or her personal funds.

~~§64-11-9~~ 71-25-9. **Management of Human Resources.**

9.1. Deployment and Supervision of Staff.

9.1.1. The provider shall have qualified individuals to deliver the services to which it commits via consumer assessments and treatment plans or treatment strategies based on the consumer's functional level and physical disability. The provider shall have a system of staff supervision that is tailored to the provider's model of service delivery and uses individual or group supervision, or both, on a regularly scheduled basis.

9.1.2. The provider shall identify an individual responsible for overall administration of the program for each site. This individual shall ensure that decisions related to care of the consumer are based on the treatment plan and assessed needs of the consumer for which informed consent has been obtained.

9.1.3. The provider shall develop a process that ensures appropriate supervision of direct service staff. Each staff person on duty shall have access to a supervisory staff person by telephone or face-to-face contact within 15 minutes of an initial attempt at supervisory contact.

9.2. Personnel practices.

9.2.1. Upon employment, the provider shall train employees regarding written policies and procedures pertaining to their employment and job responsibilities.

9.2.2. The provider shall have policies that comply with federal and state statutes, rules, and regulations regarding employment practices.

9.2.3. The provider shall review with the applicant a written job description at the time of the interview and provide a copy of a written job description upon employment and, upon significant changes in job assignment or responsibilities, provide a modified job description.

9.2.4. Staff providing direct care to consumers shall be 18 years of age or older and capable of performing the duties assigned.

9.2.5. All employees, volunteers, and students who will provide direct care shall be subject to the provisions of the West Virginia Clearance for Access: Registry and Employment Screening Act, W. Va. Code §~~16-49-1~~ 16B-15-1, *et seq.*, and ~~69CSR10~~ 71CSR11.

9.2.6. The provider shall have a policy and required training process for all employees regarding mandatory reporting of allegations of consumer abuse or neglect.

9.2.7. The provider shall have a written job description and selection criteria for each position or group of similar positions that includes the position's qualifications and responsibilities, and the title of the position's supervisor.

9.2.8. The provider shall designate a supervisor for each separate service or program. A supervisor may be responsible for more than one program.

9.2.9. The provider shall employ persons who are qualified according to the job description and selection criteria for the positions they occupy. A provider employing any person who does not possess the qualifications noted in the position's job description shall have a written statement justifying the individual's employment.

9.2.10. The provider shall verify the credentials of all employees and contractors providing consumer care, including:

9.2.10.a. Education and training;

9.2.10.b. Relevant experience; and

9.2.10.c. State licensing or certification for their respective disciplines, if any.

9.2.11. If the job description requires professional licensure or certification, but an employee under supervision for licensure or certification is employed in the position, the provider shall demonstrate that:

9.2.11.a. A person with requisite credentials provides supervision to the staff; and

9.2.11.b. The staff is actively working toward licensure or certification.

9.2.11.c. This requirement will not be construed to apply to individuals performing job duties that would not normally require licensure or certification.

9.3. Volunteers.

9.3.1. The provider shall have a policy which specifies the roles and responsibilities that volunteers shall assume.

9.3.2. The provider shall ensure that volunteers receive regular supervision to provide aid, directions, or both for activity and support.

9.3.3. Any documentation provided by volunteers to be placed in a clinical record shall include the date and signature of the volunteer's onsite supervisor prior to being placed in the record.

9.3.4. The provider shall train volunteers concerning the responsibilities of the position and the time commitments required prior to formal assignment.

9.3.5. The provider shall formally train volunteers in confidentiality prior to beginning their duties and shall maintain documentation of the training.

9.4. Students.

9.4.1. Students serving fewer than 30 hours per quarter shall be continually supervised by staff and shall not work alone with consumers. The provider shall have a policy which specifies the roles and responsibilities that students may assume.

9.4.2. Students serving an academic placement of more than 30 hours onsite per three-month quarter may work with consumers independently as defined by provider policy. However, the provider shall ensure that students receive regular documented supervision in order to provide assistance, directions for activity, and support.

Students of this type shall receive training in abuse, neglect, and mandatory reporting.

9.4.3. Any documentation provided by students to be placed in a clinical record shall include the date and signature of the student's onsite supervisor prior to being placed in the record.

9.4.4. The provider shall formally train all students in confidentiality prior to beginning their duties and shall maintain documentation of the training.

9.5. Employee, Volunteer, and Student Records.

9.5.1. The provider shall maintain current records for all employees and for students and volunteers working directly with consumers and spending regularly scheduled time in the provider's or consumer's locations. These records shall contain:

9.5.1.a. Identifying information and emergency contacts;

9.5.1.b. A job description or contract;

9.5.1.c. Evaluation of employee performance as detailed in the provider policy;

9.5.1.d. Documentation of relevant education or experience as required by job description;

9.5.1.e. Documentation of orientation and required training;

9.5.1.f. Documentation that information on the Child Abuse and Neglect Registry created under W. Va. Code §15-13-1 *et seq.* was checked for that employee, student, or volunteer;

9.5.1.g. Documentation relating to performance, including disciplinary actions and termination summaries; and

9.5.1.h. For employees of the provider, the employee record shall also contain the following:

9.5.1.h.1. An application for employment or resume;

9.5.1.h.2. Reference verification; and

9.5.1.h.3. Documentation of education, licensure, or certification.

9.5.2. Each employee shall have a record, stored separately, containing the employee's results of random drug screens if required by provider policy.

9.5.3. The files shall be secured in a confidential manner with limited access.

9.5.4. Students touring, observing, or onsite fewer than 30 hours per three-month quarter are not included in the requirements of this section.

9.6. Disciplinary reviews and termination. -- The provider shall have a policy which delineates procedures governing disciplinary actions and non-voluntary termination of staff.

9.7. Orientation of New Staff.

9.7.1. The provider shall ensure that all new staff receive an orientation within the first 10 days of employment and shall document that orientation in each individual's personnel record. The orientation shall include an introduction to the staff person's primary job responsibilities and requirements, consumer rights, and universal precautions.

9.7.2. Within the first 30 days of employment or initiation, the provider shall also train all new staff in:

9.7.2.a. Its mission, philosophy, and goals;

9.7.2.b. Its services, policies, and procedures pertaining to the employee, contract clinician, student, or volunteer's job responsibilities;

9.7.2.c. An organizational chart that delineates lines of accountability and authority pertaining to the employee, contract clinician, student, or volunteer's job responsibilities;

9.7.2.d. The provider's policies and procedures on consumer confidentiality and disclosure of information, including penalties for violation of the following policies and procedures and an orientation to federal confidentiality requirements as they apply to the provider:

9.7.2.d.1. Training on identification of abuse and neglect and mandatory reporting procedures;

9.7.2.d.2. Appropriate identification and documentation of incidents;

9.7.2.d.3. Sensitivity to differences in cultural norms and values;

9.7.2.d.4. Proper documentation procedures;

9.7.2.d.5. Fire drills and evacuation procedures (if applicable); and

9.7.2.d.6. Procedures regarding medical or other emergencies, including, but not limited to crisis intervention.

9.7.3. Employees providing direct care to consumers shall be trained in the specific care required for the consumers for which they are assigned. This training will be based on the program plan of the consumer and must include cardiopulmonary resuscitation and first aid.

9.7.4. Additionally, except for outpatient clinical staff providing only behavioral health services, program staff with direct care responsibilities in home- or site-based programs shall be trained within 30 days upon:

9.7.4.a. Psychiatric emergency procedures and management including systematic de-escalation;

9.7.4.b. Blood borne pathogens;

9.7.4.c. Infection control; and

9.7.4.d. Emergency care, first aid, cardiopulmonary resuscitation, and Heimlich's maneuver.

9.7.5. Personnel shall be able to demonstrate the skills and techniques necessary for their jobs. Documentation that personnel are qualified to perform their associated functions by virtue of training, experience, or both shall be maintained by the facility.

9.7.6. Until the training is completed, the staff person shall not work unless accompanied at all times by a staff member who is experienced and knowledgeable in these areas.

9.7.7. The provider shall document all training provided to staff.

~~§64-11-10~~ 71-25-10. **Service Environment.**

10.1. Physical Environment:

10.1.1. Water supply:

10.1.1.a. All water systems shall comply with the applicable rules of the Department of Health.

10.1.1.b. All drinking water fountains shall be sanitary and accessible.

10.1.2. Sewage disposal. -- All facilities shall be served by an approved public sewage system or by a sewage disposal system that has been approved by the Secretary according to the design standards and rules of the Department of Health.

10.1.3. Lighting, Ventilation, Heating.

10.1.3.a. By natural or mechanical means, all rooms shall provide adequate heating, illumination, and ventilation.

10.1.3.b. The following shall be prohibited:

10.1.3.b.1. Unvented, fume-producing heating devices; and

10.1.3.b.2. Unprotected open heaters.

10.1.4. Requirements for Group Homes and 24-Hour Residential Treatment Facilities owned, leased, or operated by a Behavioral Health Center.

10.1.4.a. Bedrooms shall be adequately furnished and provide a minimum of 80 square feet of floor space per person for one-person occupancy and a minimum of 60 square feet of floor space per person for two-or-more person occupancy. Bunk beds are not to be used. For infants delivered to a mother participating in a mother/baby program, a variance may be granted to the square footage requirement.

10.1.4.b. Each occupant of a facility shall be provided a permanent, separate bed with a clean, comfortable, covered mattress, clean bedding, clean towels, and other furnishings appropriate to the length of stay and needs of the occupant.

10.1.4.c. Each room shall be arranged in consideration of the occupants' clinical needs.

10.1.4.d. Each bedroom window shall have covering for privacy.

10.1.4.e. Furnishings shall be homelike and personalized.

10.1.4.f. Facilities shall have appropriate storage areas for items such as: foodstuffs, utensils, work materials, cleaning supplies, clothing, linens, medicines, and toxic materials.

10.1.4.g. Poisons and other potentially hazardous items shall be kept in a locked place but may be used by consumers who have documented training to use them.

10.1.4.h. Each facility shall provide a sufficient number, based on applicable standards and proposed consumer census, of accessible, safe, comfortable, and clean lavatories, bathtubs, and showers equipped with hot and cold running water and a mixing faucet to ensure a water temperature not to exceed 110 degrees Fahrenheit.

10.1.4.i. Each facility shall document monthly water temperature with the reading obtained from each mixing faucet.

10.1.4.j. Solid waste storage shall be sufficient to contain all solid waste in a safe and sanitary manner.

10.1.4.k. Solid waste, including garbage and refuse, shall be removed from the premises weekly or more often if necessary;

10.1.4.l. Grounds and structures shall be kept free of insects, rodents, and vermin that stand to pose a threat to the health or safety of consumers or employees by an effective pest control program. Pesticides shall be applied only by an applicator certified by the West Virginia Department of Agriculture or a registered technician operating under the supervision of a certified applicator; and

10.1.4.m. Each facility shall keep weekly temperature logs of all refrigerators and freezers that store consumer food.

10.2. Safety and Environmental Quality.

10.2.1. The provider shall provide services in an environment (buildings, grounds, and equipment) that meets all applicable federal, state, and local health, building, safety, and fire codes unless the location for provision of service is the consumer's natural family home.

10.2.2. All structures and equipment owned, leased, or rented by the provider for use with consumers shall be clean, safe, accessible, and appropriate for the needs of the consumer. All such structures and equipment shall be kept in good repair.

10.2.3. Facilities and buildings owned, leased, or rented by the provider for use with consumers shall be clean, safe, accessible, and appropriate for the needs of the consumer.

10.2.4. The provider shall post by the telephone in all provider-owned or leased direct care and residential service locations emergency telephone numbers for the fire department, poison control hotline, local police, and on-call staff. Capable consumers shall be instructed on how and when to use them.

10.2.5. Buildings owned or leased by the provider shall be in compliance with Title III of the Americans with Disabilities Act unless otherwise exempted. The provider shall develop and implement a plan to address issues of access, i.e., the removal of structural barriers through ramps, widened doorways, and accessible parking; removal of obstructing furniture; widening of toilet stalls; installation of grab bars; and other modifications that are readily achievable within the resources of the provider and based upon the needs of the consumers served.

10.2.6. All buildings owned, leased, or rented by the provider for consumer use shall conform to the current Life Safety Code of the National Fire Protection Association, unless exempted by the State Fire Marshal.

10.2.7. The provider shall have documentation that the facilities owned or leased by the provider and used for services are in substantial compliance with the State Fire Code. That evidence shall be renewed as required by the State Fire Marshal.

10.2.8. The provider shall conduct quarterly fire drills in its residential and daytime group setting locations, some of which shall be held during rest or sleeping periods.

10.2.9. The provider shall check fire extinguishers monthly to ensure they have adequate pounds per square inch and have fire suppression systems reviewed by a qualified professional annually.

10.2.10. The provider shall not maintain any firearms or chemical weapon within the structures of the facility or in a vehicle when the vehicle is used to transport a consumer.

10.2.11. All power-driven equipment used by a facility shall be kept in sage and good repair. The equipment shall be used by consumers only under the supervision of a trained staff member.

10.2.12. The provider shall provide adequate housekeeping, laundry, maintenance, storage, and other administrative support functions required to carry out the provision of behavioral health services and supports. The laundry room shall have separation between the soiled and clean laundry with mechanical ventilation in the soiled area, a clean area large enough for folding linens, and venting to the outside for any electric or gas dryer.

10.2.13. The provider shall demonstrate through infection control, emergency preparedness, and other means that it identifies, monitors, reduces, and eliminates health and safety risks.

10.2.14. The provider shall evaluate the likelihood of exposure to blood borne pathogens for all persons likely to come in contact with blood.

10.3. Food Services.

10.3.1. If food services are provided or if food is managed by the provider in a consumer residence, food shall be stored, prepared, and served in a sanitary manner.

10.3.2. The provider shall conform to the requirements for food service as specified by the ~~Department's~~ Department of Health Legislative Rule, Food Establishments, 64CSR17.

10.3.3. Food services, when provided, shall:

10.3.3.a. Meet or exceed national nutrition standards;

10.3.3.b. Be planned with regularly documented assistance;

10.3.3.c. Provide well balanced meals and snacks; and

10.3.3.d. Be provided in accordance with the consumer's development level, including all modified and special diets.

~~§64-11-11~~ 71-25-11. Compliance with Legal, Health, and Regulatory Requirements.

11.1. Emergency Planning and Response.

11.1.1. The provider shall have written procedures in place for responding to accidents, serious illness, fire, medical emergencies, flood, natural disasters, and other life-threatening situations that:

11.1.1.a. Address the needs of any special population served by the provider;

11.1.1.b. Provide staff-to-consumer ratios for the adequate protection and supervision based on the consumer's assessed needs, treatment plan or treatment strategy, functional level, identified behaviors, and physical limitations.

11.1.1.c. Specify evacuation procedures including an evacuation site, parties to notify, and emergency items to take when evacuating;

11.1.1.d. Describe relocation plans for the behavioral health center or any part thereof, if it becomes necessary; and

11.1.1.e. Specify appropriate responses to medical emergencies.

11.1.2. The provider shall have procedures in place for dealing with consumers or other individuals who threaten violence or harm to themselves or others including staff and other consumers.

11.2. Medication Control and Administration.

11.2.1. Medication shall be prescribed and monitored by a licensed physician, dentist, or physician extender according to their scope of practice and state law. Contracted medical staff functioning on the provider's premises are responsible for complying with provider policies and procedures. The physicians and other staff shall have files containing the materials or information specified in this rule.

11.2.2. The provider shall note changes in a consumer's condition including, but not limited to, adverse reactions as a result of receiving a medication.

11.2.3. The provider shall inform a consumer, and his or her legal representative, about the medication including, but not limited to, the dosage, purpose, possible side effects, effects, of not taking the medication, and about alternate treatments and their effects.

11.2.4. Providers who administer medication using approved medication assistive personnel shall comply with the ~~Department's~~ Office of Inspector General Legislative Rule, Delegation of Medication Administration and Health Maintenance Tasks to Approved Medication Assistive Personnel, ~~64CSR60~~ 71CSR17.

11.2.5. When medication is administered by the provider, the organization shall ensure that there is an individual medication administration record for those consumers who receive medications to include:

11.2.5.a. Medications administered;

11.2.5.b. The date medications were administered;

11.2.5.c. The actual time of administration, which shall be within one hour of the prescribed time;

11.2.5.d. The initials and signature of the individual administering the medication;

11.2.5.e. A record of missed medications and the reason; and

11.2.5.f. Any special instruction as directed by prescriber.

11.2.6. Prescription medications administered by the provider shall be properly labeled and packaged and remain in the original packaging until administration, and include:

- 11.2.6.a. The name of the person served;
- 11.2.6.b. The route of administration;
- 11.2.6.c. The dosage and the name of the medication;
- 11.2.6.d. The name of the prescriber; and
- 11.2.6.e. The expiration date.

11.2.7. The provider shall have written procedures that govern:

11.2.7.a. The safe disposal of discontinued, out-of-date, or unused medications, syringes, medical waste, or medication; and

11.2.7.b. Provision for locked, supervised storage of medications, including that controlled substances be double locked, with access limited to authorized staff. Authorized staff must have the authority to administer medications.

11.2.8. Medication samples are considered to be the property of the provider. Samples shall be stored in a systematic fashion in a locked area with limited access to unauthorized staff or consumers. The provider shall document distribution of sample medications in the consumer medical record.

11.2.9. If a provider both prescribes and administers medications, only licensed nursing staff shall accept verbal orders for changes in medication regimens. These shall be signed by the prescriber within one week.

11.2.10. A registered nurse or a licensed practical nurse working within his or her scope of practice, shall be responsible for:

11.2.10.a. Generating and reviewing monthly medication administration records (MARs) or reconciling them to MARs provided by a duly authorized and qualified pharmacist or pharmacy;

11.2.10.b. Matching physician's or physician extender's orders or prescriptions to the medication administration records;

11.2.10.c. Assisting interdisciplinary teams to develop educational goals for consumers taking regularly prescribed medications and participating in a supervised self-administration protocol as identified in the consumer's plan for services;

11.2.10.d. Instructing staff in dietary or medication administration issues as necessary; and

11.2.10.e. Responding to emergency calls from staff on medical issues.

11.2.11. Medications shall be self-administered under supervision of trained staff under the following conditions:

11.2.11.a. As part of the consumer's plan of need, he or she is taught to identify his or her medications, recognize possible side effects, describe the purpose of the medication, and indicate the time of day and frequency with which he or she is to take the medications;

11.2.11.b. The consumer is assessed by a registered nurse, physician, physician extender, or licensed or supervised psychologist as being cognitively capable of learning these skills;

11.2.11.c. Medication is kept in a secure location with access limited only to staff with capability of medication administration;

11.2.11.d. Staff is fully trained as to the purpose, most common side effects, and dangers of each medication prescribed for consumers in the facility or home; and

11.2.11.e. Staff is trained in emergency procedures for overdose or adverse reactions.

11.2.12. Delivering and monitoring medications in a consumer's place of residence:

11.2.12.a. If a provider delivers medications to a consumer on a regular basis, the provider must:

11.2.12.a.1. Document delivery date, time, person receiving medication, and name and amount of medication delivered;

11.2.12.a.2. Ensure that if there are children or other incapacitated adults in the home, medications are at least initially stored properly in secured containers;

11.2.12.a.3. Provide medications in properly packaged format as required by W. Va. Code §30-5-1, *et seq.*; and

11.2.12.a.4. Develop a system of monitoring the consumer's compliance with consumption of medications that is created with the agreement and participation of the consumer. This system may consist of the consumer logging consumption of his or her own medications. The consumer has the right to refuse participation in a monitoring system. However, the provider may then refuse to deliver medications to the consumer's residence and make alternative arrangements for the provision of medications.

11.2.13. Medical and Psychiatric Emergency Services. The provider shall have written policies and procedures for handling medical and psychiatric emergencies to ensure:

11.2.13.a. Communication with the nearest medical emergency services, hospital, and local police;

11.2.13.b. A 24-hour telephone response system; and

11.2.13.c. An investigation of any incident that results in serious injury or death, a reporting by the provider to the appropriate authorities and the ~~Secretary~~ Director, and a written report of the investigation.

11.2.14. Emergency Medical and Psychiatric Services in Group Homes and Residential Treatment Facilities.

11.2.14.a. The provider shall respond to a consumer's needs 24 hours a day, seven days a week, including providing appropriate triage for a consumer who poses a danger to himself, herself, or others.

11.2.14.b. The provider shall provide onsite staff with immediate access to relevant information in a consumer's record in case of an emergency.

11.2.14.c. Written policies shall be developed and implemented for the treatment, referral, and follow-up of a consumer who attempts or threatens suicide, homicide, or assault.

~~§64-11-12~~ 71-25-12. Services.

12.1. Service and Program Descriptions.

12.1.1. The provider shall develop a written description of each service or program that is available to the public and potential consumers. The description shall be updated to reflect significant changes in the service or program, and shall include:

12.1.1.a. The goals of the service;

12.1.1.b. The expected outcomes of the service;

12.1.1.c. The nature of the services provided;

12.1.1.d. The usual staffing of the service including general description of credentialing;

12.1.1.e. Eligibility criteria for consumers served by the service;

12.1.1.f. Information on how to access the service; and

12.1.1.g. Restrictions in access to the service, if any.

12.2. Admission.

12.2.1. Admission to a behavioral health center must be based on the assessment conducted in compliance with section 12.3. of this rule.

12.2.2. The assessment must indicate the consumer's need for the service or program offered by the behavioral health center.

12.2.3. The provider shall have an intake process that assesses a consumer using the criteria for admission and only admit a consumer who meets the provider's criteria or is ordered to receive services by the court.

12.2.4. The services and program offered by the behavioral health center must be appropriate for the needs for the consumer.

12.2.5. If, after the consumer is admitted, the behavioral health center is unable to meet his or her needs, the provider shall discharge the consumer and is responsible for referral and placement assistance of the consumer to an alternative level of care or provider.

12.2.6. All consumers being discharged shall have a written discharge summary and reason for discharge entered in the consumer record within 30 days.

12.3. Assessments and Intake Procedures.

12.3.1. Each consumer entering or re-entering a behavioral health center shall have an assessment by an appropriately qualified staff person, as identified by the provider credentialing committee or officer, prior to or within 48 hours of admission.

12.3.2. Assessments from other providers may be acceptable at the provider's discretion, if comprehensive and performed within the past 45 days.

12.3.3. A consumer re-entering a behavioral health center within a 12-month period may receive an abbreviated assessment. These assessments and updates must be available in the consumer record.

12.3.4. The initial assessment shall review the consumer's psychiatric and psychosocial history, history of medical and psychiatric treatment, current mental status, current medical and psychiatric status with regard to health and medications prescribed, evaluation of suicidal or homicidal ideation, screening and assessment for trauma, presenting problems as identified objectively and subjectively, and summarize the consumer's needs and preferences. The initial assessment shall also include recommendations for further evaluation, when appropriate, to identify a consumer's physical, emotional, and behavioral needs; social strengths; and preferences prior to the finalization of the treatment plan or treatment strategy. Intake documentation shall include all relevant preliminary diagnostic, social, medical, and legal information.

12.3.5. An abbreviated assessment shall review the current mental status, presenting problems identified objectively and subjectively, current medical and psychiatric status with regard to health and medications prescribed, and a summary of consumer needs and preferences.

12.3.6. If needed, psychiatric or psychological assessments shall be conducted by an appropriate professional such as a physician, licensed psychologist, or clinician under supervision of a physician or a licensed psychologist.

12.3.7. The consumer's plan of services shall be based on the most recent assessment.

12.3.8. The consumer's assessment must record any medical conditions, allergies, or dietary restrictions. The plan for services must define the provider's responsibility in management of such conditions, if any, while the consumer is on the provider's site or under the provider's supervision. The notification must be posted in the record in a way that is accessible to all staff working with the consumer or there must be documentation that staff has been advised of such conditions.

12.4. Planning for Services.

12.4.1. The provider shall ensure each consumer has a plan of service in a format consistent with the type of service the consumer receives. The plan of service shall be reviewed at 90-day intervals unless other intervals are specified by provider policy and updated or modified as necessary but shall not exceed review dates more than 180 days.

12.4.2. The consumer shall be informed and have the right and the responsibility to participate in the development of the plan of services to the extent that the consumer is willing and medically and behaviorally able.

12.4.3. If the consumer has an advanced psychiatric directive, the provider shall honor the directions provided in the advanced directive.

12.4.4. A consumer, or his or her legal representative, shall sign a written consent prior to initiating treatment and recorded in the consumer record. If written consent is not obtained, the consumer record shall indicate why the written consent was not obtained.

12.5. Participation of the ~~DLR~~ Designated Legal Representative in Planning for Services.

12.5.1. When a consumer has a ~~DLR~~ designated legal representative, the provider must obtain permission from the ~~DLR~~ designated legal representative prior to initiating treatment except in emergent conditions. If emergency treatment is rendered, the ~~DLR~~ designated legal representative must be notified as soon as possible.

12.5.2. If the consumer has a ~~DLR~~ designated legal representative whose scope of responsibility appropriately includes assisting in or directing planning for services for the consumer, the provider is responsible for documenting that the ~~DLR~~ designated legal representative has been informed of all meetings and activities regarding planning. The provider must document a good faith effort to involve the ~~DLR~~ designated legal representative in the planning and review processes. The ~~DLR~~ designated legal representative is entitled to participate in the manner he or she chooses, including by telephone.

12.5.3. If the provider has documented attempts to involve the ~~DLR~~ designated legal representative in the planning process without success, the provider may continue the current plan of service for up to 30 days past its expiration date while alternative plans are made to meet the needs of the consumer or to obtain ~~DLR~~ designated legal representative permission.

12.6. Initial Plan of Service.

12.6.1. When the consumer is admitted to a provider agency, he or she shall have a written, initial plan of projected services and needs and additional assessments recommended at the conclusion of the admission process, not to exceed seven days. The initial assessment shall be entered in the consumer's record within seven days of admission. At a minimum, this plan shall consist of the following if applicable:

12.6.1.a. Description of any further assessments or referrals that may need to be performed;

12.6.1.b. A listing of immediate interventions to be provided along with some basic objectives for the interventions;

12.6.1.c. A date for development of an expanded plan of services. The designated date must be appropriate for the planned length of service but at no time will that exceed 30 days from the date of the signing of the initial plan; and

12.6.1.d. The signature of the consumer, ~~DLR~~ designated legal representative, or both; the intake worker; and other persons participating in the development of the initial plan.

12.7. Treatment Plan or Treatment Strategy.

12.7.1. The treatment plan or treatment strategy is developed when a consumer is receiving a variety of services from a single provider provided that if all services are behavioral health services, no expanded plan is required.

12.7.2. The treatment plan or treatment strategy shall be in writing, consider a consumer's needs and preferences, relate directly to the consumer's initial or any subsequent assessments or information regarding the consumer, include all services provided to the consumer by the provider developing the plan or strategy, and consist of the following:

12.7.2.a. Date of development of the plan or strategy;

12.7.2.b. Participants in the development of the plan or strategy;

12.7.2.c. A description of the services to be provided, including known outside services, provided to a consumer and directed primarily toward achievement of the expected outcomes and with what frequency the services shall be provided;

12.7.2.d. A statement or statements of the goal or goals of services in general terms;

12.7.2.e. A listing of specific objectives relating to each goal unless the services are supportive in nature;

12.7.2.f. Specific goals shall improve and maintain the mental health and optimal adaptive functioning of the individual and be based on consumer assessments;

12.7.2.g. The measurable objectives to be used in tracking progress toward achievement of an objective, unless the services to be provided are supportive services; have an expected achievement date; and when appropriate, outcomes for discharge;

12.7.2.h. The techniques, services, or both to be used in achieving the objective unless the services are supportive;

12.7.2.i. Identification of the individuals responsible for implementing the services relating to the statement or statements of objectives; and

12.7.2.j. A date for review of the plan or strategy.

12.7.3. Treatment plans for a consumer with complex needs or for one who has experienced a significant change in functional abilities shall be developed and reviewed by an interdisciplinary team.

12.7.4. The plan or strategy shall be reviewed at least every 90 days unless an alternative timeframe is specified in the plan or strategy with rationale explaining the alternate timeframe but shall not exceed 180 days.

12.7.5. Selected objectives may be reviewed earlier than the scheduled plan review as desired by the consumer or provider.

12.7.6. Plans for supportive services are incorporated into the plan of care or treatment strategy and shall include:

12.7.6.a. Services to be provided;

12.7.6.b. How often;

12.7.6.c. By whom; and

12.7.6.d. The objectives of the support.

12.7.7. Objectives of supportive services may be stated in simple terms and outcomes shall be stated in measurable terms. Maintenance of health, daily living skills, or functionality may be an objective for a supportive service.

12.7.8. Diagnoses shall be:

12.7.8.a. Written in standard language as provided in the American Psychiatric Association's latest edition of the Diagnostic and Statistical Manual of Mental Disorders, the latest edition of the International Classification of Diseases, or the latest edition of the Classification for Mental Retardation of the American Association on Intellectual and Developmental Disabilities (AAIDD); and

12.7.8.b. Based upon accepted professional standards of examinations and factual description of a consumer's symptoms and problems.

12.7.9. When additional evaluations and assessments are completed, recommendations for treatment and training shall be entered in a consumer's record.

12.7.10. The provider shall ensure that:

12.7.10.a. A consumer is involved in treatment planning and service delivery to the extent possible;

12.7.10.b. If a consumer attends a school or day program and a release of information is signed by the consumer or his or her ~~DLR~~ designated legal representative, staff may participate with the appropriate educational or day program personnel in the development of the education component of the treatment plan;

12.7.10.c. The treatment plan provides for the review of drug dosages and types, and explains the rationale for changes or continuation of psychotropic drug regimens; and

12.7.10.d. Signed and dated progress notes or other documentation regarding services provided and outcomes are included in the consumer record.

12.8. Coordination of Service.

12.8.1. If a consumer is receiving a combination of behavioral health or support services from a team of provider agencies, the consumer shall have a comprehensive plan of services. Clear, written procedures outlining each provider's responsibility or responsibilities will be established and made available to staff and be made part of the consumer's record.

12.8.2. All providers participating in the provision of service to the consumer shall be represented in the development of the comprehensive plan, as shall the consumer or ~~DLR~~ designated legal representative as appropriate. Representation shall be documented by signature of the parties involved in the development of the comprehensive plan.

12.8.3. The team must be made aware of any advanced directives made by the consumer or any instruction for care imposed by the ~~DLR~~ designated legal representative. These directives must be included as an addendum to the plan.

12.8.4. Comprehensive plans may be completed by a case management provider who is responsible for tracking the implementation of the plan and organizing the reviews of the plan and subsequent modifications. The case management provider must be identified in the plan.

12.8.5. The comprehensive plan must clarify which provider agency is responsible for each aspect of the plan. Objectives for behavioral health treatment services must be specific and measurable.

12.8.6. It is the responsibility of the case management provider to ensure that each member of the provider team including the consumer or ~~DLR~~ designated legal representative, or both, has a copy of the plan within seven working days of its completion.

12.8.7. The comprehensive planning process shall culminate in an agreed date for review of progress in reaching the objectives described in the plan.

12.9. Reviews of Treatment Plans or Treatment Strategies.

12.9.1. The review shall be documented and shall consist of examination by the team or provider of progress toward achievement of an objective using the measurements described in the plan or in the case of supportive services, an evaluation of achievement of maintenance objectives.

12.9.2. The consumer and ~~DLR~~ designated legal representative shall be present at the scheduled review. If the consumer, ~~DLR~~ designated legal representative, or both are not present, the reason for holding the review in their absence shall be documented and for good cause.

12.9.3. The review shall summarize the amount of treatment or training provided, document progress toward the objectives, indicate problems that impeded progress, and provide a decision to continue the same plan or to modify it. The provider shall modify objectives and goals if the planned interventions have not produced evidence of improvement or maintenance, if such is the stated goal, within an amount of time to be identified in advance by the clinical team.

12.9.4. The goals or objectives of a plan may be modified if desired by the consumer or ~~DLR~~ designated legal representative.

12.9.5. At the conclusion of the review, a date shall be set for the next review. Service and treatment plans shall be reviewed at least every 90 days by the team or provider unless otherwise specific in the plan but shall not exceed 180 days. Revisions to the behavioral health service plan shall be made if necessary or a new plan may be developed.

12.9.6. Written consent by a consumer, or his or her legal representatives, shall be obtained and recorded in the consumer record. If written consent is not obtained, the consumer record shall indicate why the written consent was not obtained.

12.10. Critical Treatment Junctures.

12.10.1. The provider and consumer shall meet to review and if necessary, modify the consumer's treatment or supports services at a critical treatment juncture.

12.10.2. Critical treatment junctures occur when:

12.10.2.a. There is a proposed change in placement including admission, transfer, or discharge;

12.10.2.b. There is ongoing non-compliance with treatment;

12.10.2.c. Significant new symptoms are experienced or major changes in a consumer's condition;

12.10.2.d. There is a significant change in the consumer's environment, functional ability, health status;

12.10.2.e. Funding for the consumer's service is significantly reduced or eliminated;

12.10.2.f. The consumer loses eligibility for the service;

12.10.2.g. There is an increase or decrease in service intensity or frequency;

12.10.2.h. An event occurs that will have a deleterious or other effect on services provided to the consumer or his or her response to services; or

12.10.2.i. The consumer or ~~DLR~~ designated legal representative requests an alteration in the services he or she is receiving.

12.10.3. When a critical treatment juncture occurs:

12.10.3.a. The provider shall identify and document the situation or event and assess the immediate consumer needs;

12.10.3.b. The provider, in conjunction with the consumer, ~~DLR~~ designated legal representative, or both, shall make a determination as to a course of action and shall document the course of action adopted;

12.10.3.c. The provider shall document reasons for delay or lack of need for a full meeting of the team but shall implement the agreed modification of services at the earliest opportunity;

12.10.3.d. If there is disagreement between the provider and consumer as to a course of action, the team will meet at the earliest mutually agreeable time; and

12.10.3.e. When necessary and appropriate, a team meeting will be held including the consumer, ~~DLR~~ designated legal representative, or both. The team will:

12.10.3.e.1. Assess the situation;

12.10.3.e.2. Identify any needed alteration to the treatment or services provided;

12.10.3.e.3. Obtain approval from the consumer, ~~DLR~~ designated legal representative, or both for the modification of services; and

12.10.3.e.4. Set a date for the next review of the plan.

12.10.3.f. The team may decide to review all of the plan of services, or only a segment of the plan of services. Regardless of the extent of the review, it must be documented, and a date identified for the subsequent review of the plan in its entirety, not to exceed 90 days from the last review of the entirety of the plan unless other timeframe reviews are described in the plan, but not to exceed 180 days.

12.10.3.g. The consumer, the ~~DLR~~ designated legal representative, or both shall be provided with a copy of the plan for services and any review documents.

12.10.3.h. If a critical treatment juncture occurs for a consumer who has a comprehensive plan for services, the members of the team must be informed of the situation and participate in a decision regarding the need for the team to meet. Participation in this decision may be by telephone or other electronic or digital method.

12.11. Discharge Planning.

12.11.1. Each provider shall have a policy and procedure regarding discharge of the consumer from services.

12.11.2. Such policies shall promote an organized transition to another provider, level, or type of care or to full independence from treatment or support. Discharge planning shall follow the treatment plan. A consumer may not be discharged without appropriate appointments and services in place. If a consumer is discharged without appropriate appointments and services in place, justification and efforts made by the behavioral health center must be documented in the consumer record.

12.11.3. Consumers who are being treated at a behavioral health center pursuant to a court order, civil or criminal, may not choose to be discharged from the behavioral health center against medical advice.

12.11.4. In the event that the consumer, or the consumer's legal representative on behalf of the consumer who lacks the capacity to make health care decisions, chooses to discharge from the behavioral health facility against medical advice, the behavioral health center shall:

12.11.4.a. Immediately inform the consumer's health care providers;

12.11.4.b. Educate the consumer, and the consumer's legal representative, if appropriate, regarding the possible consequences for discharging against medical advice;

12.11.4.c. Provide information about and referral to appropriate community resources, if requested by the consumer or consumer's legal representative;

12.11.4.d. Document the consumer's reason for discharging against medical advice, if known; and

12.11.4.e. Document all actions taken and the responses by the consumer, legal representative, or both, in the consumer's medical record.

12.11.5. With permission from the consumer, ~~DLR~~ designated legal representative, or both, the provider is responsible for ensuring that sufficient information is provided to an alternative provider to enable a smooth transition of care.

12.11.6. The provider is responsible for offering transitional services. If the consumer is an incapacitated adult, the transitional services shall be individualized and delivered in a manner that facilitates the individual's movement from one health care setting to another.

12.11.7. A written discharge summary shall be entered in the consumer record within 15 days of discharge including, at a minimum, the following:

12.11.7.a. The reason or reasons for discharge;

12.11.7.b. The consumer's status and condition at the time of discharge;

12.11.7.c. A final evaluation summary of the consumer's progress toward the goals set in the treatment plan;

12.11.7.d. A plan developed in conjunction with the consumer, when available, for care after discharge and follow-up; and

12.11.7.e. The signature of the staff completing the discharge.

12.12. Medication Services.

12.12.1. The provider shall develop and implement a process for the administration, storage, and accountability of all medication including, but not limited to, provisions for a medication administration record procedure and in compliance with all applicable state and federal laws, rules, and regulations, including the provisions of this rule.

12.12.2. The provider shall obtain and record daily temperatures of all refrigerators that are used to store consumer medications.

12.12.3. The process for prescribing and administering medications shall ensure:

12.12.3.a. That all orders for medications are reviewed at least every 90 days by the physician;

12.12.3.b. That psychotropic drugs are ordered as part of the treatment plan and with documentation of the diagnosis and specific behaviors that indicate a need for the medication and the rationale for its choice;

12.12.3.c. That all medications are administered in compliance with the physician's or physician extender's order and state law allowing a one-hour window before and a one-hour window after the physician ordered administration time; and

12.12.3.d. The medication errors, as defined in this rule, and adverse drug reactions are reported immediately in accordance with written procedures including properly recording it in a consumer's record and notifying the physician who prescribed the drug.

12.13. Special Services and Populations.

12.13.1. If a provider provides specialized services to a unique population the provider shall ensure that:

12.13.1.a. The service and clinical model reflects knowledge and use of evidence-based and theory-guided practices;

12.13.1.b. Clinical and professional staff are appropriately trained, certified, or licensed in the area of service provided;

12.13.1.c. Direct care staff are trained to understand issues in clinical treatment of the population and are able to use suitable intervention techniques when necessary and appropriate;

12.13.1.d. The environment and milieu of the treatment location is clinically, structurally, and developmentally appropriate for the population served; and

12.13.1.e. The facility is suitably secure and staff ratios are consistent with the consumer's treatment plan. In cases in which a staff ratio is not specified in the consumer's plan of care, the provider shall assure that sufficient staff is present to enable consumer safety in case of emergency.

12.13.2. Consumer Groupings. Within a behavioral health center, consumer groupings shall occur that:

12.13.2.a. Serve the needs of all consumers including those experiencing a crisis who need an environment that is orderly, peaceful, and respectful for a consumer's privacy; and

12.13.2.b. Provide staff to consumer ratios, as determined in the assessment and treatment plan or treatment strategy, to ensure adequate protection and supervision.

12.13.3. Group Homes and Residential Treatment Facilities.

12.13.3.a. The provider shall have rules for conduct of consumers to follow while in the residence.

12.13.3.b. The consumers shall be offered and encouraged to consume foods that promote healthful living appropriate to the individual consumer's treatment plan and assessed needs.

12.13.3.c. Onsite staff shall ensure that each consumer receives training and practices good habits in personal care, hygiene, and grooming.

12.13.3.d. Consumers who require 24-hour staffing shall not be left unattended, including during normal sleeping hours.

12.13.3.e. Consumers shall be referred for ongoing mental health services and assisted in keeping appointments and participating in treatment programs. Documentation of referrals shall be kept in the consumer's record.

12.14. Abuse, Neglect, and Critical Incidents.

12.14.1. The provider shall report, investigate, monitor, and remediate consumer-related incidents in a manner consistent with minimum current guidelines, "Reporting and Investigation Guidelines for Incidents Involving a Licensed Behavioral Health Services and Supports Provider," set forth by the Director, in consultation of the Inspector General and made available by the ~~Inspector General~~ Director to providers and the public.

12.14.1.a. These guidelines shall be amended as necessary through a participative process including consultation with providers, consumers, and other stakeholders.

12.14.1.b. The provider's policy regarding abuse and neglect may allow the provider a range of remediation alternatives with the employee depending upon the severity of the incident and the possibility of successful remediation.

12.14.1.c. These guidelines represent a minimum standard of investigation and correction. Third party payers or providers may voluntarily require a more stringent level of correction.

12.14.2. Incidents shall be evaluated by the provider's designated representative and classified as one of the following:

12.14.2.a. An allegation of abuse, neglect, or both;

12.14.2.b. A critical incident; or

12.14.2.c. An incident requiring provider monitoring and correction.

12.15. Abuse and Neglect.

12.15.1. A provider shall immediately report to OHFLAC the neglect, abuse, or suspected neglect or abuse of any consumer who receives services from a provider licensed under the conditions of this rule.

This requirement mandates self-reporting of neglect, abuse, or suspected neglect or abuse by the service provider.

12.15.2. The initial report shall be made to the Centralized Intake for Abuse and Neglect within 24 hours by telephone followed by a written report to the Office of Health Facility Licensure and Certification within 48 hours.

12.15.3. All employees, contractors, and volunteers of a provider are considered to be mandatory reporters as defined in W. Va. Code ~~§9-6-11~~ §9-6-9.

12.15.4. A consumer has the right to report any suspicion of abuse or neglect to civil and criminal authorities in accordance with ~~the Adult Protective Services Act~~ W. Va. Code §9-6-1, et seq., in addition to using the grievance procedure of the provider.

12.16. Critical Incident.

12.16.1. Personnel shall immediately notify a supervisor of any critical incident and clear other consumers from the area.

12.16.2. Unless a consumer is in immediate danger to himself, herself, or others, staff shall implement the least restrictive methods of crisis management. If less restrictive methods are not effective, staff may use progressively more restrictive methods of crisis management until the crisis is resolved or other alternatives are established.

12.16.3. The provider must keep a central file of critical incidents for review by the ~~Inspector~~ General Director upon request.

12.16.4. The file shall contain a description of the incident, actions taken by the provider to mitigate the incident, and, at minimum, a description of systemic corrective action taken by the provider, if any, as a result of the provider investigation utilizing unique, but confidential, consumer identifiers.

12.16.5. The provider shall maintain a system for critical incident reporting and use information from the system to make necessary or appropriate improvements to treatment planning and services.

12.16.6. In the case of a critical incident involving an incapacitated adult, the provider shall follow ~~Department~~ Office of Health Facility Licensure and Certification policy regarding reporting such events to the ~~Inspector~~ General Director.

12.17. Non-critical incidents. -- Non-critical incidents must be documented, reviewed by a supervisory staff person, investigated if necessary, and filed in the central incident file.

12.18. Quality Assurance. —

12.18.1. The provider shall ensure that the central file of reports of abuse, neglect, and critical and non-critical incidents is reviewed, collated by the Continuous Quality Improvement committee or staff person, and reported to the governing body on an annual basis. The file shall be representative of efforts by the provider to utilize information to improve provider policy, procedure, performance, or a combination of the foregoing.

12.18.2. The provider shall develop and implement a systems review of the appropriateness and effectiveness of consumer services which includes, at a minimum, an analysis of the results of treatment plan reviews and, when appropriate, of recommendations and reports made by the human rights committee.

12.19. Injuries of Unknown Source.

12.19.1. An injury shall be considered an "injury of unknown source" when:

12.19.1.a. The source of the injury was not witnessed by any person and the source of the injury could not be explained by the consumer; and

12.19.1.b. The injury raises suspicions of possible abuse or neglect because of the extent of the injury or the location of the injury, e.g., the injury is located in an area not generally vulnerable to trauma; or the number of injuries observed at one particular point in time or the incidence of injuries over time.

12.19.2. Minor occurrences which are not of serious consequence to the individual and do not present as a suspicious or repetitive injury as discussed in subdivision 12.19.1.b. of this rule shall be recorded by the facility staff once they are aware of them and follow-up shall be conducted as indicated by provider policy.

12.19.3. If, however, the injury meets both criteria listed in subsection 12.19.1., the injury or injuries must be reported and investigated as required by this rule.

12.19.4. For injuries that do not rise to the level of reportable "injuries of unknown source," the provider shall follow its policies and procedures for monitoring and trending such occurrences.

12.20. Management of Continued Inappropriate Behavior.

12.20.1. The provider shall have a policy for management of regularly occurring inappropriate behavior on the part of incapacitated or minor consumers.

12.20.2. When a responsible clinician or the service planning team becomes aware that an incapacitated or minor consumer in a residential service program is consistently displaying an inappropriate behavior, a functional assessment of the behavior shall be performed.

12.20.3. The functional assessment may result in informed environmental alterations in the development of a written plan for intervention.

12.20.4. Only trained staff may be responsible for performing functional assessments of behavior and developing and monitoring plans for intervention.

12.20.5. Implementing staff shall be oriented to and fully trained on all behavior management plans for consumers with whom they are working including, but not limited to, methods of de-escalating volatile situations, using non-physical techniques in such situations, and how to deal appropriately with aggressive or out of control behavior. Training shall include demonstration of the procedures to be utilized.

12.20.6. Behavioral intervention plans shall:

12.20.6.a. Be planned and approved by the service planning team;

12.20.6.b. Be individualized, consumer-centered, and applied consistently in all environments managed by the service team;

12.20.6.c. Be based on a functional assessment of the inappropriate behavior;

12.20.6.d. Utilize positive behavior techniques that focus on replacing inappropriate behaviors with more productive pro-social behaviors;

12.20.6.e. Be based on fundamental principles of behavior;

12.20.6.f. Be data-based and monitored on an ongoing basis;

12.20.6.g. Be amended in a timely fashion if necessary;

12.20.6.h. Include positive programming to teach a consumer adaptive, more effective behavior;

12.20.6.i. Ensure that a consumer does not discipline another consumer; and

12.20.6.j. Shall specify the rationale, behavioral objectives, and methods to be used in treatment, and the data to be collected to assess progress toward objectives.

12.20.7. The following aversive consequences are not to be utilized by providers:

12.20.7.a. The application of painful stimuli to the body in an attempt to terminate behavior or as a penalty for behavior but not including aversive procedures or stimuli, including, but not limited to, corporal punishment or use of electric shock devices;

12.20.7.b. Deprivation of basic human rights;

12.20.7.c. Treatment of a demeaning nature;

12.20.7.d. Noxious or painful stimuli;

12.20.7.e. Deprivation of nutrition or hydration, excluding dietary or fluid restrictions ordered by a physician or physician extender;

12.20.7.f. Behavioral interventions that inflict physical or psychological pain; and

12.20.7.g. Conditions that promote maladaptive behavior.

12.20.8. Restraint techniques shall only be incorporated into a behavioral intervention if it is used as an intervention of last resort and only when the targeted behavior is immediately dangerous to the consumer or others in the environment. Detailed reasons for the use of restraint shall be documented,

along with attempts at the use of the least restrictive intervention that will be effective to protect the consumer, a staff member, or others from harm.

12.20.9. When behavioral intervention or emergency control measures are used, a detailed report shall be written and include, but not limited to, describing the incident and the rationale for the use of the behavioral intervention or emergency control measures.

12.20.10. Behavioral intervention shall be monitored and altered if side effects such as illness or severe physical or emotional stress or damage occur or are likely to occur.

12.21. Emergency Management of Potentially Dangerous Behavior.

12.21.1. The provider shall have in place policies and procedures regarding emergency management of potentially dangerous consumer behavior.

12.21.2. Seclusion is not an intervention permitted in any licensed community-based program.

12.21.3. Staff shall be trained and able to demonstrate competency in systematic de-escalation procedures as part of orientation. Training for direct care staff shall be renewed at intervals determined by provider policy but occur no less than yearly.

12.21.4. The provider must require staff to have education, training, and demonstrated knowledge in regard to the safe application and use of all types of restraints used, including, but not limited to, training in how to recognize and respond to signs of physical and psychological distress.

12.21.5. Staff must have education, training, and demonstrated knowledge based upon the specific needs of consumers being served. Training will consist at a minimum of the following:

12.21.5.a. Techniques to identify staff and consumer behaviors, events, and environmental factors that may trigger potentially dangerous behavior;

12.21.5.b. Use of nonphysical intervention skills;

12.21.5.c. Selection of least restrictive and least intrusive intervention based on individualized assessment; and

12.21.5.d. Safe application and monitoring of restraint as a last resort if provider policy allows restraint as an intervention.

12.21.6. Prior to or without a physician's order, a consumer shall not be placed in a restraint until he or she is either:

12.21.6.a. Examined by an attending physician or other licensed healthcare professional and a discussion is held between a member of the professional staff and available interdisciplinary team members; or

12.21.6.b. A physician or other licensed healthcare professional has ordered by telephone these emergency interventions after a member of the professional healthcare staff has discussed the

situation with the available interdisciplinary team members. In the event, an emergency intervention is required, refer also to subsection 12.21.11. of this rule.

12.21.7. Physical, mechanical, or chemical restraints may be used only as a last resort for the management of dangerous, violent, or self-destructive behavior that is an immediate threat to the consumer's physical safety or the safety of others in the immediate environment.

12.21.7.a. The use of restraints must be in accordance with a written modification to the consumer's treatment plan.

12.21.7.b. The use of restraint must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the consumer and authorized to order restraint by provide policy in accordance with state law. Orders for use of restraint must never be written as a standing order or on an as-needed basis.

12.21.7.c. A restraint does not include devices used to treat a medical condition.

12.21.7.d. All supportive or protective devices shall be assessed by the team for safety and appropriateness at annual intervals or more frequently as determined by provider policy.

12.21.7.e. Restraint may only be used when less intrusive interventions have been exercised and determined, through documentation pursuant to this rule, to be ineffective to protect the consumer or others from harm. No restraint may be utilized for more than a half hour without review of the consumer's condition by a licensed clinician to evaluate the consumer's immediate situation, the consumer's reaction to the intervention, and the consumer's medical and behavioral condition. No restraint order shall be valid for more than three hours. If ordered for longer, the interdisciplinary team shall review a consumer's status and develop a written plan for responding to a consumer's needs.

12.21.7.f. Before writing an order for the use of restraint for the management of violent or self-destructive behavior, a physician, physician extender, or other licensed independent practitioner who is responsible for the care of the consumer and authorized to order restraint by provider policy in accordance with state law must see and assess the consumer.

12.21.7.g. The use of restraint must be implemented in accordance with safe and appropriate techniques.

12.21.7.h. The restraint must be discontinued at the earliest possible time.

12.21.8. Documentation in the consumer's record must include the following:

12.21.8.a. A description of the consumer's behavior and the danger it posed to self or others;

12.21.8.b. A description of the alternatives or other less intrusive interventions that were attempted prior to the restraint;

12.21.8.c. A description of the intervention used, including the duration of the restraint if physical or mechanical or dosage if chemical; and

12.21.8.d. The consumer's response to all the intervention or interventions used.

12.21.9. Provider policy regarding restraints must include a requirement of a debriefing of any restraint used.

12.21.10. If a consumer receiving extended services exhibits a behavior which is immediately dangerous to himself or herself or others at a rate of three or more times in a six-month period, the provider shall convene the clinical team to consider development of a written plan for behavioral intervention.

12.21.11. When a psychiatric emergency exists and less restrictive measures are not effective, the provider may utilize intrusive measures to the least restrictive extent necessary to protect the consumers or others in the immediate environment until the crisis is immediately resolved or the consumer can be transported to a higher level of care.

12.22. Medical and Dental Procedures for Incapacitated Adults and Children with Developmental Disabilities.

12.22.1. Whenever indicated or warranted, a desensitization procedure shall be developed in advance to prepare incapacitated adults and children with developmental disabilities for a medical or dental procedure.

12.22.2. If the desensitization procedure is not successful in easing the consumer's agitation, anxiety or fear, medicinal interventions are to be used in preference to mechanical restraints unless otherwise agreed by the clinical team.

12.22.3. All efforts to prepare and manage a consumer during a medical or dental procedure shall be documented in the consumer's medical record.

12.23. Standards for Respite and Personal Attendant Services.

Staff providing respite and personal attendant services must receive the following training or orientation prior to assuming care of a consumer:

12.23.1. Specific information pertaining to the needs, preferences, and medical issues of the consumer for whom the staff is assuming care;

12.23.2. List of tasks for which the personal attendant or respite provider is responsible, including any unusual circumstances that could reasonably be predicted in advance;

12.23.3. List of emergency contacts including emergency contact numbers for primary caregiver and for staff supervisor;

12.23.4. Training in any specific protocols contained within the consumer's plan for services as appropriate;

12.23.5. Review of mandatory reporting obligations;

12.23.6. Any emergency procedures unique to the consumer and his or her medical or behavioral needs;

12.23.7. Orientation to the consumer's home or other service location; and

12.23.8. Boundary definition regarding the relationship of staff to primary caregiver and other family members, chain of supervisory responsibility, appropriate use of consumer resources such as food or equipment, and other issues as necessary and appropriate.

12.24. Supervision of the respite or personal attendant employee shall be the responsibility of the employing agency with regular input and consultation by the primary caregiver, consumer, or both. The agency shall provide onsite supervision of staff on a regular schedule as described by agency policy with the permission of the consumer, primary caregiver, or both. Supervision activities shall be documented by the agency.

12.25. If the respite or personal attendant service is provided at a location away from the consumer's primary residence, the location must be safe and free from immediate threat of harm to the consumer. The location must consider the needs and preferences of the consumer and his or her primary caregiver.

12.26. The respite or personal attendant provider is responsible for complying with applicable services or conditions outlined in the consumer's plan for services during the time in which the staff person is providing services for the consumer.

12.27. Documentation must include:

12.27.1. Any unusual incidents or events occurring during the period;

12.27.2. A summary of the activities of the consumer during the period;

12.27.3. Any health or behavioral issues which were of significance during the period; and

12.27.4. Any medications including dosages that were taken by the consumer during the period.

12.28. Standards for Residential Services.

12.28.1. The provider is responsible for ensuring that staff receives an orientation to the plan for services for all consumers in the home, to include:

12.28.1.a. Dietary issues as necessary and appropriate;

12.28.1.b. Unique health considerations;

12.28.1.c. Crisis plans or advance psychiatric directives, if any;

12.28.1.d. Training in any specific protocols contained within the consumer's plan for services as appropriate;

12.28.1.e. Common behavioral issues and management; and

12.28.1.f. A description of unique consumer preferences for those unable to express them directly.

12.28.2. In addition, staff shall be provided with:

12.28.2.a. A list of tasks for which the staff member is responsible;

12.28.2.b. A list of emergency contacts including emergency contact number for staff supervisor;

12.28.2.c. A review of mandatory reporting obligations;

12.28.2.d. An orientation to the consumer's home or other service location;

12.28.2.e. A review of boundary definition regarding staff use of consumer resources such as food or equipment; and

12.28.2.f. Immediate, in-home access to relevant information in a consumer's medical record in order to provide safe and appropriate care to consumers.

12.28.3. The provider must ensure that in-home staff has access to 24-hour emergency telephone contacts for supervisory staff and for parents or guardians.

12.28.4. The provider shall ensure that in-home staff has knowledge of mandatory reporting procedures and the reporting number must be easily available in the home.

12.28.5. Staff must be trained in emergency evacuation procedures.

12.28.6. The provider shall ensure availability in the home of commonly needed company policies and procedures for staff reference. The provider shall have a policy which identifies those sections of the provider staff manual that will be available in the homes.

12.28.7. The provider is responsible for training staff to be supportive of the consumer's:

12.28.7.a. Needs and preferences;

12.28.7.b. Behavioral and health management issues; and

12.28.7.c. Privacy.

12.28.8. The provider shall have a process in place to address consideration of appropriate blending of consumer populations regarding gender, developmental age, activity level, and consumer preferences in congregate living situations.

12.28.9. The service environment shall be appropriate to the physical and health needs of consumers and shall be safe from threat of immediate harm for consumers and staff.

12.28.10. The provider is responsible for monitoring and facilitating the consumer's health, including, but not limited to, providing staff coverage, as described in the individual consumer's assessment and treatment plan or treatment strategy, to manage all consumers at the residential facility.

12.28.11. The provider is responsible for linkage and referral to address the consumer's acute medical and psychiatric health concerns.

12.28.12. A referral must be made for basic primary care at least once per year.

12.28.13. Health considerations shall be incorporated into a residential consumer's plan of services and providers shall be responsible for advocating that unmet needs be addressed. The case management agency shall be responsible for advocacy if the consumer has a case manager.

12.28.14. The provider shall assist the consumers in the service environment to develop a homelike atmosphere that addresses the preferences of the individuals residing in the environment, taking into consideration the financial resources of the residents.

12.28.15. The provider shall have a process in place for facilitating choices of activity and home management that respects the needs and preferences of the residents. The provider shall promote consumer choices and control within the household to the degree possible and clinically appropriate.

12.28.16. The provider shall develop and implement policies and procedures for the transfer to an appropriate acute care facility for a consumer who poses an imminent physical danger to himself, herself, or others.

12.28.17. The provider shall develop and maintain a process for communication from one shift of staff to the next that conveys information necessary to conduct business in the home. Additionally, the provider shall supply a method of communicating information regarding consumers from one shift to the next in a confidential manner. Such communication shall include:

12.28.17.a. Any unusual incidents or events occurring during the shift;

12.28.17.b. Any health or behavioral issues which were of significance during the shift; and

12.28.17.c. Any medications that were taken by the consumer(s) during the shift.

12.28.18. If the home is owned or leased by a provider, it must have:

12.28.18.a. Adequate bedroom and living space for the number of consumers living within the home;

12.28.18.b. Private space for storing personal items for each consumer;

12.28.18.c. Adequate heating and cooling;

12.28.18.d. External windows in consumer bedrooms;

12.28.18.e. Adequate number of bathrooms and bathing facilities for the number of consumers residing within the home;

12.28.18.f. Hinged doors in bedroom doorways; and

12.28.18.g. Appropriate access for physically disabled or challenged consumers.

12.28.19. If the home is owned or leased by the consumer or DLR, the provider will respect the consumer's choice of living environment and resources while advocating for adequate housing and living conditions: *Provided*, That nothing obligates the provider to supply services in an unsafe environment. If the provider suspects that an incapacitated consumer is living in unsafe conditions, the provider is obligated to conform to statutes regarding mandatory reporting.

12.29. Standards for 24-hour Programs Requiring Medical Monitoring.

12.29.1. The provider must supply adequate staff monitoring of individuals in the program either through "eyes on" or technological methods, which do not violate the consumer's right to privacy and confidentiality. The initial plan of services will detail the necessary monitoring which may be modified on an ongoing basis as treatment moves forward and the plan of services is revised.

12.29.2. A medical staff person such as a physician, physician extender, registered nurse, or licensed practical nurse functioning within his or her scope of practice must evaluate each patient in the program each shift unless the physician documents no further need for medical monitoring, provided that no such order can occur until the consumer has been in the program for 24 hours.

12.29.3. The provider must have a policy regarding the face-to-face or telemedicine availability of medical staff to directly observe the patient after hours within 30 minutes as necessary and appropriate unless an arrangement is made for alternative medical care.

12.29.4. Behavioral health centers providing medical stabilization must provide or arrange to obtain prescribed psychotropic and general medical medications after initial review by admitting medical staff, which shall be a physician or physician extender.

12.29.5. Behavioral health centers providing medical stabilization must assist consumers in obtaining needed medications as part of discharge planning. The provider shall have a policy with associated procedures regarding the ability of consumers to retain personal medications if discharged against medical advice.

12.30. Residential Substance Use Disorder Facilities.

12.30.1. Residential substance use disorder facilities, in addition to the licensure requirements of this rule, shall also be accredited with the Commission on Accreditation of Rehabilitation Facilities International, the Joint Commission, or Det Norske Veritas to operate an inpatient facility that provides behavioral health services.

12.30.2. Residential substance use disorder facilities licensed by the Office of Health Facility Licensure and Certification pursuant to this rule as of May 20, 2024, must receive accreditation no later than January 1, 2026, and submit evidence of the same to the Office of Health Facility Licensure and Certification.

12.30.3. Any new residential substance use disorder facility, as a result of beginning new operations, opening a new location, or a change of ownership, after May 20, 2024, shall be required to receive accreditation within one year of the initial licensure.

12.30.4. In the event that the requirements of W. Va. Code §9-5-29a expire, subsections 12.30.1., 12.30.2., and 12.30.3. also will expire.

12.30.5. All residential substance use disorder facilities are subject to the provisions of W. Va. Code §16-2D-9(5).

~~§64-11-13~~ 71-25-13. Administrative Due Process, Administrative Appeals, and Judicial Review.

13.1. The Director, in consultation with the Inspector General may deny the provider's application for licensure or licensure renewal; modify or revoke a license; or order any admissions ban or reduction in consumer census for one or more of the following reasons:

13.1.1. The provider fails to submit an adequate plan of correction without formally and timely notifying the ~~Inspector General~~ Director that the provider intends to exercise its due process rights of appeal;

13.1.2. The ~~Inspector General~~ Director makes a determination that fraud or other illegal action has been committed;

13.1.3. The provider violates federal, state, or local law relating to building, health, fire protection, safety, sanitation, or zoning; or is noncompliant with payment of workers' compensation or employment security taxes, and fails to remedy such violation given sufficient notice;

13.1.4. The provider conducts practices which jeopardize the health, safety, welfare, or clinical treatment of consumers;

13.1.5. The provider fails or refuses to make records related to compliance with this rule available within a reasonable period of time as requested by the ~~Inspector General~~ Director; or

13.1.6. The provider refuses to provide access to its service locations within a reasonable period of time as requested by the ~~Inspector General~~ Director.

13.2. Where the operation of a behavioral health center clearly constitutes an immediate danger of serious harm to consumers served by the behavioral health center, the Director, in consultation with the Inspector General may issue an order of closure terminating operation of all or a specific segment of the provider's behavioral health center license clearly giving rise to the immediate danger of serious harm. A provider appealing such a closure order may continue to operate all or the specified portion of the behavioral health center license pending exhaustion of administrative appeals, judicial appeals, or both.

13.3. Any person, partnership, association, or corporation which establishes, conducts, manages, or operates a behavioral health center without first obtaining a license as herein provided, or who commits a violation as described in this section may be assessed a civil money penalty by the Director, in consultation with the Inspector General in accordance with this section. Each day of continuing violation after a civil money penalty is assessed may be considered a separate violation.

13.3.1. If a behavioral health center is found to be in violation of any provision of this rule, unless otherwise noted herein, the Director, in consultation with the Inspector General may limit, suspend, or revoke the behavioral health center's license: *Provided, That the* Director, in consultation with the

Inspector General may only suspend or revoke a license, if the licensee commits a violation which endangers the health, safety, or welfare of a person;

13.3.2. If the behavioral health center fails to take action to correct a violation after being cited for the violation, the Director, in consultation with the Inspector General may impose a civil money penalty not to exceed \$10,000 and, in the case of an owner-operator behavioral health center, limit or revoke the behavioral health center's license;

13.3.3. If the behavioral health center conducts practices which jeopardize the health, safety, welfare, or clinical treatment of consumers when such practices clearly give rise to imminent danger of serious harm or the immediate risk of imminent danger of serious harm, the Director, in consultation with the Inspector General may impose a civil money penalty not to exceed \$10,000;

13.3.4. If an owner of a behavioral health center concurrently operates an unlicensed behavioral health center, the Director, in consultation with the Inspector General may impose a civil money penalty upon the owner not to exceed \$5,000 per day;

13.3.5. If the owner of a behavioral health center that requires a license under this rule fails to apply for a new license for the behavioral health center upon a change of ownership and operates the behavioral health center under new ownership, the Director, in consultation with the Inspector General may impose a civil money penalty upon the owner, not to exceed \$5,000; or

13.3.6. If an owner operates, owns, or manages an unlicensed behavioral health center that is required to be licensed pursuant to this rule; obtains a license to operate a behavioral health center through misrepresentation or fraud; or procures or attempts to procure a license for a behavioral health center for any other person by making or causing to be made any false representation, the Director, in consultation with the Inspector General may assess a civil money penalty of not more than \$20,000. Any penalty may be in addition to or in lieu of any other action that may be taken by the ~~Secretary~~ Inspector General or any other board, court, or entity.

13.3.7. If an owner knowingly operates, owns, or manages an unlicensed behavioral health center that is required to be licensed pursuant to this rule; obtains a license to operate a behavioral health center through misrepresentation or fraud; or procures or attempts to procure a license for a behavioral health center for any other person by making or causing to be made any false representation, the Director, in consultation with the Inspector General may assess a civil money penalty of not more than \$20,000. Any penalty may be in addition to or in lieu of any other action that may be taken by the ~~Secretary~~ Inspector General or any other board, court, or entity.

13.4. Notwithstanding the existence or pursuit of any other remedy, the Inspector General may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association, or corporation to restrain or prevent the establishment, conduct, management, or operation of any behavioral health center or violation of any provision of this rule without first obtaining a license therefore in the manner hereinbefore provided.

13.4.1. The Inspector General may also seek injunctive relief if the establishment, conduct, management, or operation of any behavioral health center, whether licensed or not, jeopardizes the health, safety, or welfare of any or all of its consumers.

13.4.2. In determining whether a penalty is to be imposed, the Director, in consultation with the Inspector General will consider the following factors:

13.4.2.a. The gravity of the violation, including the probability that death or serious physical or emotional harm to a consumer has resulted, or could have resulted, from the behavioral health center's actions or the actions of the owner or any staff employed by or associated with the behavioral health center, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

13.4.2.b. What actions, if any, the owner or staff took to correct the violations;

13.4.2.c. Whether there were any previous violations at the behavioral health center; and

13.4.2.d. The financial benefits that the behavioral health center derived from committing or continuing to commit the violation.

13.5. Upon finding that a registered or licensed professional has violated the provisions of this rule, the ~~Inspector General~~ Director will provide notice of the violation to the applicable professional licensing board.

13.6. Before any behavioral health center license is limited, denied, suspended, or revoked or a civil money penalty is assessed, written notice will be given to the owner or owners of the program, stating the grounds of the denial, suspension, revocation, or penalty and the date set for any enforcement action and the date due for any civil money penalty.

13.6.1. The notice will be sent by certified mail or electronically transmitted to the owner or owners at the address where the behavioral health center concerned is located.

13.6.2. Within 10 days of receipt of the notice, the owner or owners may submit a request for an administrative hearing or an informal meeting to address and resolve the findings.

13.6.3. The behavioral health center and its owner or owners will be entitled to be represented by legal counsel at the informal meeting or at the hearing at their own expense.

13.6.4. All of the pertinent provisions of W. Va. Code ~~§29-4-1~~ 29A-5-1, *et seq.*, and 69CSR1 shall apply to and govern any hearing authorized by this rule.

13.6.5. If an owner fails to request a hearing within the time frame specified, he or she shall be subject to the full penalty imposed.

13.6.6. The filing of a request for an administrative hearing or an informal meeting does not stay or supersede the enforcement of a limitation, denial, suspension or revocation of a license; the assessment of a civil money penalty; or an enforcement order.

13.7. Informal dispute resolution. -- A provider or licensee adversely affected by citation of a deficient practice issue pursuant to this article or by a citation issued for a deficient practice pursuant to federal law may request the informal dispute resolution process. A provider may contest a cited deficiency as contrary to law or unwarranted by the facts or both. A provider may choose to have the review completed by an independent review organization. Informal dispute resolution is not available for

situations described in section 13.6. of this rule and is only available regarding the citation of a deficient practice issue.

13.7.1. The Director, in consultation with the Inspector General will contract with independent review organizations to conduct an independent informal dispute resolution process. The independent review organization will be accredited by the Utilization Review Accreditation Commission.

13.7.2. The informal dispute resolution process is not a formal evidentiary proceeding and utilizing the informal dispute resolution process does not waive the provider's right to a formal hearing.

13.7.3. The informal dispute resolution process consists of the following:

13.7.3.a. No later than 10 working days following the last day of the survey or inspection, the ~~Inspector General~~ Director will transmit to the provider a statement of deficiencies committed by the behavioral health center. Notification of the availability of the informal dispute resolution process, including the option of an independent review organization, and an explanation of the informal dispute resolution process will be included in the transmittal.

13.7.3.b. Within 10 working days of receipt of the statement of deficiencies, the provider shall return its plan of correction for the cited deficiencies to the ~~Inspector General~~ Director and may request in writing the informal dispute resolution process to refute the cited deficiencies. The provider must submit its supporting documentation and indicate its request for the informal process at the time of submission. No plan of correction is required for citations under appeal. The ~~Inspector General~~ Director may not release the report to the public until appealed citations are resolved.

13.7.3.c. Within five working days of receipt of the written request for the informal dispute resolution process made by a provider, the ~~Inspector General~~ Director, dependent upon the provider's request, will refer the request to an internal team not associated with the survey event to an independent review organization from the list of certified independent review providers approved by the state. The ~~Inspector General~~ Director will vary the selection of the independent review organization on a rotating basis.

13.7.3.d. Within 10 working days of receipt of the written request for the informal dispute resolution process made by a provider, the informal dispute resolution conference will be scheduled unless additional time is requested by the provider. Before the informal dispute resolution conference, the provider may submit additional information.

13.7.3.e. Neither the ~~Inspector General~~ Director nor the provider will be accompanied by counsel during the informal dispute resolution conference. The manner in which the informal dispute resolution conference is held is at the discretion of the independent review organization, but is limited to:

13.7.3.e.1. A desk review of written information submitted by the provider;

13.7.3.e.2. A telephonic conference; or

13.7.3.e.3. A face-to-face conference held at the behavioral health center's location or a mutually agreed upon location.

13.7.3.f. If the independent committee determines the need for additional information, clarification, or discussion after conclusion of the informal dispute resolution conference, the ~~Inspector General~~ Director, the provider, or both, will present the requested information.

13.7.3.g. Within 10 working days of the informal dispute resolution conference, the review committee shall make a determination based upon the facts and findings presented and shall transmit a written decision containing the rationale for its determination to the ~~Inspector General~~ Director.

13.7.3.h. If the ~~Inspector General~~ Director disagrees with the determination, the Director, in consultation with the Inspector General may reject it and will issue an order setting forth the rationale for the reversal of the independent review committee's decision to the provider within 10 working days of receiving the determination. The ~~Inspector General~~ Director may not assign review of the rejection to a designee.

13.7.3.i. If the ~~Inspector General~~ Director accepts the determination, the ~~Inspector General~~ Director will issue an order affirming the determination within 10 working days of receiving the independent reviewer's determination.

13.7.3.j. If the independent review committee determines that the original statement of deficiencies should be changed as a result of the informal dispute resolution process and the ~~Inspector General~~ Director accepts the determination, the ~~Inspector General~~ Director will transmit a revised statement of deficiencies to the provider within 10 working days of receipt of the determination.

13.7.3.k. Within 10 working days of receipt of the ~~Inspector General's~~ Director's order and the revised statement of deficiencies, the provider shall submit a revised plan to correct any remaining deficiencies to the ~~Inspector General~~ Director.

13.7.4. Under the following circumstances, the provider is responsible for certain costs for the independent informal dispute resolution review, which shall be remitted to the ~~Secretary~~ Director within 60 days of the informal dispute resolution order:

13.7.4.a. If the provider requests a face-to-face conference, the provider shall pay any costs incurred by the independent review that exceed the cost of a telephonic conference, regardless of which party ultimately prevails.

13.7.4.b. If the independent decision supports the entirety of the originally written contested deficiency or adverse action taken by the ~~Inspector General~~ Director, the provider shall reimburse the ~~Inspector General~~ Director for the cost charged by the independent review organization. If the independent decision supports some of the originally written contested deficiencies, but not all of them, the independent reviewer will rule as to approximate portions of the expense of the hearing to be paid by each party.

13.8. Administrative Appeals and Judicial Review.

13.8.1. Any party who disagrees with the final administrative decision as a result of the hearing may, within 30 days after receiving notice of the decision, appeal the decision to the West Virginia Intermediate Court of Appeals.

13.8.1.a. The filing of a petition for appeal does not stay or supersede the enforcement of the final decision or order of the ~~Inspector General~~ Director. An appellant may apply to the West Virginia Intermediate Court of Appeals for a stay of or to supersede the final decision or order.

13.8.1.b. The West Virginia Intermediate Court of Appeals may affirm, modify, or reverse the final administrative decision. Any party may appeal the West Virginia Intermediate Court of Appeals' decision to the Supreme Court of Appeals.

13.9. Any person aggrieved by an order or other action by the ~~Inspector General~~ Director based on this rule may request in writing a hearing by the ~~Inspector General~~ Board of Review in accordance with "~~Rules of Procedure for Contested Case Hearings and Declaratory Rulings,~~" Rules for Hearings under the Administrative Procedures Act, 69CSR1, a copy of which may be obtained from the Secretary of State.