WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION

Form #3

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2007 JUL 27 PM 4:16

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: DHHR-Office of Health Facility Licensure and Certification TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code §§ 27-9-1, 27-17-3, 27-1A-4(g), 27-1A-6(6), and 27-1A-6(7)

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 11

TITLE OF RULE BEING AMENDED: Behavioral Health Centers Licensure

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Martha Yeager Walker
Authorized Signature

BRIEF SUMMARY OF THE RULE

BEHAVIORAL HEALTH CENTERS LICENSURE RULE

64CSR11

This repeals and replaces the behavioral health center licensure rule with the effective date July 1, 2000. It sets forth the requirements for behavioral health centers to be licensed in the state of West Virginia.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

BEHAVIORAL HEALTH CENTERS LICENSURE RULE

64CSR11

The behavioral health center licensure rule has not been updated since July 1, 2000. The proposed rule brings the licensing requirements for behavioral health centers in line with current practice and current federal Centers for Medicare and Medicaid Services and state Bureau for Medical Services practices.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: BEHAVIORAL HEALTH CENTERS LICENSURE RULE

Type of Rule: X Legislative _____ Interpretive _____ Procedural

Agency: Health and Human Resources
Address: Building 3, Room 206
Capitol Complex
Charleston, West Virginia 25305

Phone Number: 558-0488 Email: roselowther-berman@wvdhhr.org

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

This repeals and replaces the behavioral health center licensure rule with the effective date July 1, 2000. It sets forth the requirements for behavioral health centers to be licensed in the state of West Virginia. The rule changes bring the licensing requirements for behavioral health centers in line with current practices and federal Centers for Medicare and Medicaid Services (CMS) and WV Department of Health and Human Resources Bureau for Medical Services practices. Civil Monetary Penalties of one thousand dollars have been added for behavioral health centers that fail to correct deficiencies cited during their licensure survey and fifty dollars per day penalties for behavioral health centers that do not submit plans of correction by the deadline.

The Department of Health and Human Resources estimates that any increases in costs to the Department, associated with the proposed rule change will be negligible and can be absorbed within the current funding level. There are one hundred eighteen licensed behavioral health centers. Revenue will increase from ten (10) dollars per license to two hundred fifty (250) dollars per license along with a licensure fee of twenty-five (25) dollars per bed. Licenses are issued every two years. Fifty-Six (56) facilities will renew their licenses in 2009 and fifty-nine (59) facilities will renew their licenses in 2010.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

Effect of Proposal	Fiscal Year		
	2008 Increase/Decrease (use"-")	2009 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues		71,390	45,760

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

Revenue estimate for SFY2009: $250 per license - $10 per license received under old rule = $240 per license increase X 56 behavioral health centers = $13,440; 342 beds X $25 per bed = $8,550; Civil Monetary Penalties: 31 facilities X $1,000 per facility = $31,000 + 46 facilities X 8 days beyond plan of correction deadline X $50 per day = $18,400 . ($13,440 + $8,550 + $31,000+18,400 = $71,390 Total Additional Revenue)

Revenue estimate for SFY2010: $250 per license - $10 per license received under old rule = $240 per license increase X 59 behavioral health centers = $14,160; 704 beds X $25 per bed = $17,600; Civil Monetary Penalties: 10 facilities X $1,000 per facility = $10,000 + 10 facilities X 8 days beyond plan of correction deadline X $50 per day = $4,000 . ($14,160 + $17,600 + $10,000 + $4,000 = $45,760 Total Additional Revenue)

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date

7/27/07

Agency

Department of Health and Human Resources

Authorized Representative

Martha Yeager Walker

Martha Yeager Walker
Secretary

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 7/27/07

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (*Agency Name, Address & Phone No.*) Office of Health Facility Licensure and Certification
Dr. Rosanna Lowther-Berman, PMII; Aimee Jackson, Paralegal. 1 Davis Square, Suite 101, Charleston, WV 25301-1799. 558-0050; 558-0687

LEGISLATIVE RULE TITLE:
Behavioral Health Centers Licensure

1. Authorizing statute(s) citation W.Va. Code §§ 27-9-1, 27-17-3, 27-1A-4(g), 27-1A6(6), 27-1A-6(7)

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

   6/27/07

   b. What other notice, including advertising, did you give of the hearing?

   c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

   7/27/07 at noon.

   d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

   Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

7/27/07

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Aimee Jackson, Paralegal, Office of Health Facility Licensure & Certification
1 Davis Square, Suite 101, Charleston, WV 25301-1799. Phone:558-0687. Fax: 558-5607. aimeejackson@wvdhhr.org

g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

Dr. Rosana Lowther-Berman, PMII, 1 Davis Square, Suite 101, Charleston, WV 25301-1799. Phone: 558-0050.

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

_____

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

_____

d. Attach findings and determinations and reasons:

Attached _____

Behavioral Health Comments:

General to Physical Environment
Comment: Change all references to Section 11 of the Guidelines for Design and Construction of Hospital and Healthcare Facilities to Section 3.2. Ron Stricker, Life Safety Program Manager, OHFLAC – 7/23/07.
Response: BPH made the change.

3.15. Abuse and Neglect
Comment: Add language at the end of the regulation so that it reads "The alleged suspected or actual occurrence of any of the following involving a consumer [*during the time care and services are being provided by the center*]. – James Cooper, Surveyor, OHFLAC - 7/26/07.
Response: Accepted. The regulation has been changed.

5.9.c.8. and 5.9.c.9. Personnel
Comment: Stating that no person can be hired in a DeTox or Substance Abuse program if they have felony drug or felony DUI offenses within the last 10 years: we would be doing a disservice to the population that we work so hard to serve if we were to allow these regulations to go into effect. – Sheila McBride, BA, CAC, Westbrook Health Services' Amity Detox and Treatment Center letter - 7/26/07.
Response: The regulation allows for waivers if the center feels that a prospective employee or contractor should be hired in spite of issues raised by a background check. It is the responsibility of Bureau of Public Health to protect the health and safety of vulnerable West Virginians, and to assure, to the best of its ability that these consumers are not subject to abuse or neglect. The regulation should stand as written.

6.2. a.1. Physical Environment
Comment: Change 6.2.a.1. to read "the current", not "2001". Ron Stricker, Life Safety Program Manager, OHFLAC - 7/23/07.
Response: BPH made the change.

6.2.a.3.A Physical Environment
Comment: delete the words "when applicable" and list when the requirements are applicable. -John Payne, International Code Council Regional Manager (Ohio Field Office) – letter 7/27/07.

Response: The applicability of the regulation would be different for each situation. The regulation should stand as written.

6.2.a.3.B Physical Environment
Comment: This should be amended to identify the West Virginia Building Code as the 2003 edition of the International Building Code. The "current edition of the International Building Code is the 2006 edition. This change would be more accurate and enforceable. John Payne, International Code Council Regional Manager (Ohio Field Office) – letter 7/27/07.
Response: This point is well taken. The regulation has been changed.

6.2.a.3.D Physical Environment
Comment: Title 64-11 should not reference the Guidelines for Construction of Hospital Care Facilities, but directly reference the 2000 edition of NFPA 101. – John Payne, International Code Council Regional Manager (Ohio Field Office) – letter 7/27/07.
Response: 6.2.a.3.D was added to address this issue.

5.11.e.7 Consumer Records
Comment: Add an additional regulation to state "5.11.e.8. – To the state's federally mandated protection and advocacy system" pursuant to access authority provided under the PAIMI (Protection and Advocacy for Individuals with Mental Illness) Act at 42 USCA 10805-10806 and the PADD (Protection and Advocacy for Individuals with Developmental Disabilities) Act at 42 USC 10542 (a). - West Virginia Advocates, Teresa Brown by letter 7/27/07.
Response: The point is well taken. The regulation was added.

7.6.d Abuse and Neglect Reporting
Comment: Add "The state's federally mandated protection and advocacy system." - West Virginia Advocates, Teresa Brown by letter 7/27/07.
Response: The point is well taken. The statement was added to 7.6.d.

7.6.d (7.7) Critical Incidents and Crisis Management
Comment: Death of any consumer should be reported to the state's federally mandated protection and advocacy system, pursuant to access authority provided under the PAIMI (Protection And advocacy for Individuals with Mental Illness) Act at 42 USCA 10805-10806 and the PADD (Protection and Advocacy for Individuals with Developmental Disabilities) Act at 42 USC 10542.

Response: This is contained in 7.6.d. The commenter had identified a regulation from a previous draft. Critical Incidents include death. The regulation should stand as written.

10.8.c. Consumer Confidentiality
Comment: Change 10.8.c to conform with 64-74-11 - Steve Small, Attorney for BBHHF - 7/23/07 – this was made during a conference call 7/23/07.
Response: BPH made the change so that 10.8.c conforms with 64-74-11.

THE FOLLOWING WERE SUBMITTED BY THE BEHAVIORAL HEALTH CARE ASSOCIATION ON 7/24/07. THEY REFERENCE AN EARLIER VERSION OF THE REGULATION, NOT THAT POSTED ON THE SECRETARY OF STATE'S WEB SITE. THE REGULATION NUMBER IN PARENTHESES IS THE NUMBER CITED IN THE COMMENTER'S DOCUMENT.

1.6. Purpose
Comment: The new words added to this section" traumatic brain injuries" have not been included in previous rules. The majority of behavioral healthcare providers has not served individual with traumatic brain injuries in the past, and would not know how to meet their special needs unless described elsewhere in this Rule.
Response: There are persons with traumatic brain injuries who are currently served by some behavioral health centers. No center is required to serve persons if the center does not feel capable of doing so. If the center does not serve persons with traumatic brain injury, the rule would not apply. The regulation should stand as written.

3.1.a. Physical Abuse
Comment: This definition should be made consistent with definitions of physical abuse which are already in statute under the DHHR protective services requirements.
Response: This definition expands the protections covered in the protective services requirements to better preserve the health and safety of vulnerable West Virginians. It is consistent with federal CMS rules for ICFs/MR. The regulation should stand as written.

3.13. Consumer Record
Comment: Language which allows only a written and signed record should be adjusted to allow for the evolution to electronic medical and clinical records.

Response: This was corrected earlier. The commenter did not use the right version.

3.15. Critical Incident

Comment: The language here should be changed to reflect that the requirements would be consistent with incidents occurring in a 24 hour licensed residential setting. Critical incident reporting would not be an appropriate requirement for those who access services for short period of times during the day or month on an outpatient basis. Nor is there any distinction drawn between requirements related to incapacitated individuals or individuals emancipated.
Response: Critical incidents may occur in any setting, and involve any type of individual. OHFLAC will not limit protections to certain types of individuals, but is committed to the protection of all. OHFLAC has changed the language by adding "during believes the regulation should stand as written.

3.15.j. Dietary or Medication Errors

Comment: The word 'potential' should be removed. It is too subjective a term. A single dietary error for instance does not generally cause true harm to an individual.
Response: The regulation should stand as written. A single medication or dietary error may cause harm or death.

3.27 (3.25). Individual Support Plan

Comment: The language here models language elsewhere in the Rule related to requirements for treatment plans. However, it does not allow for fewer documentation and record keeping requirements now recognized by the Bureau for Medical Services and APS Healthcare reviewers for what are known as 'low end services'.
Response: This is covered in the proposed rule under **3.27**. The commenter did not use the right version. The proposed rule does address this issue under section 8.3. The regulation should stand as written.

3.33 (3.31). Neglect

Comments:
1) The definition here is not consistent for neglect as found elsewhere in Code related to DHHR protective services requirements.
2) This definition of neglect is too subjective, and will result in undue hardship for agencies and staff. A proper definition of neglect should include mention that the wrongful act or acts resulted in placing the consumer at risk for injury or for death.

3) In addition, neglect should not apply only to a single incident, but rather should be applicable to 'intent,' to 'repeated instances,' or to a 'pattern' of findings.
Response: This is covered in the proposed rule under **3.33**. The commenter did not use the right version. This definition expands the protections covered in the protective services requirements to better preserve the health and safety of vulnerable West Virginians. It is consistent with federal CMS rules for ICFs/MR. The regulation should stand as written.

3.33.a (3.31.a). Failure to carry out an individual support plan
Comment: A pattern of findings should support the determination of neglect, rather than single instances of not following through on the individual support plan.
Response: This is covered in the proposed rule under **3.33.a**. The commenter did not use the right version. A single instance of not following a plan may place a consumer at risk of injury or death. The regulation should stand as written.

3.33.b (3 .31.b). Failure to provide adequate nutrition, clothing or health care
Comment: A pattern of findings should be required rather than single instances.
Response: This is covered in the proposed rule under **3.33.b**. The commenter did not used the right version. A single instance of not providing this care may place a consumer at risk of injury or death. The regulation should stand as written.

3.33.d (3.31.d). Failure to follow written center policies and procedures
Comment: More definition or examples are needed here, or else there should be a pattern established of failing to follow policies and procedures. If one fails, for instance, to fill out internal paperwork as specified in policy, this constitutes neglect?
Response: This is covered in the proposed rule under **3.33.d**. The commenter did not use the right version. Paper compliance does not jeopardize a consumer's health or safety. If a failure to follow policy does not jeopardize a consumer's health or safety, if would not be considered neglect. The regulation should stand as written.

3.51 (3.49). Staff
Comment: This needs to be clarified. Staff on the agency's payroll is different than individuals having a contractual relationship. Nor does the section make a

distinction regarding 'difficulty of care' payments recognized by State and Federal officials in years' past.
Response: This is covered in the proposed rule under **3.51, 3.20, and 3.26**. The commenter did not used the right version. The issue was addressed earlier, resulting in the addition of sections for employee (3.20) and independent health contractor (3.26). The regulation should stand as written.

3.36 (3.54). Treatment Plan
Comment: Treatment Plan requirements should differ for those who are enrolled in 24 hour services or for individuals for instance with developmental disabilities who would have specific habilitation requirements tied to measurable goals and objectives. This language at 3.54 does not make accommodation for those receiving low end services on a limited outpatient basis.
Response: This is covered in the proposed rule under **3.56**. The commenter did not use the right version. The issue of low end services was addressed by the addition 8.3. The regulation should stand as written.

3.55. Triage
Comment: Triage is typically reserved for inpatient medical clinics and hospitals but not for licensed outpatient behavioral healthcare sites.
Response: This was deleted in earlier revisions. The commenter did not use the right version.

4.2.a. License Application: Costs
Comment: It is nearly impossible for not for profit agencies to demonstrate six months' of operating expenses are on hand, either to open a new program, or to renovate or expand an existing center. This is excessive.
Response: Financial viability must be in a form as listed to provide credible evidence of financial resources. To ensure the health and safety of consumers, OHFLAC must have evidence that the center is fiscally viable. This information must be provided to the Health Care Authority, and so would not pose a hardship. The regulation should stand as written.

4.2.a. Licensing Application: General Requirements
Comment: Licensing staff should not address these issues as found listed here. These are requirements already with the Health Care Authority application process to make a determination before finding that a service is needed or necessary. It is duplicative of HCA requirements.
Response: See previous comment. The regulation should stand as written.

4.1.3.1 (4.2.b). Licensed Sites
Comment: The Rule should define which kinds of sites, for instance, individual's own homes, do not have to be licensed by the State even though in homes services such as those related to the MR/DD Waiver are delivered there.
Response: This is in the current rule, verbatim, as **4.1.3.1**, and was not changed in the revision. There has been no confusion on this issue during the 17 years that the current rule has been in force. The regulation should stand as written.

4.3.a (4.2.d). Renewal Applications
Comment: The new fee schedule being proposed is too high compared to the current fee. Who sets the fee and on what basis is the fee schedule set?
Response: This is covered in the proposed rule under **4.3.a**. The commenter did not use the right version. Fees have not increased in at least 17 years. The changes were calculated to address some of the cost of inflation. The fee is set by the regulation. The regulation should stand as written.

4.2.e.3. License Application
Comment: Renovations or conversions of facilities should be the purview of the Health Care Authority, not licensing. This is duplicative.
Response: This regulation clarifies the term "extensive renovations" used in the current regulations (4.2.b.). The regulation should stand as written.

4.2.f. License Application
Comment: The penalty proposed here should be the purview of the Health Care Authority. They issue Orders to close or to cease operations if healthcare entities have exceeded the terns of the service being offered or the sites offering those services.
Response: This penalty is designed to deter centers from making changes in sites and services without notifying OHFLAC. It has nothing to do with the Health Care Authority, but could affect the health and/or safety of consumers. The regulation should stand as written.

4.3.c. Licensing fee
Comment: The licensing fee here of $ 500 is excessive compared to the current $ 10 fee which is paid only every two years. Why is this increase necessary?
Response: The commenter did not use the right version. The proposed rule has a fee of $250. Fees have not increased in at least 17 years. The changes were calculated to address some of the cost of inflation. The regulation should stand as written.

4.3.c (4.3.d). Cost per bed
Comment: The proposed fee of $ 25 per bed in addition to the fee for centers without beds is excessive and will force providers to consider closing community based beds in which case more individuals will end up in state hospitals or in diversionary beds in private hospitals.
Response: This is covered in the proposed rule under **4.3.c**. The commenter did not use the right version. This fee parallels similar fees charged by the Assisted Living Program and brings the Behavioral Health Program in line with similar programs within OHFLAC, The regulation should stand as written.

4.5. Construction and Renovation
Comment: Some of the requirements in this section should be regulated by the Health Care Authority, not licensing which is responsible for health and treatment services. The added cost implied for contracting architectural and structural and engineering services, not previously required in this Rule, particularly for renovations, will all but preclude small, not for profit licensed behavioral healthcare centers and agencies from renovation or improving any existing properties due to cost considerations. Under the existing Rule we believe licensed contractors are acceptable for additions and renovations.
Response: OHFLAC is charged with the health and safety of behavioral health consumers. Cost is not additional, but is covered in 4.2.b of the current rule. This regulation does not expand, but clarifies the current regulation. The regulation should stand as written.

4.5.b. Construction and Renovation
Comment: Conducting a safety risk assessment or an infection control assessment, for instance, for renovations such as new carpeting in offices or in the building is excessive to say the least.
Response: This regulation brings the OHFLAC regulation in compliance with the Guidelines for Design and Construction of Hospital and Healthcare Facilities. The regulation should stand as written.

4.5.c.1. Site Selection
Comment: It is fine to require licensed agencies to conform to existing state or local zoning requirements or to state Code requirements. It is not practical in a rural state such as ours to locate needed services in approved sites dose to centers of population or near medical staff or facilities, or existing transportation services. Many licensed centers have satellite offices in very small communities in their rural counties in addition to the main center office and service sites.
Response: The comment is well taken. The regulation has been deleted.

4.6.f. Inspections
Comment: Inspectors sometimes seek to inspect private residences. This Rule should specify that private residences are not to be considered licensed sites operated by the centers.
Response: This regulation is verbatim from the current rule. The regulation has been deleted.

4.6.j. Contested findings
Comment: Clear rules should exist in writing in this section regarding the informal dispute resolution process: Providers need to know who can be present for each side, if lawyers may participate, if a statement of deficiencies or plan of correction must be agreed upon before the proceedings can be initiated, and timelines for all of the appeals and required documentation should be in writing in this Rule.
Response: These issues are covered in OHFLAC procedures that encompass not only behavioral health centers, but also ICFs/MR, and nursing homes. They are based on federal guidelines. The regulation should stand as written.

4.7.c. Complaint investigations
Comment: Providers are not always advised of the general nature of the complaint being investigated. This violates their due process right to know the concern rather than to be subjected to something little more than a fishing expedition. In earlier Rules this section required Health Facilities staff to specify the actual reason for the complaint so that the scope of the review remained focus on that circumstance, and that the review of operations did not become a fully involved licensure review.
Response: The current rule does not require the actual reason for the complaint, nor did the previous rule. The proposed rule does require that the general nature of the complaint be identified. The regulation should stand as written.

4.6.a (4.9.a). Plans of Correction
Comment: Please delineate what 'variance' means and on what basis, or under what circumstances a provider might request one, or the Secretary might grant one.
Response: This is covered in the proposed rule under **4.6.a**. The language is identical. The regulation should stand as written.

4.9.d (4.9.b). Directed Plans of Correction

Comment: Directed Plans of Correction are sometimes made a requirement for providers in this section of the Rule. However, this Rule never previously, nor does it currently, propose any language regarding a 'directed plan of correction.' Rather we believe this is a concept borrowed from Federal certification activities applicable in nursing home settings, and regulated under Federal Rules. This Rule is a state-only, behavioral healthcare licensing Rule. Certification activities do not apply to licensed WV behavioral health care sites.
Response: This is covered in the proposed rule under **4.9.d**. The commenter did not use the right version. Current and previous OHFLAC practice has been to implement the directed plan of correction as a last resort when the center, after repeated attempts, did not submit an acceptable plan of correction. The regulation should stand as written.

4.9.g. Findings Available for Review
Comment: It is fine to require centers to post notice that official records are available for review upon request. However, results of investigations, particularly internal investigations, are not public record and should not be posted for review. This would create an undue liability issue.
Response: This regulation is for survey and complaint results only, not internal investigations. The regulation was amended to distinguish that the results of OHFLAC surveys, inspections and investigations should be available.

5.2. Governing Body
Comment: The governing body should not 'set policy' as stated in this portion of the Rule. The Governing body should hire an administrator who is required to carry out the day to day operations as specified by the Board. Boards should govern only, and this role should be distinguished from the operations role which is given to center management. In the previous Rule, this description of Governing Body responsibilities was instead found under the section entitled "Administration' which we believe is where it rightfully belongs.
Response: This is covered in the current rule under **5.2.a**. The language is identical. The regulation should stand as written.

5.2.d.7. Governing Body
Comment: Governing bodies should not have to see to it that a policy and procedure manual is maintained. That is the role of 'administration'.
Response: The governing body could delegate this to the administration, as they delegate other tasks. Assigning it to the administration, would limit the authority of the governing body. The regulations should stand as written.

5.2.d.8. Governing Body
Comment: Governing bodies should not have to see that policies and procedures are available to all staff in all programs. That is the role of' administration.'
Policies should be available to all staff in all programs as appropriate to their assigned duties. Fiscal and business policies for instance, would not routinely be made available to direct care program staff.
Response: The governing body could delegate this to the administration, as they delegate other tasks. Assigning it to the administration, would limit the authority of the governing body. The regulations should stand as written.

5.5. Fiscal Protections
Comment: Centers should be protected from being placed in the position of being accused of 'abuse' as has happened with licensure visits in instances where incidents occurred related to writing checks on behalf of clients, or otherwise managing their funds. The Rule here does not distinguish under fiscal protections what is abuse as compared with what is an incident.
Response: The rule addresses abuse and incidents under **3.1 and 7.6,** not under 5.5. The regulation should stand as written.

5.5.a. Purchase of Insurance
Comment: Centers should not be required to purchase automotive liability. Centers instead should be required to assure that those who drive vehicles on behalf of work, and as related to their job functions, are in compliance with state vehicular insurance laws.
Response: This regulation was amended to apply only to company owned or leased vehicles. The regulation should stand as written.

5.6.f. Bonding
Comment: The Rule should require only that bonding is obtained in an amount sufficient to handle client funds. The Rule goes too far when requiring 'in an amount not less than $ 2500."
Response: This is covered in the current rule under 5.4.h. The language is identical. The regulation should stand as written.

5.7.e. Discrimination
Comment: The Rule language here should reflect the same language as is currently required by Federal definition of protections to be afforded under 'equal employment opportunities.'

Response: This regulation covers the Federal definitions when it references "any other category protected by applicable law". The regulation should stand as written.

5.7.g. Reporting
Comment: Reporting should be limited to reports as required by state law. This section of the Rule has been over-interpreted to the extent that 'every thing' is reported, leaving providers to guess what is reasonable to report and what is excessive when having to report.
Response: The rule is a state law. This is covered in the current rule under 5.5.h. The language is identical. The regulation should stand as written.

5.7.h.l. Release of Information
Comment: The Rule should seek to specify the effective date of the release, when the release expires, to whom information can be released, and under what circumstances. It should also specify when the release expires, requiring the renewal of the release.
Response: These issues are covered in 5.7.h.1-5.7.h.7. It was changed earlier. The regulation should stand as written.

5.8. Relationships with Other Centers
Comment: The Rule here should require that centers 'demonstrate' good faith effort to obtain written agreements or contracts. In some instances centers cannot compel external organizations to enter into signed agreements.
Parts of the language in this section appear to apply to individual contractors, not other licensed healthcare facilities although the section of the Rule conveys that it should apply to 'other centers' only.
Response: The 'other centers' issue was clarified in revisions subsequent to the comenter's version. The regulation should stand as written.

5.8.a.9. External Entities
Comment: The proposed Rule here is unreasonable. In some instances, independent contractors are not employees of a licensed center. The Rule language should be adjusted to reflect that independent contractors conform with licensing standards as established by their state regulating Board or Authority, such as the Board of Nursing.
Response: This comment was well taken. 5.8.a.9 was deleted from the regulations.

5.8.b. "Contracted Employees"
Comment: The language proposed in this section is erroneous. One cannot be a 'contracted employee'. Contractors have independent status while employees are governed by licensure requirements. Contractors and employees are viewed in different fashion by employment law and by IRS determinations regarding 'employees'.
Response: This issue was corrected in the current proposed regulation, and independent health contractor was defined. The current regulation should stand as written.

5.8.c.3. Refusal to Provide Services
Comment: The proposed language in this section of the Rule is failing to recognize that individuals sometimes engage in what is known as 'doctor shopping.' Refusal to provide additional services would be appropriate.
In addition, some consumers receive services at other agencies as authorized by the APS Healthcare prior authorization process under Medicaid. If consumers have received the maximum allowable amount of service under the authorization at another center, there should not be an expectation that they can continue to approach other centers to receive care which would not be reimbursed at all by Medicaid.
Response: If doctor shopping is identified in the assessment process, and is a legitimate problem, the issue would be addressed in the treatment plan.
OHFLAC does not regulate consumer's attempts to gain additional services from other centers. The regulation should stand as written.

5.9.a. Employment and Personnel Policies
Comment: Licensure staff should not be regulating workers comp and unemployment rules. This is the purview of other state agencies overseeing employment law in West Virginia.
Response: OHFLAC does not regulating workers compensation and unemployment. The rule only requires the center to have policies that address these issues. The regulation should stand as written.

5.9.c. Background Checks
Comment: It is unreasonable to expect background checks from all 50 states. There is no known mechanism for doing a national background search. In WV the State Police background check is limited to WV residents. The cost of checking with 50 states would be prohibitive.
Response: There are several mechanisms for doing national background checks. This regulation is designed to address staff that have worked and lived

in other states as well as West Virginia. It protects consumers from convicted felons, what ever the state. The regulation should stand as written.

5.9.c. Contracted Employees
Comment: This is an incorrect term. One cannot be an external contractor and an employee.
Response: This issue was corrected in the proposed regulation, and independent health contractor was defined. The regulation should stand as written.

5.9.c.1. Proposed List of Convictions or Offenses
Comments:
1) Some of the items on the list would not limit one's ability to work in a billing office for instance, and not having client contact.
2) Other items on the list, if the conviction occurred 10- 20 years ago, would no longer be relevant, such as 'domestic battery' for instance.
3) Centers should not be asked or expected to conduct background checks on independent contractors who also happen to be the parents of individuals for whom they receive state funds to delivery care or oversight. If a parent does have a past conviction, what then would the center be expected to do in the way of a remedy?
4) The applicable list used by Health Facilities licensing requirements should be exactly the same as already recognized and placed in state statute for purposes of Adult Protective Services and Child Protective Services oversight activities.
Response: The regulation allows for waivers if the center feels that a prospective employee or contractor should be hired in spite of issues raised by a background check. It is the responsibility of Bureau of Public Health to protect the health and safety of vulnerable West Virginians, and to assure, to the best of its ability that these consumers are not subject to abuse or neglect. The regulation should stand as written.

5.9.d. National Sex Abuse Registry
Comment: There is no national registry.
Response: This is available on line. The regulation should stand as written.

5.9.e.3. References
Comment: This proposed Rule is too restrictive. Some agencies may not require references for every level of staff. The Rule should propose that each center have and follow its own policies as regards references.

Response: This is covered in the current rule under 5.6.d.3. The language is identical. The regulation should stand as written.

5.9.e.5. Verification of Job Requirements
Comment: The Rule here is too prescriptive. Being qualified to do one's job should be the role of internal and external peer review, or payor requirements. The Rule here is outdated and does not reflect state of the art practice.
Response: This is covered in the current rule under 5.6.d. This regulation clarifies that regulation. The state is not dictating the individual's qualifications, but is requiring that center abide by its own job descriptions. The regulation should stand as written.

5.10.a. Orientation
Comment: The words 'these shall be kept current' should be omitted. Orientation only occurs on a one-time basis.
Response: This is covered in the current rule under 5.7.a. The language is identical. The regulation should stand as written.

5.10.b. Direct Care staff
Comment: Please define what is meant as 'direct care staff.' In the past this has been the subject of disagreement.
Response: This is covered in the current rule under 5.7.a. The language of the proposed rule was altered to include both employees and staff. The commentator did not have the correct version. The regulation should stand as written.

5.10.g.2. Qualifications
Comment: The Rule here is overly prescriptive. It is in conflict in some regards with other standards already in place under WV Medicaid rules regarding those permitted to conduct clinical evaluations, or those permitted to offer supportive counseling.
Response: This language was entered at the request of the Office of Behavioral Health Services and is designed to improve the quality of services to consumers. The regulation should stand as written.

5.10.3. Qualified Practitioners
Comment: It would be sufficient here to say 'qualified'. It is not necessary to say 'or fully credentialed.'
Response: 'Fully credentialed' is all that is stated in the current proposed rule.

The commenter did not have the correct version. The regulation should stand as written.

5.11.c. Timely Access to Records
Comment: The Rule is too vague and subjective. What would be considered 'timely?" In addition, records are to be made accessible to whom?
Response: This is covered in the consumer rights section. It has been deleted here.

5.11.d. Record Retention
Comment: The Rule should reflect medical records' retention requirements elsewhere already in WV Statute, or else by national HIPPA requirements governing records.
Response: This meets or exceeds Hippa requirements and other state statutes. The regulation should stand as written.

5.11.j (5.11.h). Records Safe from Loss
Comment: Until electronic records are fully permitted in WV, there remains the possibility of loss due to fires, explosions, and flooding.
Response: This is covered in the proposed regulation under 5.11.j. The commenter had the wrong edition of the proposed regulation. There is, of course, always the possibility of loss, even with electronic records. This regulation was altered to state "The Center shall ensure reasonable safety and protection of records, including service and organizational records, from...."

5.12.a. Quality Assurance
Comment: The proposed Rule is too prescriptive when requiring peer review, health and safety review of all facilities, reviews of outcomes. The Rule should allow individual centers latitude to interpret 'quality assurance' measures.
Response: This is covered in the current rule under 5.11.a. It clarifies the existing rule. The regulation should stand as written.

6.1.b. Evidence of Adequate Insurance
Comment: The Rule is too prescriptive. It is already a requirement under WV Law that drivers be licensed and have insurance coverage. Centers cannot continue to monitor employees on a daily and monthly basis one's evidence of insurability.

Response: This regulation is designed to protect consumers who ride in employee vehicles. It is the responsibility of the center to protect these employees and monitor them. The regulation should stand as written.

6.2. Physical Environment
Comments:
1) Although the standards prescribed herein may be applicable in the current year, they are sure to change in future years. It would be better not to prescribe use of 200 I Guidelines, and rather to say only 'the applicable Code or Guideline.
2) In addition, applying these Rules to renovations may be cost prohibitive and result in a decision not to make future renovations.
3) It would be more desirable rather than to be so prescriptive, for the Rule to say instead, meets the applicable State building, zoning, fire and environmental codes.
Response: This change was reflected in the proposed regulation. The commenter did not use the current proposed regulation. The regulation should stand as written.

6.2.c.1. Square Footage
Comment: This is a new addition to the Rule and will pose a hardship for some providers. Previously rooms could be smaller in terms of total square footage. Is this a Code requirement?
Response: This is a code requirement. The regulation should stand as written.

6.2.c.5. Bedrooms
Comment: This is a new section. Is it required in Code that each bedroom be accessible to a main corridor, and each bedroom have an exterior window?
Response: This is a code requirement. The regulation should stand as written.

6.2.c.14.b. Dietitians
Comment: Requiring the involvement of dietitians in simple meal planning is cost prohibitive and is not normalizing.
Response: This point is well taken. The regulation has been deleted.

6.2.c.15. Food Handler's Card
Comment: The proposed Rule is too broad. Current practice in WV allows the supervisor to have the valid food handlers' card, and permits them in turn to train staff accordingly.
Response: This point is well taken. The regulation has been deleted.

6.2.c.18. Emergency Operations Plan
Comment: This is a new requirement. The Rule does not specify enough detail. What if a center already addresses emergencies in its policy and procedures manual as most already have?
Response: This is required under Life Safety Codes. The regulation should stand as written.

7.3.b (7.2.a. and b). Retention of Screening Records
Comment: The Rule is too prescriptive. Centers do not currently maintain records of screenings for two years' time because it is not required by any federal or state law. Centers would have no way to access records of screenings conducted two years ago.
Response: This is covered in the proposed rule under **7.3.b**. The commenter did not use the right version. Corrections were made in 7.3.b to alter the time line to 180 days.

7.5 (7.4.a). Consumer Discharge
Comment: Requiring a 'treatment plan' for each consumer is no longer a requirement in Medicaid for 'low end' consumers. The language here should be changed to 'based upon the consumer's needs.'
Response: This is covered in the proposed rule under **7.5**. The commenter did not use the right version. This issue is also covered under section 8.3 of the proposed rule, which was not available to the commenter. The regulation should stand as written.

7.6.d.2 (7.5.d.2). Reports to Health Facilities
Comment: Not all allegations of abuse and neglect should be reported to Health Facilities. Only those substantiated upon internal review or those substantiated by external review such as by Adult Protective Services staff should be reported.
Response: This is covered in the proposed rule under **7.6.d.2**. The commenter did not use the right version. Centers are required by Adult Protective Services documentation to report allegations of abuse and neglect immediately to OHFLAC, not when the allegation has been substantiated by the center's internal investigation. The regulation should stand as written.

7.6.e (7.5.e). Investigative Policies and Procedures
Comment: This section of the Rule is too prescriptive. Health Facilities has prepared, in its own words, guidelines for investigating incidents. Therefore they are not in any Rule, and exist as training and technical assistance. It is unrealistic

therefore for Health Facilities to then expect agencies to develop policies and to carry out procedures which follow items offered up as guidelines.
Response: This is covered in the proposed rule under **7.6.e**. The commenter did not use the right version. The OHFLAC guidelines do not prescribe policies and procedures, only practices that protect consumers and comply with the existing rule. The regulation should stand as written.

7.6.f (7.5.f). Appeal of Investigative Findings or Results
Comments:
1) This section is overly prescriptive. It should suffice to say that clients are to be advised of their rights, including the right of appeal, and the right to avail themselves of the center's grievance policy.
2) Centers currently must follow the WV Code requirements regarding notices and the grievance processes under client rights.
3) Governing bodies govern, and do not become involved in day to day operations. It is not appropriate that consumers can take appeals directly to the governing body.
Response: This is covered in the proposed rule under **7.6.f**. The commenter did not use the right version. The regulation is in the current rule under 8.2.d and is verbatim (outside of the Code changes) from that rule. The regulation should stand as written.

7.7 (7.6). Medical Information
Comment: Most of the listed items in this section such as recent medical complaints, routine lab reports, or sexual and reproductive health records are not appropriate for outpatient behavioral health settings and records. These requirements are typical of records in medical labs and clinics and personal doctors' offices. This list of requirements should be deleted, and require only necessary health information as prescribed by HIPAA.
Response: This is covered in the proposed rule under **7.7**. The commenter did not use the right version. These items are necessary to maintain a continuum of care and ensure proper treatment procedures are being utilized. They protect the health of vulnerable West Virginians. The regulation should stand as written.

8.2.b (8.1.b). Assessments
Comment: Not every client seen on an outpatient basis will require all of these items to be assessed. For instance, those on medication management only will not need to be assessed regarding family supports, or guardianship, or daily living skills. The language should be changed to 'clients/consumers will be assessed according to the consumer's particular needs' .

Response: This is covered in the proposed rule under **8.2.b**. The commenter did not use the right version. Any consumer who enters a center should have a full social and medical assessment to determine all aspects of his/her condition. The center would have no legitimate way to determine which services the consumer should have, without this assessment. This assessment should be done when the consumer first enters the center. The regulation should stand as written.

8.2.c.1 (8.1.c). Frequency of Assessments

Comment: Assessments may differ from screenings. The Rule should make a distinction between requirements for in depth assessments and for routine screenings. Assessments are expensive and should be geared to consumer needs and preferences.

Additionally, requiring a preliminary assessment prior to admission is an outdated practice. Centers would not admit someone into service unless there was an indication that the service is needed. What would a preliminary assessment entail? Is a preliminary assessment required of someone experiencing a psychiatric crisis?

Response: This is covered in the proposed rule under **8.2.c.1**. The commenter did not use the right version. This point is well taken. The regulation was revised to read "at the time of admission", not "prior to admission".

8.2.c.3 (8.1.c.3). Long Term Assessment

Comment: What is meant by a 'long term assessment?' The Rule needs to include an appropriate definition. What this be a longitudinal study of some sort?

Response: This is covered in the proposed rule under **8.2.c.3**. The commenter did not use the right version. This is defined in the current proposed regulation as "longer than 30 days." The regulation should stand as written.

8.2.c.4 (8.1.c.4). Annual Assessment

Comment: It is inappropriate for the Rule to specify that assessments should be conducted annually. Rather it should be at the discretion of the professional practitioner, or determined by consumer need.

Response: This is covered in the proposed rule under **8.2.c.4**. The commenter did not use the right version. This is a legitimate issue. The regulation has been rewritten to delete "and at least annually." The regulation should stand as written.

8.2.c.1 (8.1.e.1). Record of Assessments

Comment: Assessments or screenings should be entered into the record prior to the delivery of regular services. In the event that assessments were not indicated, the record would indicate a reason.
Response: This is covered in the proposed rule under **8.2.c.1**. The commenter did not use the right version. This is in the current rule under 7.2.d, verbatim. The regulation should stand as written.

8.2.g.2 (8.1.g.2). Frequency of Reviews
Comment: We do not know why the language here specifies 360 days. We assume it is in reference to an annual review. However, it would be better to insert language which conforms to existing industry standards such as reviews at 'critical junctures', or else to be less prescriptive by allowing reviews to occur as consumer individual needs vary.
Response: This is addressed in the proposed rule under **8.2.g.2**. The commenter did not use the right version. The 360 was changed to 365 in the proposed regulation. However, the support plan should be reviewed at least annually. The critical junctures issue is covered in **8.2.g.1.D**. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.3 (7.1.c). Individual Support Plan
Comment: Requiring each consumer to have an individual support plan, or a treatment plan fails to recognize current practice in Medicaid regarding the minimum which may be in place in order to serve what are known as 'low end consumers'. The word 'plan' should be replaced by 'identified needs. '
Response: This has been addressed in the current proposed rule under section 8.3. The commenter was using a previous draft rule. The regulation should stand as written.

8.3 (8.1.f.2). Individual Support Plan Implementation
Comment: Not every consumer will require an individual support plan. Medicaid no longer requires this for those who are receiving 'low end services.'
Response: This is addressed in the proposed rule under **8.3**. The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.3 (8.1.f.4.K). Physician Notes as Part of the Treatment Plan
Comment: Treatment Plans are not required for every consumer. In addition, treatment plans should not have to be re-done in their entirety each time a physician changes a dosage or makes similar changes in overall medication

management for instance. Rather the physician's regular notes and the medication sheets maintained by the center should be sufficient.
Response: This is addressed in the proposed rule under **8.3**. The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.3 (8.1.g). Program Plan Review
Comment: Depending upon whether the consumer receives 24 hour services in a residential licensed setting or whether they receive low end services only, some consumers would have a program plan review, while others would have only case notes. The requirement in this section is too prescriptive given the range of service options available.
Response: This is addressed in the proposed rule under **8.3**. The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written

8.3 (8.5.c). Medications Listed on Treatment Plans
Comment: Not all consumers have a treatment plan if receiving 'low end' services as allowed by existing Medicaid rules. In addition, physician regular notes and medication sheets should satisfy any documentation requirements.
Response: This is addressed in the proposed rule under **8.3**. The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.4 (8.2). Residential Services
Comment: Please clarify if 'residential services' refers only to 24 hour services licensed under the center's umbrella license such as an ICF/MR group home.
Response: This is addressed in the proposed rule under **8.4**. The commenter did not use the right version. 8.4. delineates both licensed and unlicensed residential services. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.4.a (8.2.a). Emergency Medical and Psychiatric Services in Residential Facilities
Comment: 'Assure' should be removed from this draft language. Centers cannot 'assure' availability as listed. They can make the same accommodation as would be available to any resident in any community, that emergency response or emergency vehicles would be accessed via local community response, dialing 911, or, or transport to hospital or other local medical facilities.

Response: This is addressed in the proposed rule under **8.4.a**. The commenter did not use the right version. The examples used by the commenter are ways that a center can 'assure' medical emergency services. The regulation should stand as written.

8.4.b.2 (8.2.b.2). Medical Examinations for Those in Licensed Residential Settings

Comments: 1) Please clarify if this applies to crisis residential units in local communities as well.

2) This should be part of the consumer's routine medical care with the local medical practice. Our own physical examinations' records and medical charts are not kept in our own homes but rather at the doctor's office.

Response: This is addressed in the proposed rule under **8.4.b.2**. The commenter did not use the right version. It does apply to crisis residential units, as they are residential. General consumer records would not be kept in the homes, but at the central office. The center would need to have the information/documents available to employees, in the same way that you and I have access and copies (if we wish) of our medical records. The regulation should stand as written.

8.4.b.4 (8.2.a.4). Policies Regarding Committing or Threatening Assault

Comment: Centers should not be expected to develop a separate policy for threatened or actual assaults by consumers. Rather, the center's regular policy and procedure for emergencies probably contains sufficient protective measures to assure protection and oversight.

Response: This is addressed in the proposed rule under **8.4.b.4**. The commenter did not use the right version. Since the threat of suicide/homicide is in the current rule addressed in 7.8.a, this regulation stands to clarify the existing rule. The regulation should stand as written.

8.4.b.5 (8.2.b.5). Menus Planned by Dietitians

Comment: This is overly prescriptive and not normalizing. We do not have menus at home prepared by licensed dietitians, but we remain well nourished. Annual reviews of menus by dietitians, in addition, will be cost prohibitive.

Response: This is addressed in the proposed rule under **8.4.b.5**. The commenter did not use the right version. The comment is well taken. The regulation was revised to read "the consumers shall be provided foods that promote healthful living."

8.5 (8.3.a). Medical Management
Comment: This section is overly prescriptive. Medical management of center clients is within the purview of their personal physicians in medical clinics and physical healthcare facilities.
Response: This is addressed in the proposed rule under **8.5**. The commenter did not use the right version. This regulation (8.5.b) only applies to residential consumers. The regulation should stand as written.

8.5.b (8.3.b). Medical and Dental Care
Comment: Centers cannot be expected to be medical or dental clinics. It is cost prohibitive to employ general practitioners or dentists. The wording in this section should be changed to eliminate the word 'provide'. In addition, the wording should be altered to allow that there is sufficient evidence that the center attempted to 'arrange' medical and dental care for consumers based upon their individual needs.
Response: This is addressed in the proposed rule under **8.5.b**. The commenter did not use the right version. This was already corrected and now reads "shall either provide or arrange..." The regulation should stand as written.

8.7.a (8.5.h). Medication Administration Record
Comment: This is not realistic for outpatient services, but rather only for 24 hour residential sites.
Response: This is addressed in the proposed rule under **8.7.a.** The commenter did not use the right version. This not required for outpatient services, unless the medications are administered by the outpatient center. The regulation should stand as written.

8.7.b (8.5.b). Orders for Medications Reviewed Each 90 Days
Comment: This is too prescriptive. Our own physicians do not review our medications every 90 days, but rather when new symptoms develop, or the medication begins to lose its previous effectiveness.
Response: This is addressed in the proposed rule under **8.7.b**. The commenter did not use the right version. This is contained in the current rule under 7.10.b., verbatim. The regulation should stand as written.

8.8.b (8.6.b). Assessment of Capability to Self Administer
Comment: This is not realistic for an outpatient service, or with those who are not incapacitated. Assessments are expensive, and must be appropriate for the type of licensed setting under consideration.

Response: This is addressed in the proposed rule under **8.8.b**. The commenter did not use the right version. The whole 8.8. section only pertains to consumers on self administration of medication programs. It does not apply to outpatient. The regulation was changed to add the word "self" prior to medication management.

8.8.c (8.6.c). Medications are Double Locked
Comment: This is an antiquated requirement carried forward from the licensing of state hospital settings. Medical practitioners these days are adequately trained by their professions to safe guard the storage of medications appropriately. Double locking would be cost prohibitive in our multitude of sites.
Response: This is addressed in the proposed rule under **8.8.c**. The commenter did not use the right version. The comment is well taken. The regulation has been revised to read "The center shall provide double locked storage for all controlled substances and single locks for all others."

8.8.d (8.6.d). Refrigeration of Medications
Comment: Some medications are required to be refrigerated. The rule should not be so prescriptive as not to allow licensed agencies to develop their own procedures to safeguard medications which must be refrigerated.
Response: This is addressed in the proposed rule under **8.8.d**. The commenter did not use the right version. This is an infection control issue, as well as an accessibility issue. The regulation should stand as written.

8.9 (8.7.b). Behavior Intervention
Comment: The Rule needs to specify or to define the terms 'routine,' 'problem,' or 'reasonably' when combined with the term 'behaviors'.
Response: This is addressed in the proposed rule under **8.9**. The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

8.9.c (8.7.c). Functional Analysis
Comment: The proposed Rule in this section is completely over stated and overly prescriptive, and does not allow behavioral intervention strategists or psychologists the necessary latitude to do the job for which they were hired, nor does it afford the client an individually customized intervention suited to his particular needs. In addition, there is reference to an interdisciplinary team which mayor may not exist with every consumer entered into service. Nor are there always minutes of treatment team meetings, but rather a treatment plan is generated as the result of a team meeting.

Response: This is addressed in the proposed rule under **8.9.c**. The commenter did not use the right version. This regulation does not limit the types of interventions that may be used, nor does it limit individualized interventions. It does limit how much time a center can spend on assessment prior to the development of a plan. It requires that a rationale must be fully explained through the functional analysis. The regulation should stand as written.

9.1 (9.2). Consumer Protections
Comment: Please provide more definition regarding a 'consumer'. If an agency provides 'low end services' only, for instance, to thirty or fewer individuals must it have a three-member human rights committee?
Response: This is addressed in the proposed rule under **9.1**. The commenter did not use the right version. Consumer is defined in the proposed rule. The regulation should stand as written.

9.3. Eligible Individuals
Comment: For small agencies it would be helpful if family members as well as consumers themselves could be allowed to serve on a human rights committee.
Response:. This is in the current regulation (5.9.c) and is repeated verbatim in the proposed rule. The regulation should stand as written.

10.1. Consumer Rights
Comment: Consumer Rights under this Rule should be consistent with consumer rights in any health care setting already established in law and in Code by the WV Legislature. This Rule should be no different.
Response: This regulation is consistent with the consumer rights section. . The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

10.1.a.5. Rights in General
Comment: The rights specified in this section should be no different than those recognized under Federal and State law.
Response: This regulation is consistent with the consumer rights section. . The commenter did not use the right version. The changes were made regarding this issue in the current proposed rule. The regulation should stand as written.

10.1.c.6 (10.1.c.2). Right to Move About Freely

Comment: This is new language, to allow individuals to move about freely in a day services setting. It might be counter therapeutic to allow an individual to wander in a facility when treatment should be occurring instead. It might also hinder the right to treatment by others receiving services if they are interrupted by the wandering, and it might violate their right to confidentiality.
Response: This is addressed in the proposed rule under **10.1.c.6** as well. Rights may be restricted if to do so is therapeutic, or protect the consumer and/or others. The regulation should stand as written.

10.1.c.7. Acceptable Standards
Comment: More definition is needed here. What are defined as acceptable standards of behavioral and medical practices? Without definition, subjective determinations will be made.
Response: This rule reflects the Behavioral Health Consumer Rights rule. The regulation should stand as written.

10.2.b. Advance Directives
Comment: Consumers should be advised to seek qualified legal advice in preparing an advance directive. Centers should not be asked to provide legal advice.
Response: This rule reflects the Behavioral Health Consumer Rights rule. The regulation should stand as written.

10.4.i. Participation in Plan Development
Comment: The mention of the words treatment plan and individual support plan in this section does not allow the recognition that Medicaid considers some individuals to be 'low end' and not to have requirements for written plans.
Response: This rule reflects the Behavioral Health Consumer Rights rule. The regulation should stand as written.

10.4.m. Outdoor Exercise and Activity Programming
Comment: Exceptions should be allowed here in cases of individuals who are extremely suicidal, for instance, and the team believes they should remain indoors and under supervision.
Response: This rule reflects the Behavioral Health Consumer Rights rule. The regulation should stand as written.

11.11.b (4.11.a). Penalties

Comment: 'Civil penalties' is something which has never appeared in this licensure Rule in the past. We also believe the concept was meant to be 'civil monetary penalties.' However at any rate it is a concept borrowed from the Federal certification activities related to the regulation of Medicare or Medicaid-participating nursing facilities. In addition, no civil monetary penalty amount or range of amounts is specified in this section of the Rule making the assessment of a civil monetary penalty a completely subjective determination.
Response: This is covered in the proposed rule under **11.11.b**. The commenter did not use the right version. Corrections were made in 11.11.b that address these issues. The regulation should stand as written.

12.1 (7.3.c). Health Facilities' Contact Information
Comment: The Rule is too prescriptive. It should require only that the center have an approved grievance procedure which would bring matters eventually to the attention of the Administrator. Centers should not be required to offer the external remedy only of Health Facilities to the exclusion of other bodies such as the WV Advocates, legal representation of their own choosing, and the like.
Response: This is covered in the proposed rule under **12.1**. The commenter did not use the right version. The regulation is in the current rule under 11.1 and is verbatim from that rule. The regulation should stand as written

TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH

SERIES 11
BEHAVIORAL HEALTH CENTERS LICENSURE

§64-11-1. General.

1.1. Scope. -- This rule establishes general standards and procedures for the licensure of behavioral health services and programs. This rule should be read in conjunction with the definitions in W. Va. Code §27-1-1 et seq. and the provisions of W. Va. Code §§27-9-1 and 27-17-1 et seq. The W. Va. Code is available in public libraries and on the Legislature's webpage http://www.legis.state.wv.us/.

1.2. Authority. -- W. Va. Code §§27-9-1 and 27-17-3 and 27-1A-4(g) in conjunction with 27-1A-6(6) and -7.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Repeal and Replacement of Former Rule. -- This legislative rule repeals and replaces "Behavioral Health Centers Licensure," 64CSR11, effective July 1, 2000.

1.6. Purpose. -- This rule is the basis for the licensing and approval of agencies, centers, and other entities providing behavioral health services for residents of West Virginia. Licenses are issued if the applicable rules and regulations are met. The purpose is to regulate the provision of behavioral health treatment for adults and children with behavioral, emotional, and/or developmental challenges caused by mental illness, developmental disabilities addiction/substance abuse and traumatic brain injuries through the formulation, application, and enforcement of minimum licensing requirements.

§64-11-2. Application and Enforcement.

2.1. Application. This rule applies to a Center, as defined by this rule that offers services to individuals with mental illness, mental retardation, behavioral disabilities, developmental disabilities or addiction, or offers preventive services for these disabilities.

2.2. Enforcement. This rule is enforced by the Secretary of the Department of Health and Human Resources.

2.3. Applicability to Other Standards. When an individual receives care or treatment from a behavioral health center, state and federal requirements, accreditation standards applicable to the behavioral health center and the standards set forth in this rule apply. If there is a conflict between those requirements, accreditation standards and the standards specified in this rule, the more stringent standard applies, unless the federal standard must be met for the purposes of Medicare or Medicaid participation, then the federal standard prevails.

2.4. Exceptions.

2.4.a This rule shall not apply to the following:

2.4.a.1. Hospitals, Long Term Care Facilities, and Assisted Living Facilities regulated by the West Virginia Department of Health and Human Resources.

2.4.a.2. Entities operated by the state or federal government.

2.4.a.3. Specialized family care homes under the supervision of the West Virginia Department of Health and Human Resources;

2.4.a.4. Self help groups;

2.4.a.5. Information and referral services;

2.4.a.6. A private practice as defined in this rule;

2.4.a.7. Non-supervised apartment living quarters occupied by consumers of a Center; and

2.4.a.8. Any person providing uncompensated services to a family member.

§64-11-3. Definitions.

3.1. Abuse.

3.1.a. Physical Abuse. -- Any act or failure to act by an employee or staff of a behavioral health service that was knowingly, recklessly, or intentionally performed, or that was failed to be performed, and that caused, or is likely to cause pain, psychological harm, injury, or death to a consumer, including, but not limited to:

3.1.a.1. The rape or sexual assault of the consumer;

3.1.a.2. The striking of a consumer with a part of the body or with an object;

3.1.a.3. Shoving, pushing, pulling, tugging, or twisting any part of the consumer's body with fingers or nails;

3.1.a.4. Burning or sticking the consumer with an object;

3.1.a.5. Acts of retaliation even in response to a physical attack;

3.1.a.6. The use of excessive force when placing an individual in bodily restraints;

3.1.a.7. The use of physical or chemical restraints that is not in compliance with federal or State law; or

3.1.a.7. The use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment.

3.1.b. Psychological/Emotional Abuse. -- Humiliation, harassment, and threats of punishment or deprivation, sexual coercion, intimidation, whereby individuals suffer psychological harm or trauma.

3.1.c. Verbal Abuse. -- Any use of oral, written or gestured language by which abuse occurs. This includes demeaning and derogatory terms to describe persons with disabilities. Verbal abuse includes, but is not limited to:

3.1.c.1. Yelling or using demeaning, derogatory, vulgar, profane or threatening language;

3.1.c.2. Threatening tones in speaking;

3.1.c.3. Teasing, pestering, molesting, deriding, harassing, mimicking or humiliating a consumer in any way; or

3.1.c.4. Making sexual innuendo.

3.2. Advance Psychiatric Directive. -- Any instruction written and signed by a consumer, describing preferences in health care written when the consumer is competent and psychiatrically stable and implemented when the consumer is not able to make informed decisions in the absence of an advance psychiatric directive.

3.3. Administrator. -- The person responsible for carrying out the governing body's policy and the day-to-day operation of the Center.

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. Approved Medication Assistive Personnel. -- The unlicensed facility employee or staff, who meets eligibility requirements, has successfully completed the required training and competency testing, and is considered competent by the facility's registered nurse to administer medications to consumers of the facility in accordance with W. Va. Code §16-50-1.

3.6. 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.

3.7. Behavioral Health. -- Mental health, developmental disabilities, or substance abuse.

3.8. Behavioral Health Services. -- Inpatient, residential or outpatient services for the care, training, and treatment of individuals with mental illness, developmental disabilities or substance abuse.

3.9. Behavioral Intervention Plan. -- A documented plan whose outcome is to teach positive adaptive behaviors and reduce or extinguish maladaptive behaviors in order to allow the individual to function successfully in the environment.

3.10. Center. -- An entity or organization that provides behavioral health services.

3.11. 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.

3.12. Consumer. -- An individual receiving treatment or services in or from the Center.

3.13. Consumer Record. -- A dated and signed documented compilation of information that describes and documents the evaluation and present and prospective treatment of a consumer.

3.14. Corporal Punishment. -- 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.

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

3.15.a. Abuse;

3.15.b. Neglect;

3.15.c. Death due to any cause;

3.15.d. Attempted suicide;

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

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

3.15.g. Any major involvement with law enforcement authorities;

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

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

3.15.j. A potential serious consequence resulting from an apparent error in medication or dietary administration;

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

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

3.16. Detoxification. -- The process of eliminating the toxic effects of drugs and alcohol from the body.

3.17. Discharge. -- The termination of a consumer's affiliation with the Center.

3.18. Discharge Planning. -- The organized process of identifying the approximate length of stay and the criteria for exit of a consumer from the current service, and less restrictive alternatives if possible.

3.19. Documentation. -- A written record relating to compliance with this rule.

3.20. Employee – Any person who performs personal services for the center in exchange for monetary compensation where such personal service, including the results to be accomplished as well as the details and the means by which the results are accomplished, are controlled and directed by the center in accordance with the provision of this rule.

3.21. Emergency Procedures. -- Procedures necessary to control severely aggressive or destructive behaviors that place a consumer or others in imminent danger of physical harm when the timing of those behaviors reasonably could not have been anticipated.

3.22. Functional Analysis. -- A comprehensive assessment process that includes at least: an analysis of the problem behavior, a history of the problem, the antecedent, consequence of the behavior, and an hypothesis as to the function of the behavior.

3.23. Goal. -- An expected result or condition that is specified in a statement of relatively broad scope, and provides guidance in establishing intermediate objectives toward its attainment.

3.24. Governing Body. -- A person or persons with the legal authority and responsibility to set policy and oversee the operations of the Center.

3.25. Human Rights Committee. -- A committee whose primary function is to assist the Center 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. Independent Health Contractor - A licensed, certified, and/or registered health care provider who performs personal services for the center in exchange for monetary compensation, where the center has the right to specify the result to be accomplished by the work, but not the means and methods by which the result is accomplished.

3.27. Individual Support Plan. -- A written design based on the assessment of a consumer's needs and strengths that identifies problems, sets consumer-centered goals and objectives and describes all services, programs and activities currently required to support the achievement of the goals and objectives. See treatment plan.

3.28. Informed Consent. -- The written verification:

3.28.a. That a consumer has or does not have the legal capacity to give informed consent;

3.28.b. That a consumer or his or her legal representative has been informed of the advantages and disadvantages of all aspects of the treatment provided to a consumer; and

3.28.c. That a consumer or his or her legal representative agrees to the treatment.

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

3.30. Legal Representative. -- A person or agency with legal authority to exercise some degree of control over a consumer's affairs; namely, one of the following that is the most appropriate to the decision to be made:

3.30.a. A conservator, temporary conservator or limited conservator appointed pursuant to the West Virginia Legal Guardianship and Conservatorship Act, W. Va. Code §44A-1-1 et seq., within the limits set by the order;

3.30.b. A guardian, temporary guardian or limited guardian appointed pursuant to the West Virginia Guardianship and Conservatorship Act, W. Va. Code §44A-1-1 et seq., within the limits set by the order;

3.30.c. An individual appointed as committee or guardian prior to June 9, 1994, within the limits set by the appointing order and W. Va. Code §44A-1-2(d);

3.30.d. A representative payee under the U.S. Social Security Act, Title 42 US Code §301 et seq., within the limits of the payee's legal authority;

3.30.e. A surrogate decision-maker appointed pursuant to the West Virginia Health Care Decisions Act, W. Va. Code §16-30-8 et seq., or the West Virginia Do Not Resuscitate Act, §16-30C-1 et seq.,

within the limits set by the appointment;

3.30.f. An individual having a durable power of attorney pursuant to W. Va. Code §39-4-1, or a power of attorney under common law, within the limits of the appointment;

3.30.g. An individual identified pursuant to W. Va. Code §16-3C-4 to grant consent for HIV-related testing and for the authorization of the release of test results;

3.30.h. A parent or guardian of a minor; or

3.30.i. An individual lawfully appointed in a similar or like relationship of responsibility for a consumer under the laws of this State, or another legal jurisdiction, within the limits of the applicable law.

3.31. Mechanical Supports. -- Devices used to support or align an individual's proper body position.

3.32. Medication Error. --

3.32.a. The failure to administer a drug ordered by a physician; or

3.32.b. The administration of a drug:

3.32.b.1. Without a physician's order;

3.32.b.2. In the wrong dosage;

3.32.b.3. In the incorrect form;

3.32.b.4. By the incorrect method; or

3.32.b.5. That is incorrect itself.

3.33. Neglect. -- The failure or omission of a caregiver to provide the care, goods, or services necessary to maintain the health or safety of a vulnerable consumer including, but not limited to, food, clothing, medicine, shelter, supervision, and medical services. Neglect may be repeated conduct or a single incident. Neglect includes, but is not limited to:

3.33.a. The failure to establish or carry out a consumer's Individual Support Plan or treatment plan that placed or may have placed a consumer at risk of injury or death;

3.33.b. A failure to provide adequate nutrition, clothing, or health care;

3.33.c. A failure to provide a safe environment;

3.33.d. A failure to follow written center policies and procedures which jeopardizes consumer health or safety; or

3.33.e. A failure to maintain sufficient, appropriately trained staff and employees.

3.34. Objective. -- An expected result or outcome that is stated in measurable terms, has a specified time for achievement and is related to the attainment of a goal.

3.35. Policy. -- A statement of the principles that guide and govern the activities, procedures and operations of a program.

3.36. Positive Programming. -- An educational process for behavior change that is based on a functional analysis of the presenting problems and involves systematic

instruction in more effective ways of behaving.

3.37. Private Practice. -- The individual or group who practice a healing art or behavioral health profession and who hold(s) a license issued by a state health regulatory board as a prerequisite for such practice.

3.38. Procedures. -- The methods by which policies are implemented.

3.39. Program. -- A system of services designed to address the treatment needs of consumers.

3.40. Protective Device. -- Any appliance such as a brace, pad, helmet, covering, bandage, etc., that is used to aid in the healing of an injury.

3.41. Psychiatric Emergency. -- An incident during which a consumer loses control and behaves in a manner that poses substantial likelihood of physical harm to himself or herself or to others.

3.42. Psychotropic Drugs. -- Medications prescribed by physicians to reduce depression, anxiety, and other manifestations of mental or emotional disturbance.

3.43. Quality Assurance. -- A program designed to objectively monitor and evaluate the quality and appropriateness of consumer services and identify methods to improve services and resolve problems.

3.44. Residential Facility. -- A structure in which is provided an interdisciplinary, therapeutic treatment program on a twenty-four (24) hour-a-day basis for behavioral health consumers

3.45. Restraint. -- A system or device to control a consumer, physically and/or behaviorally.

3.45.a. Chemical Restraint. -- The use of medication as a behavior control mechanism to substitute for seclusion or other restraint.

3.45.b. Physical Restraint. -- Any manual method or physical or mechanical device that the individual cannot remove easily, and that restricts the free movement of, normal functioning of, or normal access to a portion or portions of a consumer's body. Examples of manual methods include therapeutic or basket holds and prone or supine containment. Examples of mechanical devices include arm lap belts, side rails, splints, posey mittens, helmets, and straight jackets. Physical guidance and prompting techniques of brief duration and mechanical supports are excluded.

3.46. Seclusion. -- The placement of a consumer alone in a room or enclosed space with closed doors that a consumer cannot open from inside. Persons with a mental retardation/development disability diagnosis may not be secluded.

3.47. Secretary. -- The Secretary of the West Virginia Department of Health and Human Resources or his or her designee.

3.48. Self-Administration of Medications. -- The act of a consumer who is independently capable of reading and understanding the labels of drugs ordered by a physician in opening and accessing prepackaged drug containers, accurately identifying and taking the correct dosage of the drugs as ordered by the physician and the correct time and circumstances.

3.49. Self-Help Group. -- A group with the following components:

3.49.a. Mutual Help. -- All members who receive help also contribute help.

3.49.b. Member-owned and operated.

3.49.c. Members are peers, with the same problem or experience.

3.49.d. Members are volunteers.

3.50. Service. -- A functional division of a program; the delivery of care.

3.51. Staff. -- Any person or persons who perform personal services for the center in exchange for monetary compensation where such personal services, including the results to be accomplished as well as the details and the means by which the results are accomplished, are controlled and directed by the center, regardless of whether monetary compensation is effect through the center's payroll system or the center's accounts payable system.

3.52. Substance Abuse. -- A pattern of psychoactive substance misuse indicated by at least one of the following:

3.52.a. Continued use despite knowledge of having a social, occupational, psychological, or physical problem that is caused or exacerbated by use of the substance; or

3.52.b. Recurrent use in hazardous situations, such as driving.

3.53. Substantial Compliance. -- A level of compliance with the requirements of this rule so as to not to impose a risk to the rights, health and safety of a consumer.

3.54. Time-Out. -- A procedure in which a consumer is isolated from an environment to reduce or eliminate a behavior thought to be reinforced by that environment. Different types of time-out include:

3.54.a. Placing a consumer in a quiet corner of the room; or

3.54.b. Removing the consumer to another room which is not locked.

3.55. Treatment. -- A broad range of planned habilitative and/or rehabilitative services, including diagnostic evaluation, counseling, medical, psychiatric, psychological, training, education, and other social/support services that are provided to enable a consumer to meet identified goals and objectives.

3.56. Treatment Plan. -- A written design based on the assessment of a consumer's needs and strengths that identifies problems, sets consumer-centered goals and objectives and describes all services, programs and activities currently required to support the achievement of the goals and objectives. See Individual Support Plan.

3.57. Variance. -- A declaration that a rule may be accomplished in a manner different from the manner set forth in the rule.

3.58. Volunteer. -- A person who provides direct services for no direct financial remuneration, and who meets the Center's employment qualifications for health, safety, and training.

3.59. Waiver. -- A declaration that a certain regulation is inapplicable in a particular circumstance.

§64-11-4. State Administrative Procedures.

4.1. General Licensure Provisions.

4.1.a. The Center is responsible for compliance with this rule and other relevant federal and state laws.

4.1.b. The Center shall submit data to the Secretary as requested.

4.1.c. All licensed Centers must have a business certificate/license from the Secretary of State.

4.1.d. Before establishing, operating, maintaining or advertising within the State of West Virginia, a Center shall first obtain from the Secretary a license authorizing the operation.

4.1.e. If the Secretary determines not to issue a license as applied for, the applicant is notified.

4.1.f. A license is valid for the Center named in the application and is not transferable.

4.1.g. An expired or otherwise invalid license shall be surrendered to the Secretary on written demand.

4.2. License Application.

4.2.a. The governing body shall ensure adequate resources to support the Center's services. If a new Center or an expansion of an existing Center, the governing body must demonstrate sufficient operating funds for at least six (6) months. Such demonstration may include reserves, line of credit, or history of adequate cash flow from an existing program to support a new program for six months.

4.2.b. An application shall identify all service locations and offices operated by the Center.

4.2.c. Initial applications shall be received by the Secretary not less than thirty (30) days and not more than sixty (60) days prior to the initiation of services, along with a non refundable fee, and any additional information the Secretary may require.

4.2.d. Renewal applications shall be received by the Secretary not less than ninety (90) days prior to the expiration of the current license, along with a non refundable fee, and any additional information the Secretary may require.

4.2.e. Amended license applications are required by the Secretary under the following circumstances:

4.2.e.1. A change in the geographic location of a service or facility;

4.2.e.2. A change in bed capacity; or

4.2.e.3. Any extensive renovation or conversion of an existing facility costing in excess of $5000.

4.2.f. There will be a $500 penalty assessed from any Center that does not amend its license pursuant to this rule.

4.2.g. An application for an initial or renewal license shall identify the governing body, and administrator of the Center by name and home address.

4.2.h. An application shall be accompanied by the following:

4.2.h.1. Insurance coverage to include general, professional and vehicular

liability and property damage;

4.2.h.2. Evidence that the Center will be audited at least annually by an independent certified public accountant;

4.2.h.3. The annual budget approved by the governing body; and

4.2.h.4. Any policies or procedures created or amended since the last survey.

4.2.i. After a complete application with required fee for a renewal license has been received, according to Subsection 4.4.b., the existing license shall not expire until the new license has been issued or denied.

4.3. Fees.

4.3.a. A nonrefundable application fee in the amount of $100 for an initial or amended behavioral health license shall be paid at the time application is made for the license.

4.3.b. All direct costs for the initial licensure inspection shall be borne by the applicant and shall be received by the Secretary prior to the issuance of an initial license.

4.3.c. The license fee for renewal of a license shall be at the rate of $250 plus $25 per licensed bed, if any.

4.3.d. The Secretary may annually adjust the licensure fees for inflation based upon the consumer price index.

4.4. Issuance.

4.4.a. An initial, renewal, or provisional license shall not be issued, unless an inspection has been completed.

4.4.b. Following an application review, and onsite inspections and plans of correction, the Secretary shall, if there is substantial compliance with this rule, issue a license in one of three categories:

4.4.b.1. An initial six (6) month license shall be issued to a Center establishing a new program or service found to be in substantial compliance on initial review with regard to policy, procedure, organization, and recordkeeping regulations;

4.4.b.2. A provisional license shall be issued when a Center seeks a renewal license, and the Center is not in substantial compliance with this rule, but does not pose a significant risk to the rights, health and safety of a consumer. It shall expire not more than six (6) months from date of issuance, and not be consecutively reissued, unless based on the provisional recommendation is that of the state fire marshal; or

4.4.b.3. A renewal license shall be issued when a Center is in substantial compliance with this rule, and shall expire not more than two (2) years from date of issuance. A license may be issued for any duration up to two (2) years at the discretion of the Secretary.

4.4.c. The Secretary may provide consultation and technical assistance in obtaining compliance with this rule.

4.4.d. The Center shall notify the Secretary within thirty (30) days after the name of the Center is changed and apply for license renewal.

4.5. Construction and Renovation.

4.5.a. For new construction, renovations, and alterations, a Center shall submit to the secretary for review, complete construction drawings and specifications for the Center's construction project which alters a floor plan, impacts life safety, or requires approval under W. Va. Code §16-2D-1 et seq. prior to beginning work on the project. An architect or engineer registered to practice in West Virginia shall prepare and sign the drawings and specifications including architectural, life safety, structural, mechanical, and electrical drawings and specifications.

4.5.b. Prior to starting any renovations, a Center shall complete an infection control and safety risk assessment and shall develop a plan to control exposure of consumers, employees, staff, and the public. This plan shall be implemented prior to and during construction phases.

4.5.c. Site Selection.

4.5.c.1. There shall be adequate drainage, electricity, telephone, sanitation, water, transportation, and other necessary facilities available on or near the site.

4.5.c.2. Local building codes and zoning restrictions shall be observed. Where local codes or regulations permit lower standards than required by this rule, the standards contained in this rule shall take precedence.

4.5.c.3. Site conditions shall comply with the relevant sections of the current edition of "The Guidelines for Design and Construction of Hospital and Healthcare Facilities" as recognized by the American Institute of Architects Academy of Architecture for Health.

4.5.c.4. A Center shall request in writing an inspection of a proposed site and obtain approval for construction from the Secretary before beginning construction.

4.5.c.5. The Secretary shall inspect new locations for all residential facilities and additions to existing residential facilities prior to the architect's beginning work on final drawings and specifications.

4.6. Inspections.

4.6.a. To carry out the intent of this rule, the Secretary requires inspections by authorized representatives.

4.6.b. Inspections shall include, but are not limited to:

4.6.b.1. Observation of the service delivery milieu;

4.6.b.2. Review of life safety and environment;

4.6.b.3. Review of clinical and administrative records; and

4.6.b.4. Interviews with consumers, employees, staff and/or administrators.

4.6.c. Each licensed Center shall be inspected at least once every two (2) years, except for residential facilities that are inspected at least once a year.

4.6.d. A licensed Center shall be inspected ninety (90) days prior to the expiration of its license, at a minimum.

4.6.e. If a licensed Center is accredited by an accreditation body, it shall supply copies of all relevant accreditation

reports to the licensing body within ten (10) days of receipt.

4.6.f. Inspections shall include every licensed location operated by the Center, if feasible.

4.6.g. The Center shall comply with any reasonable requests from the Secretary to have access to the service, staff, employees, consumers (with their permission), and records.

4.6.h. Within fifteen (15) working days of completion of an inspection, the Secretary shall issue a report.

4.6.i. Based on a Center's previous substantial compliance with this rule, an onsite inspection is not always required for issuance of an amended license.

4.6.j. The Center may contest any finding by the Secretary or oversight body. Such disagreement must be supported by documentation or other credible evidence. Appeals of citations must be filed in writing with supporting documentation and may be followed if necessary by an informal meeting for the purposes of dispute resolution should either party desire.

4.7. Complaint Investigation.

4.7.a. Any person may file a complaint with the Secretary alleging violation of applicable laws or rules by a Center. A complaint shall state the nature of the complaint and the Center by name.

4.7.b. The Secretary may conduct unannounced inspections of Centers or services involved in a complaint and any other investigations necessary to determine the validity of a complaint.

4.7.c. At the time of the investigation, the investigator shall notify the administrator or person in charge of the location involved in the complaint and the general reason for the complaint, without identifying the complainant.

4.7.d. Within fifteen (15) working days of the investigation, the Secretary shall provide to the Center a written report of the results of the investigation, along with any violations.

4.7.e. The Secretary shall provide to the complainant a determination of whether the complaint was substantiated. The secretary may provide to the complainant a description of the corrective action the Center is required to take and of any disciplinary action the Secretary will take.

4.7.f. The names of a complainant and of any consumer involved in the complaint or investigation, and any information that could reasonably lead to their identification, shall be kept confidential and shall not be disclosed without their written consent, and before disclosure of investigative information to the public such identifying information shall be deleted, unless the public interest requires disclosure in the particular instance.

4.7.g. 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.h. Centers are prohibited from discriminating in any way against a consumer, staff, or employee who has been a complainant, on whose behalf a complaint has been submitted or who has participated in an investigation process.

4.7.i. The Secretary may suspend or revoke a license for violating the prohibitions of this section.

4.8. Reports and Records.

4.8.a. The Secretary shall keep on file a report of any inspection or investigation.

4.8.b. A report shall specify the deficiency and the provision of the rule it violates, and describe the precise data that supports such a deficiency.

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

4.8.c.1. As specified in Subsection 4.7. of this rule;

4.8.c.2. Information of a personal nature from a consumer or personnel file; and

4.8.c.3. Information required to be kept confidential by state or federal law.

4.8.d. A report made public shall also state whether a plan of correction has been submitted to, or approved by the Secretary.

4.9. Plans of Correction.

4.9.a. Within ten (10) working days after receipt of the inspection report, the Center shall submit to the Secretary, for approval, a written plan to correct all deficiencies that are in violation of this rule, unless a variance is requested by the Center and granted by the Secretary. The plan shall specify:

4.9.a.1. Action taken or procedures proposed to correct the deficiencies and prevent their reoccurrence;

4.9.a.2. Date of completion of each action taken or to be taken; and

4.9.a.3. Signature of the administrator or his or her designee.

4.9.b. The Secretary shall approve, modify or reject the proposed plan of correction in writing. Modifications may be made by the Center in conjunction with the Secretary.

4.9.c. The Secretary shall state the reasons for rejection or modification of any plan of correction.

4.9.d. When the Secretary rejects a plan of correction, a revised plan shall be submitted within ten (10) working days upon receipt of the rejection. The Secretary may issue a directed plan of correction if the revised plan submitted by the Center is not approved.

4.9.e. The Center shall immediately correct a violation that severely risks the health or safety of a consumer or other persons.

4.9.f. The Secretary may determine if corrections have been made.

4.9.g. The Center shall make the results of the Office of Health Facility Licensure and Certification's surveys, inspections, and investigations as well as plans of correction available for examination in a place readily accessible to consumers and shall post a notice of their availability.

4.10. Waivers.

4.10.a. The Secretary may grant a waiver or variance to a provision of this rule

if its application clearly would be impractical and if any alternate arrangements are not detrimental to the health, well-being, or safety of the consumer of the entity or Center

4.10.b. All waivers shall be in writing.

4.10.c. No waiver may be granted for an issue involving the health or safety of consumers or that violates any state or federal statute.

4.10.d. A waiver shall be granted with each licensure renewal.

§64-11-5. Management and Administration.

5.1. Operating Authority.

5.1.a. The Center has documentation of the source of its operating authority, e.g., certificate of incorporation, partnership agreement, prominently displayed.

5.1.b. The Center and all of its service locations shall prominently display a current license, except in residential facilities where it shall be shown upon request.

5.2. Governing Body.

5.2.a. The Center shall have a governing body that sets policies, develops a mission statement, defines services, guides development and ensures the accountability of the Center

5.2.b. The governing body shall evaluate and ensure implementation of its policies.

5.2.c. The governing body shall appoint an administrator who has the authority and responsibility to manage the Center and implement policy.

5.2.d. The governing body members must:

5.2.d.1. Receive an orientation to the governing body, to the responsibilities of membership, and to the Center's organization, mission, and history;

5.2.d.2. Receive a current manual that specifies the member's fiduciary and other responsibilities to the organization;

5.2.d.3. Be instructed as to federal and state rules of confidentiality;

5.2.d.4. Receive annual reports from management;

5.2.d.5. Maintain minutes and records generated from all meetings, if the governing body is more than one person;

5.2.d.6. Hold quarterly meetings at a minimum;

5.2.d.7. Maintain comprehensive policies and procedures that include governing body-approved policy statements each of which shall included effective dates and most recent dates of revision;

5.2.d.8. Ensure that the comprehensive policies and procedures shall be available to all staff in all programs; and

5.2.d.9. Ensure that the Center complies with all laws related to fiscal accountability and governance.

5.3. Administration.

5.3.a. The governing body shall appoint an administrator.

5.3.b. The governing body shall evaluate the administrator's performance in writing at least annually.

5.3.c. The administrator shall define structure and lines of authority for the Center.

5.3.d. The administrator shall develop a plan of operation with a mission statement, program goals and a description of services.

5.4. Conflicts of Interest.

5.4.a The Center shall have a policy which defines and prohibits conflicts of interest.

5.5. Fiscal Protections.

5.5.a. The Center shall purchase insurance including, but not limited to: general liability, workers' compensation, professional liability, automotive liability for Center-owned or leased vehicles, and malpractice.

5.5.b. The Center shall ensure that all employees who sign checks, handle cash or contributions, or manage consumer funds, are bonded or that the Center maintains insurance coverage to cover potential losses at no cost to the consumer.

5.5.c. A Center that provides transportation for consumers served as part of a service shall maintain adequate vehicular insurance coverage.

5.5.d. All insurance policies shall be at a financial level adequate to cover the Center in case of accident or suit. All bonding policies shall be adequate to replace the aggregate of funds managed by the Center.

5.6. Consumer Funds.

5.6.a. The governing body shall establish policies and operational procedures that comply with legally applicable requirements regarding the protection of consumer's assets under the control of the Center.

5.6.b. If the Center handles consumer funds or disburses non-fee-for-service funds, such as allowance funds, the Center is a fiduciary for the funds and shall maintain a current record and keep separate accounts for each consumer's funds. The Center shall provide to a consumer at least monthly and upon request, a statement of his or her account.

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

5.6.d. Centers shall allow a consumer or his or her legal representative to use his or her personal funds.

5.6.e. Centers shall not commingle a consumer's funds with the Center's funds or with the funds of any person other than another consumer.

5.6.f. If a Center handles consumer funds in excess of $25 per consumer and in excess of $500 for all consumers per month, the Center shall obtain a bond in an amount approved by the Secretary sufficient to cover all consumer accounts, and the amount shall not be less than $2500. When the amount of any bond is insufficient to adequately protect the funds of consumers, the Center

shall obtain an additional bond in such amount as necessary to adequately protect the funds of consumers.

5.7. Center Responsibility.

5.7.a. Centers shall clearly define the population for whom services are designed, so as to inform potential consumers and referral sources of the Center's capacities, availability, and the means required for payment of those services.

5.7.b. Centers shall develop and implement a code of ethics that includes, but is not limited to those provisions covered in Section 10 of this rule.

5.7.c. At the time of, or prior to, service delivery, the Center shall inform a consumer in writing of charges for services.

5.7.d. The Center will release consumer information only according to its written policies and legal requirements.

5.7.e. Centers shall not discriminate in any matter of employment on the basis of race, color, national origin, ancestry, religion, disability or gender, or any other category protected by applicable law.

5.7.f. If the Center uses volunteers, it shall implement written policies and procedures for the utilization of volunteers.

5.7.g. The Center shall ensure that all allegations of neglect or abuse, as well as injuries of unknown sources, are reported immediately to the administrator or to other officials in accordance with state law.

5.7.h. Except as permitted by law, before releasing information about a consumer, the Center shall obtain consent from the consumer, or his or her legal representative, that includes the following:

5.7.h.1. Specific information to be released;

5.7.h.2. The time-period in which this consent is in effect;

5.7.h.3. The recipients;

5.7.h.4. The purpose of the release;

5.7.h.5. The date on which the release is signed;

5.7.h.6. The event or condition upon which the authorization expires; and

5.7.h.7. Information as to how and when the authorization can be revoked.

5.7.i. The Center shall protect the confidentiality of a consumer by prohibiting:

5.7.i.1. A consumer's participation in public performance without the consent of the consumer or his or her legal representative; and

5.7.i.2. The use of photographs or videotapes for public relations purposes without the consent of the consumer or his or her legal representative.

5.7.j. Except in cases of abuse, neglect or exploitation in which the Center has responsibility to report to protective services, a consumer or his or her legal representative shall be the primary source of information about the consumer's service needs.

5.7.k. The Center shall have and periodically review and revise policies for

effective service delivery and protection of consumer rights and shall provide a copy or make a copy of these policies available to all new employees.

5.7.1. The Center shall implement a policy pertaining to communicable diseases affecting consumers, employees, and staff.

5.8. Relationships with Other Providers.

5.8.a. If the Center arranges externally or contractually for the provision of services, the Center shall have a written agreement or contract, which specifies:

5.8.a.1. Roles and responsibilities of the Center and the external entity;

5.8.a.2. Documentation required of the external entity with timelines for provision of such documentation;

5.8.a.3. Services to be provided and timelines for such service delivery;

5.8.a.4. Provision of liability or malpractice insurance either by the Center or external entity;

5.8.a.5. Procedures for the exchange of information;

5.8.a.6. Consumers to be served;

5.8.a.7. Terms of payment; and

5.8.a.8. Assurances that the external entity adheres to state and federal requirements governing the provision of the contracted services.

5.8.b. The Center shall maintain a record on each independent health contractor who provides direct services to Center consumers, including:

5.8.b.1. Job description for the service(s) provided;

5.8.b.2. Identifying information and emergency contacts;

5.8.b.3. Verification of education;

5.8.b.4. Verification that the independent health contractor meets all criteria for the position as stated in the job description;

5.8.b.5. Records of orientation and current training as required for full time independent contractors or the documented lack of need for such training;

5.8.b.6. Performance evaluations;

5.8.b.7. References;

5.8.b.8. Criminal background check;

5.8.b.9. Verification of nurse aide abuse registry and national sex abuse registry check, if applicable; and

5.8.b.10. An Adult Protective Services and Child Protective Services background check.

5.8.c. Multiple Service Providers.

5.8.c.1. If a Center serves consumers who are also served by another Center or Centers, there shall be a written agreement or memorandum of understanding between the Center delineating the responsibilities and functions of each.

5.8.c.2. There shall be evidence that the procedures are mutually agreeable to both Centers.

5.8.c.3. A Center shall not refuse to provide services to a consumer on the basis that the consumer is being served by another agency.

5.9. Personnel.

5.9.a. The Center shall have policies that address unemployment and workers' compensation.

5.9.b. The Center shall provide an adequate number of qualified personnel during all hours of operation to support the functions of the Center and ensure the provisions of quality care.

5.9.c. Criminal background checks covering all fifty (50) states shall be completed for all staff, employees, and independent health contractors, within thirty (30) days of hiring. Organizational policy shall prohibit employment of staff, employees, or independent health contractors who have a history of conviction for:

5.9.c.1. Abduction;

5.9.c.2. Any violent felony crime including, but not limited to, rape, sexual assault, homicide, felonious physical assault, or felonious battery;

5.9.c.3. Child/Adult abuse or neglect;

5.9.c.4. Crimes which involve the exploitation of a child or an incapacitated adult;

5.9.c.5. Domestic battery or domestic assault;

5.9.c.6. Felony arson;

5.9.c.7. Felony or misdemeanor crime against a child or incapacitated adult which causes harm;

5.9.c.8. Felony drug related offenses within the last the ten (10) years;

5.9.c.9. Felony DUI within the last the ten (10) years;

5.9.c.10. Hate crimes;

5.9.c.11. Kidnapping;

5.9.c.12. Murder/Homicide;

5.9.c.13. Neglect or abuse by a caregiver;

5.9.c.14. Pornography crimes involving children or incapacitated adults;

5.9.c.15. Purchase or sale of a child; and

5.9.c.16. Sexual offenses including, but not limited to, incest, sexual abuse, or indecent exposure.

5.9.d. The Center shall have evidence that staff and employees directly serving consumers are not listed on the National Sex Abuse Registry and the Nurse Aide Abuse Registry for West Virginia and the state in which the staff or employee resides, if available.

5.9.e. For all employees, the Center shall maintain a personnel record that includes:

5.9.e.1. The job description and application;

5.9.e.2. Identifying information and emergency contacts;

5.9.e.3. References;

5.9.e.4. Verification of education for employees;

5.9.e.5. Verification that the employee meets all criteria for their position as stated in the job description;

5.9.e.6. Orientation and training records; and

5.9.e.7. Employee performance evaluations.

5.9.f. The Center shall provide to an employee, or to his or her designee, access to his or her personnel record.

5.10. Personnel Training.

5.10.a. Beginning on the first day of employment, professional and direct care employees shall begin orientation and training on treatment policies and procedures, consumer rights and the use of emergency procedures, such as crisis intervention and restraints. Training shall be kept current.

5.10.b. As part of employee orientation, all direct care employees and staff shall be trained in first aid, infectious disease control, cardiopulmonary resuscitation and Heimlich maneuver. These shall be kept current.

5.10.c. Employees and staff providing services to consumers shall be trained in the proper care of the consumers to whom they will be providing services (including special needs, health, and behavioral health needs) prior to, or within ten (10) days after being assigned to work with the individual. Fully trained staff shall be available until newly hired staff are fully trained.

5.10.d. The Center shall have a training and development program that allows employees to improve their knowledge, skills and abilities.

5.10.e. Staff and employees shall be able to demonstrate the skills and techniques necessary for their jobs and provide evidence that they are qualified to perform the functions associated with them.

5.10.f. All professional employees, professional independent health contractors, and consultants of the Center shall be in compliance with applicable State professional licensure requirements.

5.10.g. Specialized Personnel Requirements.

5.10.g.1. Employees and staff providing direct care to consumers shall be eighteen (18) years of age or older and capable of performing the duties assigned.

5.10.g.2. Employees who are hired as mental health or substance abuse professionals must be either fully credentialed to practice mental health or substance abuse treatment or actively working on becoming fully credentialed to practice mental health or substance abuse treatment.

5.10.g.3. Staff and employees who are hired to provide mentally retarded/developmentally disabled waiver services shall be fully credentialed in compliance with state mentally

retarded/developmentally disabled waiver standards.

5.10.g.4. Approved medication assistive personnel shall meet all the criteria specified in "Medication Administration by Unlicensed Personnel," 64CSR60.

5.11. Records Management.

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

5.11.b. Consumer records shall contain information essential to the services or treatment and include, but not be limited to:

5.11.b.1. Identification data;

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

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

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

5.11.b.5. Treatment plans and special treatment procedures;

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

5.11.b.7. Legal representative documents;

5.11.b.8. Court orders; and

5.11.b.9. A record of any signed and dated physician's orders prescribed by the Center's physician.

5.11.c. Consumer records shall be retained for a minimum of six (6) years following discharge. In the case of minors, records shall be retained until six (6) years after the consumer's eighteenth birthday.

5.11.d. Consumer records shall be released without written consent as follows:

5.11.d.1. In a proceeding to disclose the results of an involuntary civil commitment;

5.11.d.2. In a proceeding to disclose the results of an involuntary examination:

5.11.d.3. Pursuant to a court order based upon a finding that said information is sufficiently relevant to a proceeding before the court to outweigh the importance of maintaining the confidentiality established by this rule;

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

5.11.d.5. For treatment or internal review purposes, to employees of the mental health facility where the consumer is being cared for or to other health professionals involved in treatment of the consumer;

5.11.d.6. To the medical examiner's office and child and adult protective services during an open investigation;

5.11.d.7. As provided under the Privacy Rule of the Federal Health Insurance Portability and Accountability Act of 1996, 45 CFR §164.506 for thirty (30) days from the date of admission to a mental health facility if: (i) the Center makes a good

faith effort to obtain consent from the consumer or legal representative prior to disclosure; (ii) the minimum information necessary is released for a specifically stated purpose; and (iii) prompt notice of the disclosure, the recipient of the information, and the purpose of the disclosure is given to the consumer or legal representative.

5.11.d.8. To the state's federally mandated protection and advocacy system, pursuant to access authority provided under the PAIMI (Protection and Advocacy for Individuals with Mental Illness) Act at 42 USCA 10805-10806 and the PADD (Protection and Advocacy for Individuals with Developmental Disabilities) Act at 42 USC 10542.

5.11.e. A consumer's records shall be released only with the written consent of the consumer or his or her legal representative and only to the persons and to the extent necessary to satisfy the purpose of the release.

5.11.f. No consent or authorization for the transmission or disclosure of confidential information is effective unless it is in writing and signed by the patient or by his or her legal representative.

5.11.g. Every person signing an authorization shall be given a copy.

5.11.h. The Secretary shall have full access to a consumer's records as needed in administering state and federal requirements.

5.11.i. The Center shall ensure reasonable safety and protection of records, including service and organizational records, from destruction by fire, water, loss, or other damage, and from unauthorized access.

5.12. Quality Assurance.

5.12.a. The Center shall have and implement a systems review of the appropriateness and effectiveness of consumer services, which includes peer review/document review, health and safety review of all facilities, and a review of the outcomes, including an analysis of the results of treatment plan reviews and of reports by the human rights committee.

§64-11-6. Health and Safety.

6.1. Transportation Services.

6.1.a. When transportation is provided for consumers, the Center shall maintain adequate insurance coverage.

6.1.b. Employees and staff transporting consumers in their own vehicles as a part of their duties shall provide the Center with evidence that they are insured in case of automobile accident.

6.1.c. The Center shall have and follow written policies and procedures for:

6.1.c.1. Proper maintenance of vehicles;

6.1.c.2. Adequate passenger supervision;

6.1.c.3. Appropriate passenger restraining systems;

6.1.c.4. Licensure of drivers; and

6.1.c.5. Provision of first-aid kits in each vehicle.

6.2. Physical Environment.

6.2.a. General.

6.2.a.1. The provisions of this section shall apply to all behavioral health facilities. A behavioral health site licensed prior to the effective date of this rule shall be maintained in accordance with applicable standard of practice as referenced in the current edition of the Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy for Health.

6.2.a.2. The Center shall implement programs in an environment that is safe, accessible, sanitary, and appropriate for the needs of the consumers.

6.2.a.3. The following documents are adopted as construction, equipment, physical facility, and related procedural standards for all new construction and any additions, alterations, renovations, or conversions of existing buildings.

6.2.a.3.A. The Center shall meet regulatory requirements for Psychiatric Facilities in the 2006 edition of the Guidelines for Design and Construction of Hospital and Healthcare Facilities as recognized by the American Institute of Architects Academy for Health, where applicable.

6.2.a.3.B. The Center shall comply with the West Virginia Code as the 2003 edition of the International Building Code.

6.2.a.3.C. The Center shall comply with the guidelines set forth in the Americans with Disabilities Act (28 CFR Part 36) and shall develop a plan to address the most significant 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 Center.

6.2.a.3.D. All Centers shall follow the current State Fire Code as adopted by the State Fire Commission.

6.2.a.4. The Center shall provide adequate housekeeping, laundry, maintenance, storage, and other administrative support functions required to carry out its services.

6.2.a.5. The Center shall have procedures for infection control, emergency preparedness to identify, monitor, reduce and eliminate health and safety risks.

6.2.a.6. The Center shall evaluate the likelihood of exposure to blood borne pathogens for all persons likely to come in contact with blood.

6.2.a.7. The Center shall have written procedures to deal with fire, medical emergencies, natural disasters and other life-threatening situations.

6.2.a.8. The Center shall post by the telephone in all direct care and residential service locations, emergency telephone numbers for the fire department, local police and on-call employees, and capable consumers shall be instructed on how to use them.

6.2.a.9. A standard first-aid kit shall be readily accessible at all times at each site.

6.2.b. Fire Code.

6.2.b.1. The Center shall have evidence that facilities rented, owned or

used for services are in full compliance with applicable rules of the West Virginia State Fire Commission.

6.2.b.2. The Center shall conduct quarterly fire drills in its residential and daytime group setting locations, some of which shall be held during rest or sleeping periods.

6.2.b.3. The Center shall have fire extinguishers reviewed by a qualified professional annually.

6.2.c. Requirements for Residential Facilities and 24 Hour Residential Treatment Services.

6.2.c.1. For construction occurring after the enactment of this rule, bedrooms shall provide a minimum of one hundred (100) square feet of floor space per person for one (1) person occupancy and a minimum of eighty (80) square feet of floor space per person for two (2) person occupancy. There shall be a maximum of two (2) persons per bedroom.

6.2.c.2. Each consumer 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.

6.2.c.3. Each room shall be arranged in consideration of the consumer's clinical needs.

6.2.c.4. Each room shall be arranged and equipped to preserve the dignity, comfort, and privacy of consumers.

6.2.c.5. Each bedroom shall be directly accessible from a corridor or common use activity room and have an exterior window. Each bedroom shall have windows covered for privacy.

6.2.c.6. Furnishings shall be homelike and personalized and maintained in good condition.

6.2.c.7. There shall be separate storage areas for items including: foodstuffs, utensils, work materials and cleaning supplies, clothing, linens, and medicines.

6.2.c.8. Poisons and other potentially hazardous items shall be kept in a locked place, but may be used by consumers who have been trained to use them.

6.2.c.9. There shall be a sufficient number 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 one hundred ten (110) degrees Fahrenheit. The minimum number of bathrooms is calculated at a minimum of one per ten consumers.

6.2.c.10. Solid waste storage shall be sufficient to contain all solid waste in a safe and sanitary manner.

6.2.c.11. Solid waste, including garbage and refuse, shall be removed from the premises weekly, or more often, if necessary.

6.2.c.12. Grounds and structures shall be maintained free of insects and rodents of public health significance.

6.2.c.13. Food shall be stored, prepared and served in a sanitary manner.

6.2.c.14. Food services, when provided, shall:

6.2.c.14.A. Meet or exceed national nutritional standards; and

6.2.c.14.B. Provide three well-balanced meals and snacks. Exceptions may be approved by the Secretary.

6.2.c.15. Use of paper and/or throw-away plates, beverage containers and utensils are to be limited and not used in day-to-day meal service.

6.2.c.16. A minimum of an emergency three (3) day supply of food sufficient for all consumers provided food services shall be maintained.

6.2.c.17. Each site shall have an emergency operations plan in effect for managing the consequences of power failures, natural disasters, and other emergencies that would interrupt normal operations or affect the Center's ability to provide care.

§64-11-7. Consumer Services Standards - General.

7.1. Applicability.

7.1.a. General Consumer Services Standards apply to all licensed Centers.

7.2. Program Description.

7.2.a. Each program shall have a written description that shall include:

7.2.a.1. A description of the population to be served;

7.2.a.2. A description of the types of services offered; and

7.2.a.3. Exclusion criteria.

7.2.b. The Center shall admit only those consumers whose service needs are consistent with its service description, to whom services are available, and for which staffing levels and types meet the needs of the consumers to be served.

7.2.c. The Center shall assure that all services provided shall be based on each consumer's identified needs.

7.3. Consumer Screening.

7.3.a. The Center shall maintain written documentation of each screening performed, including:

7.3.a.1. Date of initial contact;

7.3.a.2. Name, age, and gender of the individual;

7.3.a.3. Address and phone number, if applicable;

7.3.a.4. Presenting needs or situation to include psychiatric/medical problems, current medications and history of medical care;

7.3.a.5. Name of screening employee or independent health contractor;

7.3.a.6. Method of screening;

7.3.a.7. Screening recommendation; and

7.3.a.8. Disposition of individual referral.

7.3.b. The Center shall retain documentation for each screening. For individuals not admitted, documentation shall be retained for one hundred eighty

days. Documentation shall be included in the individual's record, if the individual is admitted.

7.4. Consumer Admission.

7.4.a. A consumer or his or her legal representative shall sign a written consent for the Center's services prior to treatment.

7.4.b. The consumer or his or her legal representative shall sign verification that he/she was informed in writing of his/her rights as contained in Section 10 of this rule upon admission.

7.4.c. Upon admission, the consumer or his or her legal representative shall sign verification that he/she was informed in writing that he/she may contact the Office of Health Facility Licensure and Certification if they are unsatisfied with any aspect of their treatment. This information shall include the address, phone number, and fax number for such contact.

7.4.d. The Center shall have a formal intake process that assesses a consumer using its criteria for admission and only admits a consumer who meets those criteria.

7.4.e. Intake documentation shall include all relevant preliminary screening, diagnostic, social, medical and legal information, and shall be signed and dated by the person completing the intake.

7.5. Consumer Discharge.

7.5.a. Discharge planning shall be based on consumer needs.

7.5.b. A written discharge summary shall be entered in a consumer's record within thirty days of discharge and include:

7.5.b.1. The reasons for discharge;

7.5.b.2. A consumer's status and condition at discharge;

7.5.b.3. A final evaluation summary of a consumer's progress toward the goals set in the treatment plan;

7.5.b.4. A plan developed in conjunction with the consumer, when available, for care after discharge and for follow-up; and

7.5.b.5. The signature of the staff completing the summary.

7.6. Critical Incidents.

7.6.a. The Center shall maintain a system for critical incident reporting and tracking and demonstrate that it uses the system to protect the rights, health, and safety of consumers.

7.6.b. The Center shall classify each incident as:

7.6.b.1. An allegation of abuse and/or neglect;

7.6.b.2. A critical incident; or

7.6.b.3. An incident requiring monitoring and follow-up.

7.6.c. The Center shall investigate all incidents. When multiple Centers or agencies are involved in an investigation, the investigation may be cooperative. This shall not negate the timelines for investigation.

7.6.d. Allegations of abuse and/or neglect shall be reported immediately to the

following entities:

7.6.d.1. Adult Protective Services, Institutional Investigative Unit, or Child Protective Services, as applicable;

7.6.d.2. The Office of Health Facility Licensure and Certification;

7.6.d.3. The guardian/health care surrogate, if any;

7.6.d.4. Any advocate identified in the consumer record and/or the State's federally mandated protection and advocacy system; and

7.6.d.5. The administrator or designee.

7.6.e. The Center shall have and implement investigative policies and procedures that comply with the Office of Health Facility Licensure and Certification Guidelines for Incidents.

7.6.f. If the findings and actions of a Center following an investigation are unfavorable, insufficient, or not forthcoming within the timelines specified in Subsection 7.6.e. of this rule, the affected consumer or his or her legal representative may appeal to the grievance process of the Center, the State licensure body, an advocate, or other appropriate resource, including an attorney. Consumers shall be informed of the appeal process in writing.

7.6.f.1. The final order by the Secretary after a hearing before the State licensure body shall be binding upon the parties, unless appealed in accordance with W. Va. Code §§29A-5 and 29A-6.

7.7. Medical Information.

7.7.a. The Center shall maintain a health history and emergency medical information for all consumers.

7.7.a.1. The health history shall include:

7.7.a.1.A. Allergies and symptomatologies;

7.7.a.1.B. Recent medical complaints and conditions;

7.7.a.1.C. Chronic conditions and duration;

7.7.a.1.D. Communicable diseases and treatment;

7.7.a.1.E. Disabilities or restrictions on physical activities, if any, and any adaptive equipment needed;

7.7.a.1.F. Past serious illnesses, serious injuries, and hospitalizations;

7.7.a.1.G. Current or past drug usage including alcohol, prescription and nonprescription medications, illicit drugs, and current treatment, if any;

7.7.a.1.H. Sexual health and reproductive history;

7.7.a.1.I. Routine laboratory reports and communicable disease screening as recommended by the Centers for Disease Control and Prevention; and

7.7.a.1.J. Immunization history and records.

7.7.a.2. The health history shall be completed as a part of the screening process.

7.7.a.3. The emergency medical information shall include:

7.7.a.3.A. The current name, address, and phone number of the consumer's primary care physician, and any recently seen specialists;

7.7.a.3.B. The current name, address, and phone number of any relative, legally authorized representative, or other person to be notified;

7.7.a.3.C. Current Medical insurance information, if any;

7.7.a.3.D. Currently prescribed medications and over the counter medications used by the consumer and diagnostic rationale for their use;

7.7.a.3.E. Medication and food allergies and reactions;

7.7.a.3.F. Any history of substance abuse;

7.7.a.3.G. Significant medical problems;

7.7.a.3.H. Significant communication problems, any communicative devices used; and

7.7.a.3.I. Advance directives, if any.

7.7.b. Current emergency medical information shall be readily available to employees or contractors wherever services are provided.

7.8. Medical and Psychiatric Emergency Management.

7.8.a. The Center shall have policies and procedures for handling medical and psychiatric emergencies that ensure:

7.8.a.1. Communication with the nearest medical emergency service, hospital and police; and

7.8.a.2. A twenty-four (24) hour telephone response system, toll-free to a consumer.

§64-11-8. Consumer Services Standards - Specific.

8.1. Applicability.

8.1.a. Specific Consumer Services Standards apply to a licensed Center only if the specific service is provided by the Center.

8.2. Assessment and Planning.

8.2.a. The Center shall document and implement an assessment policy. The policy shall define how assessments will be documented.

8.2.b. The Center shall conduct an assessment to identify an individual's strengths, preferences and needs, in these areas, as applicable: physical, medical, behavioral, functional, and social abilities. The assessment shall address:

8.2.b.1. Onset/duration of problems;

8.2.b.2. Social/behavioral/developmental/family history;

8.2.b.3. Employment/vocation/educational background;

8.2.b.4. Previous interventions/outcomes;

8.2.b.5. Financial resources and benefits;

8.2.b.6. Health history and current medical care needs;

8.2.b.7. Legal status, including guardianship, commitment and representative payee status, and relevant criminal charges or convictions, probation or parole status;

8.2.b.8. Daily living skills;

8.2.b.9. Social/family supports;

8.2.b.10. Housing arrangements; and

8.2.b.11. Ability to access services.

8.2.c. Frequency of assessments:

8.2.c.1. A preliminary assessment shall be done at the time of admission;

8.2.c.2. The preliminary assessment shall be updated and finalized during the first thirty (30) days of service and prior to completing the individualized support plan;

8.2.c.3. Longer term assessments may be included as part of the individualized services plan. The Center shall document the reason for assessments requiring more than thirty (30) days; and

8.2.c.4. Reassessments shall be completed when there is a need based on the medical, psychiatric or behavioral status of the individual.

8.2.d. The Center shall make and document reasonable attempts to obtain previous assessments.

8.2.e. Assessment documentation:

8.2.e.1. Initial assessments shall be entered in a consumer's record within five working days of intake interview;

8.2.e.2. Diagnoses shall be:

8.2.e.2.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 for Mental Deficiency; and

8.2.e.2.B. Based upon accepted professional standards of examinations and factual description of a consumer's symptoms and problems.

8.2.e.3. When additional evaluations and assessments are completed, recommendations for treatment and training shall be entered in a consumer's record.

8.2.f. Individual Support Plan.

8.2.f.1. The Center shall develop a preliminary individual support plan for the first thirty (30) days.

8.2.f.2. A preliminary individual support plan shall be developed and implemented within twenty-four (24) hours of admission and shall continue in effect until the individual support plan is

developed or the individual is discharged, whichever comes first.

8.2.f.3. Centers providing short-term services must develop and implement a policy for the development of individual support plans within a time frame consistent with the expected length of stay of consumers.

8.2.f.4. The individual support plan shall include:

8.2.f.4.A. The consumer's needs and preferences;

8.2.f.4.B. Relevant psychological, behavioral, medical, rehabilitation and nursing needs, as indicated by the assessments;

8.2.f.4.C. Individualized strategies and methods, including the frequency of services needed and staffing levels required;

8.2.f.4.D. The behavior intervention plan, if applicable;

8.2.f.4.E. Identification of the treatment plan participants and documentation of their participation;

8.2.f.4.F. Descriptions and dates of the assessments on which the individual support plan goals and objectives are based;

8.2.f.4.G. Specific goals to improve or maintain the mental health and optimal adaptive functioning of the individual;

8.2.f.4.H. Measurable objectives related to the goals and expected achievement dates;

8.2.f.4.I. At least one (1) objective per goal shall identify the expected outcome of the goal for the consumer;

8.2.f.4.J. A description of all services, including services provided by other Centers, provided to a consumer and directed primarily toward achievement of the expected outcomes; and

8.2.f.4.K. The physician notes, as part of the treatment plan, including the consumer's current medications, dosages, and diagnoses related to the use of these medications, and the rationale for changes or continuation of psychotropic drug regimens.

8.2.f.5. The individual support plan shall be developed by an interdisciplinary team consisting of:

8.2.f.5.A. Representatives of the Center(s) serving the consumer;

8.2.f.5.B. The consumer;

8.2.f.5.C. The consumer's legal representative, if any;

8.2.f.5.D. Other persons as determined by the consumer; and

8.2.f.5.E. Other service agencies such as schools, as applicable.

8.2.g. Support Plan Review.

8.2.g.1. A review or revision shall occur at significant times including, but not limited to:

8.2.g.1.A. Admission, transfer, and discharge from a Center's

services;

8.2.g.1.B. Changes in the living arrangements of a consumer;

8.2.g.1.C. Major changes in a consumer's condition; and

8.2.g.1.D. Crisis points including, but not limited to hospitalization.

8.2.g.2. There will be a support plan review at least every three hundred sixty-five (365) days.

8.2.g.3 Each review shall summarize the amount of treatment or training provided, document progress towards the objectives, identify problems that impeded progress, and provide a decision to continue the same plan or to modify it.

8.3. Assessment and Planning for Limited-Outpatient Clinic Services.

8.3.a. When a consumer is receives only medication management and/or individual therapy from the Center, the assessment and planning process is simplified, as follows:

8.3.a.1. Assessment, following screening, shall be limited to the service of medication management and/or therapy as needed;

8.3.a.2. Initial assessments shall be entered into a consumer's record within five (5) working days of the intake interview;

8.3.a.3. Diagnoses shall be:

8.3.a.3.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 for Mental Deficiency; and

8.3.a.3.B. Based upon accepted professional standards of examinations and factual description of a consumer's symptoms and problems;

8.3.a.4. Documentation of consumer progress:

8.3.a.4.A. Consumer progress shall be reviewed at each treatment juncture and shall be documented in the case note; and

8.3.a.4.B. The case note shall include the presenting problem, the results of the treatment juncture, and a plan for future treatment.

8.3.b. In the event that the consumer's needs require additional services, the assessment and planning process will follow Subsection 8.2 of this rule.

8.4. Residential Services.

8.4.a. Emergency Medical and Psychiatric Services in Residential Facilities.

8.4.a.1. The Center shall ensure the availability of a physician for medical consultation twenty-four (24) hours per day, seven (7) days per week.

8.4.a.2. The Center shall respond to a consumer's needs twenty-four (24) hours a day, seven (7) days a week,

including providing appropriate triage for a consumer who poses a danger to self or others.

8.4.a.3. The Center shall assure that the onsite employees have immediate access to treatment and medical information in a consumer's records in the case of an emergency.

8.4.a.4. Written policy shall be developed and implemented for the treatment, referral and follow-up of a consumer who attempts or threatens suicide or homicide, or commits or threatens assault.

8.4.b. Licensed Residential Facilities.

8.4.b.1. Centers providing residential services shall either provide or arrange for the provision of appropriate medical care. The Center shall define instances when it shall provide or arrange for appropriate medical and dental care and instances when it shall refer the consumer to appropriate medical care.

8.4.b.2. A physical examination by a qualified practitioner shall be administered or obtained within thirty (30) days of admission to a licensed residential site. This physical may be completed prior to admission, but cannot be more than (60) sixty days old. For Title XIX MR/DD Waiver, if the consumer has a valid (within the current year) Waiver annual physical evaluation, a nursing assessment conducted within thirty (30) days of admission shall be accepted in lieu of a repeat physical examination.

8.4.b.3. The physical examination for placement in a residential service shall include:

8.4.b.3.A. General physical condition (history and physical);

8.4.b.3.B. Evaluation for communicable diseases;

8.4.b.3.C. Recommendations for further diagnostic tests and treatment, if appropriate; and

8.4.b.3.D. The date of the examination and the signature of the qualified practitioner.

8.4.b.4. The Center shall have rules of conduct for consumers to follow while in residence.

8.4.b.5. The consumers shall be provided foods that promote healthful living.

8.4.b.6. Onsite employees shall ensure that each consumer receives training and practice good habits in personal care, hygiene, and grooming.

8.4.b.7. Consumers who require twenty-four (24) hour staffing shall not be left unattended during normal sleeping hours.

8.4.b.8. Consumers shall be referred for ongoing mental health services and shall be assisted in keeping appointments and participating in treatment programs. Documentation of referrals shall be kept in the consumer's record.

8.4.c. Public Inebriate Shelters.

8.4.c.1. Trained employees or staff shall screen a consumer to determine his or her need for medically monitored detoxification or for referral to acute medical care.

8.4.c.2. The shelter shall monitor a consumer at not less than fifteen (15) minute intervals for the first four (4) hours following admission, and each hour thereafter, and provide:

8.4.c.2.A. A documented evaluation of a consumer;

8.4.c.2.B. Documentation of vital signs including the blood alcohol count, taken every four hours; and

8.4.c.2.C. Documentation of any changes in withdrawal symptoms.

8.4.c.3. A shelter shall not discharge a consumer to a responsible adult until after an evaluation is complete, unless there are unusual circumstances, e.g., transfer for medical or security reasons.

8.4.c.4. A shelter shall not discharge a consumer, unless the committing authority has approved the release, or until a consumer's blood alcohol count is below .05 and there is no observable indication of intoxication.

8.4.c.5. If a consumer leaves the shelter prior to being discharged, the referring court and the sheriff's office shall be notified.

8.4.c.6. The shelter shall inform a consumer of alternative services and, upon a consumer's request, assist in arranging follow-up appointments.

8.4.c.7. The shelter shall submit recommendations to the court as required for the disposition of publicly inebriated individuals.

8.4.c.8. If the shelter is located in a building housing another agency or program, the shelter shall have:

8.4.c.8.A. A separate entrance; and

8.4.c.8.B. A separate bathroom and shower facilities for the sole use of shelter consumers.

8.4.d. Detoxification Services.

8.4.d.1. The Center shall perform a physical examination and screening at a consumer's intake to determine the need for medical services.

8.4.d.2. A physician shall be available for medical consultation twenty-four (24) hours per day, seven (7) days per week.

8.4.d 3. During the withdrawal process, qualified employees shall maintain contact with a consumer regarding the consumer's detoxification protocol.

8.4.d.4. The Center shall refer a consumer to a more intensive level of medical care if screening and medical examination indicate that more intensive medical monitoring or management is required.

8.4.e. Residential Substance Abuse Services.

8.4.e.1. The Center shall ensure the availability of onsite nursing staff sufficient to address the assessed medical needs of a consumer.

8.4.e.2. The Center shall maintain policies and procedures to handle contraband substances brought into the group residential facility.

8.5. Medical Management.

8.5.a. The Center shall develop and implement a written policy for the provision of adequate medical care.

8.5.b. Centers providing residential or inpatient services shall either provide or arrange for the provision of appropriate medical and dental care for residential consumers. A Center providing other services shall define instances when it shall provide or arrange for appropriate medical care and instances when it shall refer the consumer to appropriate medical and dental care.

8.6. Medical Equipment.

8.6.a. The Center shall develop and implement a policy on the maintenance and use of medical equipment, including personal medical equipment and devices. There shall be timeframes for preventative maintenance and cleaning.

8.7. Medication Services.

8.7.a. The Center shall develop a process for the administration, storage and accountability of all medication that includes provisions for a medication administration record procedure and is in compliance with state and federal requirements.

8.7.b. All orders for medications shall be reviewed at least every ninety (90) days by the physician.

8.7.c. Psychotropic drugs shall be ordered only as part of the treatment plan and with documentation of the diagnosis and the specific behaviors that indicate a need for the medication and the rationale for its choice.

8.7.d. All medications shall be administered in compliance with the physician's order.

8.7.e. All medications shall be administered only by persons authorized by state law.

8.7.f. Medication errors, as defined by this rule, and adverse drug reactions shall be reported immediately to the physician.

8.7.g. Medication errors shall be monitored and tracked in accordance with the Office of Health Facility Licensure and Certification Behavioral Health Program Guidelines for Incidents and the "Medication Administration by Unlicensed Personnel" rule, 64CSR60.

8.7.h. An individual medication administration record of all medications received and refused by each consumer shall be kept.

8.7.h.1. This record shall include the signature and job title of all employees or staff administering medications.

8.7.h.2. This record shall include any errors in the administration process.

8.7.h.3. This record shall include notation of any missed medications and the reason for the omission, including refusals.

8.8. Medication Management.

8.8.a. The Center shall note in the consumer record any changes in a consumer's condition, including adverse reactions, as a result of receiving a medication.

8.8.b. A consumer to the extent

capable shall administer his or her own medication. All consumers receiving self medication management shall be assessed to determine the extent of self medication capability. This assessment shall be completed with any significant change in self administration skills and at least annually.

8.8.c. The Center shall provide double-locked storage for all controlled substances and single-locked storage for all other medications.

8.8.d. Medication and food items shall not be stored in the same container or area.

8.8.e. The Center shall have evidence of written informed consent from a consumer, or his or her legal representative, about the medication(s) prescribed: the dosage, purpose, possible side affects, affects of not taking the medication; and about alternate treatments and their affects.

8.8.f. The Center shall promptly dispose of discontinued drugs, outdated drugs, and drug containers with worn, illegible, or missing labels according to the applicable regulations of the West Virginia Board of Pharmacy.

8.9. Behavior Intervention.

8.9.a. Program and direct care employees and staff shall be trained in behavior management, including methods of deescalating volatile situations and of using nonphysical techniques in such situations, to deal appropriately with aggressive or out of control behavior.

8.9.b. The Center shall ensure that all interventions for "predictable" problem behaviors are based on a functional analysis of the behavior.

8.9.c. Once a problem behavior has been identified, the functional analysis shall be completed within twenty (20) calendar days. The development of formal interventions, based on the functional analysis, shall occur within fifteen (15) days of the completion of the functional analysis and its rationale and shall be clearly identified in the behavioral intervention plan. If the functional analysis determines that the behaviors are a symptom of psychosis (hallucinations, delusion, etc.), then a Behavior Intervention Plan is not required. However, the interdisciplinary team must objectively monitor the symptoms in order to evaluate the effectiveness of the intervention employed.

8.9.d. The behavior intervention plan shall:

8.9.d.1. Include positive programming to teach the consumer adaptive, more effective behavior;

8.9.d.2. Ensure that a consumer does not discipline another;

8.9.d.3. Ensure that seclusion and physical restraints are used only as a last resort and used only as long as necessary to mange behavior; and

8.9.d.4. Include a mechanism of data collection/measurement that allows an objective measurement of progress toward the behavioral outcome.

§64-11-9. Consumer Protections.

9.1. Human Rights Committee.

9.1.a. The Center shall maintain a human rights committee to:

9.1.a.1. Hold meetings and keep written minutes of all meetings, including the names and titles of all members and guests present and members absent;

9.1.a.2. Report activities and recommendations, if any, at least annually to the governing body, or a standing committee of the governing body;

9.1.a.3. 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;

9.1.a.4. Review internal and external investigations of complaints and consumer grievances, including alleged abuse, mistreatment or neglect;

9.1.a.5. Review and approve (prior to implementation) research activities and monitor them every three (3) months, or when changes are contemplated; and

9.1.a.6. Ensure that aversive procedures are used only with the written consent of a consumer or his or her legal representative.

9.2. A Center with fewer than thirty (30) consumers shall have a minimum of three (3) members on the human rights committee, and a Center with more than thirty (30) consumers shall have a minimum of five (5) members.

9.3. At least one-third of the committee members shall be consumers or consumer legal representatives and no more than one-third shall be employees of the Center.

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

§64-11-10. Consumer Rights.

10.1. General Consumer Rights.

10.1.a. A consumer shall have rights protected and promoted including, but not limited to, the following general rights:

10.1.a.1. The right to be informed orally and in writing in appropriate language and terms, of the rights described in this section. The Center shall have the consumer or his or her legal representative sign and date an acknowledgement of receipt of rights information as part of the intake process. The acknowledgement shall become a part of the consumer's record;

10.1.a.2. The right to be informed of this rule. Upon request, the Center shall provide a consumer or his or her legal representative a copy of this rule;

10.1.a.3. The right not to be discriminated against because of the receipt of behavioral health services;

10.1.a.4. The right to exercise his or her civil rights, except as abrogated by court order or for the reasons provided in this rule; and

10.1.a.5. The right to all available services without discrimination because of race, religion, color, sex, sexual orientation, disability, age, national origin or marital status.

10.1.b. A consumer shall have the following additional rights:

10.1.b.1. The right to a legal representative when unable to act on is or

her own behalf;

10.1.b.2. The right to access an advocate in order to understand, exercise and protect his or her rights;

10.1.b.3. The right to access his or her own consumer records in accordance with state law;

10.1.b.4. The right to be informed in advance of any charges for services;

10.1.b.5. The right to be free from physical, verbal, sexual or psychological abuse or punishment, and neglect;

10.1.b.6. The right to appropriate referrals to other licensed Centers;

10.1.b.7. The right to be free from retaliation;

10.1.b.8. The right to be free from humiliation; and

10.1.b.9. The right to be free from financial or other exploitation.

10.1.c. A residential or day services consumer shall have the following rights:

10.1.c.1. The right of a consumer to be served with other consumers of similar age and need, unless otherwise specified in the consumer's Individual Support Plan or treatment plan;

10.1.c.2. The right to privacy and the right to move about freely, unless his or her safety or the safety of others is threatened;

10.1.c.3. The right to unimpeded access to his or her attorney, advocate or religious advisor;

10.1.c.4. The right to constant access to his or her personal possessions, unless contraindicated by treatment needs. The reason for the restriction shall be clearly documented in the consumer's record and approved by the treatment team and human rights committee prior to implementation. The treatment team shall periodically reevaluate the need for continuation of the restriction;

10.1.c.5. The right to unimpeded private communication by any means with whomever a consumer chooses, except as specified in Subsection 10.10 of this rule;

10.1.c.6. The right not to be deprived of any right as punishment or for clinical reasons, except when an incident occurs related to the exercise of a right, the right may be deprived for clinical reasons, but only for as long as is necessary to permit correction of a situation. The restriction and the clinical reasons for it shall be clearly documented in the consumer's record and shall be approved by the human rights committee prior to implementation; and

10.1.c.7. The right of a consumer receiving care and treatment to receive it in accordance with accepted behavioral health and medical practice standards.

10.2. Advance Psychiatric Directive Rights.

10.2.a. A consumer with psychiatric or mental health needs has a right to an advance psychiatric directive prepared at a time when the individual has not been adjudged to be incompetent. Any advance

psychiatric directive written and signed by a consumer may be withdrawn at any time verbally or in writing.

10.2.b. A consumer has the right to be informed by the Center of the availability and applicability of an advance psychiatric directive and to receive education and assistance from the Center in preparing such a document.

10.2.c. A consumer has the right to refuse to create an advance psychiatric directive.

10.2.d. A consumer with an advance psychiatric directive has the right to have it entered into his or her clinical record at the Center at which he or she is receiving or may receive care or treatment.

10.2.e. An advance psychiatric directive shall be honored, unless:

10.2.e.1. It is withdrawn verbally or in writing by a consumer;

10.2.e.2. The Center lacks sufficient resources; or

10.2.e.3. A professional employee member of the Center believes that the directive would endanger the consumer's life or be dangerous to others.

10.2.f. A consumer has the right to be informed of the Center's reason for not honoring his or her advance psychiatric directive.

10.2.g. Nothing in this section should be interpreted to prevent any individual with behavioral health needs from entering into an advance directive related to preferences in health care or conduct of business.

10.3. Informed Consent Rights.

10.3.a. The Center shall have the consumer or his or her legal representative sign a general consent to receive treatment.

10.3.b. In order for a consumer to give informed consent for care or treatment, the Center shall inform him or her of the following:

10.3.b.1. The rights provided under this rule;

10.3.b.2. The nature of his or her condition and the treatment proposed;

10.3.b.3. Any reasonable alternative treatments available;

10.3.b.4. That consent for any part of treatment may be withdrawn at any time in writing or verbally to a member of the treatment staff. Revocation of consent shall be documented on the consent form, and further treatment shall not be provided except as authorized in an emergency;

10.3.b.5. The reason for taking a proposed medication, including the likelihood of the consumer's condition improving or not improving without the proposed medication;

10.3.b.6. The type, dosage, including the use of PRN (as needed) orders, the method of administration (oral or injection), and the duration of taking the proposed medication; and

10.3.b.7. The common side effects, any side effects probable with the particular consumer, and additional side effects that may occur when taking the proposed medication longer than three

months.

10.3.c. In the absence of written consent, if treatment is provided to a consumer, he or she or his or her legal representative has the right to documentation of the precipitating causes for providing the treatment.

10.3.d. The procedures outlined in this section shall not apply to those individuals who:

10.3.d.1. Need life-saving medication for chronic medical conditions, such as diabetes or heart disease; or

10.3.d.2. Have been taking medications prior to admission and have not refused to continue the medication, even though they may not be able to give informed consent.

10.3.e. A consumer has the right to be free from unnecessary or excessive medication.

10.4. Right to Treatment.

10.4.a. A consumer has the right to treatment in the least restrictive, most appropriate and potentially most effective setting possible and that supports a consumer's personal liberty and result in positive outcomes to the maximum extent possible.

10.4.b. A consumer has the right to treatment that is provided humanely in an environment that affords them full protection of their rights and promotes personal dignity and self-esteem.

10.4.c. A consumer has the right to treatment by sufficiently trained and competent employees and staff capable of implementing the consumer's individual support plan or treatment plan.

10.4.d. A consumer has the right to employee and staff to consumer ratios sufficient for adequate protection and supervision.

10.4.e. A consumer has the right to periodic evaluations related to his or her needs while an active consumer of a behavioral health service.

10.4.f. A consumer has the right to treatment based on diagnosis and assessment of their needs.

10.4.g. A consumer has the right to treatment based on a treatment plan that identifies immediate needs and interventions and responsibility for implementing the plan.

10.4.h. A consumer has the right to have treatment plans updated as his or her needs change.

10.4.i. A consumer has the right to participate in the development of his or her individual support plan or treatment plan and any revisions. The consumer or his or her legal representative shall sign and date to give consent for the individual support plan or treatment plan and any revisions.

10.4.j. A consumer has the right to have a copy of his or her individual support plan or treatment plan.

10.4.k. A consumer has the right to have present at any treatment planning or discharge planning meeting representatives of all disciplines providing treatment to the consumer and any other individual, including this consumer's case manager, advocate and family members.

10.4.l. A consumer has the right to have all treatments administered recorded in his or her record.

10.4.m. A consumer who resides in an inpatient behavioral health facility has the right to outdoor exercise and activity programming conforming with the "Behavioral Health Client Rights," 64CSR59, §§14.1-14.3.

10.5. Right to Refuse Treatment.

10.5.a. As a participant in the program planning process, a consumer has the right to object to or refuse any aspect of the individual support plan or treatment plan.

10.5.b. If informal discussion and negotiation do not resolve differences, a consumer's right to object to or refuse treatment shall be recognized as legitimate, and shall be responded to in accordance with the provisions of the Center's consumer grievance procedure.

10.5.c. A consumer who has refused psychotropic medications or other recommended therapy or treatment has the right to have an agreed-upon effective alternative treatment offered, and it shall be provided if the consumer consents and if within the scope of the Center's practice.

10.5.d. A consumer has the right to orally refuse medication or other treatment that overrides prior written consent, except in emergency situations in which it is documented that the absence of medication or other treatment would be harmful to the consumer or others.

10.6. Right to Refuse Research and Experimental Treatment.

10.6.a. A consumer or his or her legal representative has the right to refuse to participate in or be subjected to research or experimental treatment. Participation by a consumer shall require voluntary, informed and written consent, and an opportunity for consultation with independent specialists.

10.7. Rights Regarding Seclusion and Restraints.

10.7.a. A consumer has the right to freedom from seclusion and restraints, unless the restraints are documented as clinically necessary and all other less restrictive measures have been exhausted. Seclusion or restraint shall cease as soon as clinically possible.

10.7.b. A consumer with a diagnosis of mental retardation or another developmental disability has the right not to be secluded or restrained, but time-out procedures may be used when they have been developed specifically for the consumer as part of an authorized behavioral support or management plan and described in the consumer's treatment plan.

10.7.c. A consumer has the right to not have seclusion or restraint used as punishment. Seclusion or restraint may be used only as a last resort as an emergency measure to control imminent destructive behavior that is a threat to a consumer or to others or to prevent injury to a consumer or others.

10.7.d. A consumer has the right to not have physical restraints used as punishment or as a convenience of employees.

10.7.e. A consumer has the right for drugs or medications to not be used as punishment, as a convenience of employees,

as a substitute for adequate staffing, or as a substitute for an individualized programming or treatment.

10.8. Right of Confidentiality.

10.8.a. A consumer has the right to have all information about his or her diagnosis and treatment kept confidential.

10.8.b. A consumer shall have the right to confidentiality in accordance with federal regulations (42 CFR Part 2) and the Health Insurance Portability and Accountability Act of 1996;

10.8.c. Confidential information includes, but is not limited to:

10.8.c.1. Information obtained during diagnosis or treatment, including the fact that an individual is or has been a consumer;

10.8.c.2. Information provided by a consumer or his or her family for purposes related to diagnosis or treatment;

10.8.c.3. Information provided by the treatment staff;

10.8.c.4. Diagnoses, opinions or remarks made by treatment staff that relate to a consumer's treatment;

10.8.c.5. Advice, instructions, or prescriptions issued in the course of diagnosis or treatment; and

10.8.c.6. Any record of a consumer's treatment.

10.8.d. Confidential information does not include:

10.8.d.1. Information which does not identify a consumer;

10.8.d.2. Information from which a person acquainted with a consumer would not recognize the consumer; and

10.8.d.3. Encoded information from which there is no possible means to identify a consumer.

10.8.e. A consumer has the right to have information relating to his or her treatment disclosed only:

10.8.e.1. In a proceeding under W. Va. Code §27-5-4 to disclose the results of an involuntary examination made pursuant to W. Va. Code §27-5-2 or §27-5-3;

10.8.e.2. In a proceeding under W. Va. Code §27-6A-1 et seq. to disclose the results of an involuntary examination made pursuant to those provisions;

10.8.e.3. Pursuant to an order of any court based upon a finding that the information is sufficiently relevant to a proceeding before the court to outweigh the importance of maintaining the confidentiality established by this section;

10.8.e.4. To the attorney of the consumer, whether or not in connection with pending judicial proceeding;

10.8.e.5. To agencies requiring information necessary to make payments to or on behalf of the consumer pursuant to contract or in accordance with law, provided that only such information shall be released to third-party payers as is required to certify that covered services have been provided;

10.8.e.6. To protect against a clear and substantial danger of imminent

injury by a consumer to self or another;

10.8.e.7. For treatment or internal review purposes, to staff of the Center where the consumer is being cared for or other health professionals involved in treatment of the consumer; and

10.8.e.8. Without the consumer's consent as provided for under the Privacy Rule of the federal Health Insurance Portability and Accountability Act of 1996, 45 CSR §164.506 for thirty days from the date of admission to a Center if: (i) the provider makes a good faith effort to obtain consent from the patient or legal representative prior to disclosure; (ii) the minimum information necessary is released for a specifically stated purpose; and (iii) prompt notice of the disclosure, the recipient of the information and the purpose of the disclosure is given to the consumer or legal representative.

10.8.f. A consumer has the right to be informed about the limits of confidentiality in this rule.

10.9. Consent for Disclosure of Confidential Information.

10.9.a. A consent for the disclosure of confidential information shall be in writing and signed by the consumer or by his or her legal representative. A consumer who signs a consent has the right to a copy of the consent.

10.9.b. A consumer shall not be denied treatment on the basis of refusing to provide consent to disclose confidential information, except when and to the extent disclosure is necessary for treatment, or for the substantiation of a claim for payment for treatment from a source other than the consumer.

10.10. Right to Unrestricted Communication.

10.10.a. A consumer has the right to unimpeded and private communication by any means with whomever a consumer chooses, except as specified in this rule.

10.10.b. A consumer's right to communication, except for that with his or her legal representative, attorney or religious adviser, may be restricted or denied if authorized by the treatment team for a specified time not to exceed thirty (30) days, after which time the restriction may be reviewed and reinstated.

10.11. Rights Regarding Labor, Earnings and Funds.

10.11.a. A consumer has the right not to be required to perform uncompensated labor that involves the operation and maintenance of the Center, but may voluntarily perform it with compensation in accordance with the requirements of relevant State and federal requirements.

10.11.b. A consumer shall not suffer consequences for refusing to perform uncompensated labor for the Center.

10.11.c. A consumer may perform vocational training tasks that do not involve the operation and maintenance of the Center when the assignment:

10.11.c.1. Is an integrated part of a consumer's individual support plan or treatment plan;

10.11.c.2. Has been approved as a program activity by the treatment staff; and

10.11.c.3. Is supervised by an employee or staff person.

10.11.d. A consumer has unlimited access to his or her funds except as provided by state law, or by regulations promulgated by the Social Security Administration.

10.12. Additional Rights of Juveniles.

10.12.a. A consumer under the age of eighteen (18) has the right to be housed separately from emancipated consumers over the age of eighteen (18), except in the case of unusual circumstances where a juvenile over the age of sixteen (16) is developmentally similar to the adults with whom the juvenile will reside and the treatment team and legal representative approve of the arrangement.

10.12.b. A consumer under the age of eighteen (18) has the right to an education.

10.12.c. A consumer under the age of eighteen (18) has the right to appropriate contact and communication with his or her family members, unless restricted by the West Virginia Department of Health and Human Resources for good reason when the juvenile is in the legal custody of the West Virginia Department of Health and Human Resources.

10.12.d. A consumer under the age of eighteen (18) has the right to be informed about behavior expectations for the protection of others.

10.12.e. All other rights under this rule apply to consumers under the age of eighteen (18).

10.13. Right of Advocacy and Grievance Procedure.

10.13.a. A consumer has the right to be informed of and receive a written copy of the Center's grievance procedure.

10.13.b. A consumer or another person acting on a consumer's behalf has the right to file a grievance, orally or in writing, with the Center concerning any alleged violation of the rights afforded by this rule.

10.13.c. A consumer has the right to receive a reasonable and timely written decision from the Center.

10.13.d. A consumer or his or her legal representative has the right to a response to his or her grievance within fifteen (15) working days of its filing with the Center.

10.13.e. A consumer may, after receipt of the decision or lack of a timely decision on his or her grievance, request a hearing by the Secretary or bring action in circuit court against the Center.

10.13.f. A consumer has the right to withdraw his or her grievance at any time.

10.13.g. If the 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 has the right to appeal to the governing body of the Center, the State licensure body, an advocate or other appropriate resource, including an attorney.

10.13.h. A consumer has the right to pursue other relief even if he or she does not file a grievance.

10.13.i. A consumer has the right to report any reasonable suspicion of abuse or neglect to civil and criminal authorities in accordance with the applicable Adult Protective Services Act, W. Va. Code §9-6-1 et seq. or Child Protective Services act, W. Va. Code §49-6A-1 et seq., in addition to using the grievance procedure of the Center.

10.13.j. 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 Center 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 is or her legal rights granted under state or federal law.

§64-11-11. Penalties.

11.11.a. The Secretary may deny the Center's application for licensure or licensure renewal; revoke or suspend a license; and/or order an admissions ban or reduction in consumer census for one or more of the following reasons:

11.11.a.1. The Secretary makes a determination that there has been a conviction for fraud or other illegal action;

11.11.a.2. The Center has violated federal, state, or local law relating to building, health, fire protection, safety, sanitation, or zoning;

11.11.a.3. The Center conducts practices that jeopardize the health, safety, well-being, or clinical treatment of a consumer;

11.11.a.4. The Center has refused to provide access to its location or records as requested by the Secretary; or

11.11.a.5. The Center has failed or refuses to submit reports or make records available as requested by the Secretary.

11.11.b. The Secretary may assess civil monetary penalties for one or more of the following reasons:

11.11.b.1. Failure to submit a plan of correction in accordance with Subsection 4.9 of this rule, for which the civil monetary penalty shall be $50 per each day the Center is delinquent; or

11.11.b.2. Failure to correct the following deficiencies, if cited in the previous licensure inspection, for which the civil monetary penalty shall be $1000:

11.11.b.2.A. Subdivision 5.9.a, 5.9.b, 5.9.c and 5.9.d. regarding personnel;

11.11.b.2.B. Subsection 5.12 regarding quality assurance;

11.11.b.2.C. Subsection 6.2 regarding physical environment; or

11.11.b.2.D. Subsection 7.6 regarding critical incidents.

11.11.c. If a license has been revoked, the Secretary may stay the effective date of the revocation by no more than ninety (90) days, if the Center can show that the stay is necessary to ensure appropriate referral and placement of consumers.

§64-11-12. Administrative Due Process.

12.1. Any person aggrieved by an order or other action by the Secretary based on this rule, or W. Va. Code §§27-9-1 or 27-17-1 et. seq., may request in writing a hearing by the Secretary in accordance with "Rules of Procedure for Contested Case Hearings and Declaratory Rulings," 64CSR1, a copy of which may be obtained from the Secretary of State.