WEST VIRGINIA SECRETARY OF STATE

KRIS WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: Office of the Inspector General TITLE-SERIES: 71-16

RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No

RULE NAME: Neonatal Abstinence Syndrome Centers Licensure

CITE STATUTORY AUTHORITY: W. Va. Code 16B-21-2

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) SB300

Section W. Va. Code 16B-1-1 Passed On 2/8/2024 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

May 28, 2025

This rule shall terminate and have no further force or effect from the following date:

August 01, 2030

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

Yes

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

71CSR16
TITLE 71
LEGISLATIVE RULE
OFFICE OF INSPECTOR GENERAL

SERIES 16
NEONATAL ABSTINENCE SYNDROME CENTERS LICENSURE

§71-16-1. General.

1.1. Scope. -- It is the purpose of this rule to implement state law governing the licensing, operation, and standards of care in neonatal abstinence syndrome centers located within the state of West Virginia.

1.2. Authority. -- W. Va. Code §16B-21-2.

1.3. Filing Date. -- May 28, 2025.

1.4. Effective Date. -- May 28, 2025.

1.5. Sunset Date. -- This rule will terminate and have no further force or effect on August 1, 2030.

1.6. Application. This rule applies to neonatal abstinence syndrome center patients and legal representatives as well as every individual and every form of organization, whether incorporated or unincorporated, trust, association, or political subdivision of the state that operates or applies to operate a neonatal abstinence syndrome center as defined in this rule and the authorizing state law.

1.7. Enforcement. This rule is enforced by the Inspector General. The Inspector General designates the director of the Office of Health Facility Licensure and Certification to enforce the provisions of W. Va. Code §§16B-21-1, *et seq.*, and the provisions of this Rule, except where otherwise stated.

§71-16-2. Definitions.

2.1. Abuse — means the threat to a patient's health or welfare by a person who knowingly or intentionally inflicts, attempts to inflict or knowingly allows another person to inflict physical injury or mental or emotional injury upon the patient; or sexual abuse or sexual exploitation.

2.2. Addiction — means a disease characterized by an individual pursuing reward and/or relief with substance use and/or other behaviors. Addiction is characterized by impairment in behavioral control, craving, inability to consistently abstain, and diminished recognition of significant problems with one's behaviors and interpersonal relationships; likely to involve cycles of relapse and remission.

2.3. Administrator — means an individual designated by the governing body of the neonatal abstinence center to be responsible for the day-to-day operation of the neonatal abstinence syndrome center.

2.4. Adult Protective Services/Child Protective Services (APS/CPS) Background Check — means an authorized disclosure of an individual's history with the West Virginia Department of Human Services as an identified adult or child abuse maltreater.

2.5. Annual Inspection — means a recurring inspection by the Office of Health Facility Licensure and Certification that will take place once every nine to 15 months.

2.6. Applicant — means the person or entity who submits an application for a license or renewal of a license to operate a neonatal abstinence syndrome center.

2.7. Bed Capacity — means the maximum number of beds a neonatal abstinence syndrome center is licensed to offer residential care and occupancy.

2.8. Care Plan — means a document, based on a comprehensive assessment and prepared by the interdisciplinary team in conjunction with the patient's parent, family and/or legal representative that identifies measurable goals and objectives for the highest level of functioning the patient is expected to attain or maintain.

2.9. Change of Ownership — means any transaction that results in the change of control over the capital assets of a neonatal abstinence syndrome center including, but not limited to, a conditional sale, a sale, a lease or a transfer of title or controlling stock.

2.10. Complaint — means a verbal or written statement made by a patient, family member, legal representative and/or community member and filed with the program administrator or a state oversight agency alleging inadequate or inappropriate service on the part of a neonatal abstinence syndrome center.

2.11. Conflict of Interest — means any action that results in, or has the appearance of resulting in, personal, organizational, or professional gain.

2.12. Critical Incident or Adverse Event — means an incident resulting in or the potential for significant harm or death to a patient; an immediate threat to care or safety of an individual, either staff or patient; the possibility of serious operational or personnel problems within the center; or the potential to undermine public confidence in the neonatal abstinence syndrome center.

2.13. Deficiency — means a neonatal abstinence center's failure to meet a specific requirement under the provisions of this rule. A deficiency cited by the Department shall explicitly state which requirement was not met and include evidence to support the Department's decision of noncompliance.

2.14. Director — means the Director of the Office of Health Facility Licensure and Certification, or his or her designee.

2.15. Diversion Control Plan — means a required plan developed by the neonatal abstinence syndrome center to minimize the diversion of methadone or other medications to illicit use.

2.16. Employee — means any person who performs personal services for the neonatal abstinence syndrome center in exchange for monetary compensation. Such personal services that include 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 neonatal abstinence center. Monetary compensation is affected through the neonatal abstinence center's payroll system.

2.17. Experimental Research — means development and testing of clinical treatments, such as an investigational drug or therapy, involving treatment or control groups or both. For example, a clinical trial of an investigational drug is experimental research.

2.18. Facility — means the physical building in which a neonatal abstinence syndrome center services are provided.

2.19. Family — means a group of two or more persons related by blood, marriage, foster relationship, or adoption.

2.20. For-Cause Inspection — means an inspection by the state oversight agency that may be operating in violation of state neonatal abstinence syndrome center standards, may be providing substandard treatment or may be serving as a possible source of diverted medications.

2.21. Governing Body — means the person or persons identified as being legally responsible for the operation of the neonatal abstinence syndrome center. A governing body may be a board, a single entity or ownership or a partnership.

2.22. Grievance — means a written or oral complaint filed with the program administrator or the state operating agency alleging inadequate or inappropriate treatment by the neonatal abstinence syndrome center.

2.23. Harm — means noncompliance with this rule that has negatively affected the patient so that the patient's physical, mental or psychosocial well-being has been compromised, and is not temporary in nature.

2.24. Immediate Jeopardy — means a situation in which the neonatal abstinence syndrome center's noncompliance with one or more requirements of this rule has caused, or is likely to cause, serious injury, harm, impairment, or death of a patient.

2.25. Individualized Plan of Care — means a plan of treatment and care developed by the patient's interdisciplinary team that outlines the attainable short term and long-term treatment goals, the services to be provided, the frequency of services, and the responsible party for each goal and service.

2.26. Informed Consent — means written acknowledgment and verification by the patient's legal representative stating that information on the advantages and disadvantages of all aspects of the treatment provided to the patient and that the patient's legal representative agrees to the treatment.

2.27. Inspector General – means the Inspector General of the Office of Inspector General as described in W. Va. Code §16B-2-1 or his or her designee.

2.28. Interdisciplinary Team — means a group of professionals and paraprofessionals responsible to develop, approve, and coordinate the individualized treatment plan of care and services for the patient.

2.29. Legal Representative — means the parent or parents of a minor patient, or a person appointed as guardian pursuant to the West Virginia Guardianship and Conservatorship Act, W. Va. Code §§44A-1-1,

et seq., within the limits set by the appointing order, or the legal custodian as identified by the person appointed as guardian.

2.30. License — means the document issued by the Office of Health Facility Licensure and Certification that constitutes the neonatal abstinence syndrome center's authority to receive patients and perform services within the scope of this rule.

2.31. Licensed or Registered — means the person licensed or registered to follow a profession by the proper authority within the state of West Virginia. When applied to a neonatal abstinence syndrome center, it means the facility is licensed by the Office of Health Facility Licensure and Certification.

2.32. Licensee — means a person, persons or entity holding a license to operate a neonatal abstinence syndrome center, and who is responsible for compliance with all rules and minimum standards.

2.33. Medical Director — means the physician licensed within the state of West Virginia who assumes responsibility for administering all medical services performed by the neonatal abstinence syndrome center, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director's supervision.

2.34. Medication Error — means any preventable event where a dose of medication received, or not received by a patient differs from what the prescriber has prescribed.

2.35. Misappropriation — means the deliberate misplacement, exploitation or wrongful use of a patient's belongings or money.

2.36. Neglect — means the failure to provide goods and services, including but not limited to, adequate nutrition, clothing, shelter, supervision, medical care or education, or abandonment.

2.37. Neonatal — means the period of time covering the first 28 days after birth.

2.38. Neonatal Abstinence Syndrome Center — means any center or facility, however named, within the state of West Virginia, which is advertised, offered, maintained or operated by the ownership or management, whether for consideration or not, for the express or implied purpose of providing accommodations and care, for a period of more than 24 hours but not to exceed 30 days, unless the physician recommends a longer length of stay based on documented evidence-based practices and the infant's individual response to treatment.

2.39. Neonatal Abstinence Syndrome — means a group of symptoms that occur in a newborn who was exposed to addictive drugs while in the mother's womb and includes prenatal exposure to a neuroactive substance and exhibits clinical signs and symptoms of withdrawal, regardless of whether pharmacological treatment is required.

2.40. Noncompliance — means any deficient practice or non-conformity that causes a neonatal abstinence syndrome center to not be in substantial compliance with this rule.

2.41. Non-Pharmacological Intervention — means evidence-based treatment, excluding the use of pharmacological interventions, for neonatal abstinence syndrome that is recognized by the American

Academy of Pediatrics, or a nationally recognized organization with expertise in neonatal abstinence syndrome.

2.42. Office of Health Facility Licensure and Certification — means the West Virginia Office of Health Facility Licensure and Certification within the Office of Inspector General.

2.43. Orientation — means the introduction of the legal representative, parents, and/or family to the policies and procedures of the neonatal abstinence syndrome center.

2.44. Patient — means an individual under six months old receiving treatment from a neonatal abstinence syndrome center.

2.45. Pharmacological Treatment — means the use of prescribed medications indicated to relieve moderate to severe signs of neonatal abstinence syndrome and to prevent complications such as fever, weight loss, and seizures that is recognized by the American Academy of Pediatrics, or a nationally recognized organization with expertise in neonatal abstinence syndrome.

2.46. Physician — means an individual licensed to practice allopathic medicine by the West Virginia Board of Medicine pursuant to W. Va. Code §§30-3-1, *et seq.*, or osteopathic medicine by the West Virginia Board of Osteopathic Medicine pursuant to W. Va. Code §§30-14-1, *et seq*.

2.47. Plan of Care — means the overall profile of services and expected outcomes of care that may include plans to meet the person's needs after discharge. This includes all care and services outlined in the medical record.

2.48. Plan of Correction — means a written description of the actions the neonatal abstinence syndrome center intends to take to correct and prevent the recurrence of violations of a rule or policy identified by the designated state oversight agency during an investigation or survey.

2.49. Program Sponsor — means the person named in the application for licensure of a neonatal abstinence syndrome center who is responsible for the operation of the neonatal abstinence syndrome center, and who assumes responsibility for all of its employees, and contractors. The program sponsor is not required to be a licensed physician but shall employ a licensed physician for the position of medical director.

2.50. Protective Services — means Child or Adult Protective Services operating under the West Virginia Department of Human Services.

2.51. Repeat Deficiency — means a deficiency that meets all of the following conditions: is cited on the current inspection; was cited on the previous inspection or any intervening inspection between the current inspection and the previous inspection; has had a plan of correction submitted for the previous inspection or any intervening inspection that was accepted by the Director; and is cited based on the same regulatory grouping.

2.52. Scoring System — means a formal, validated method for assessing neonatal abstinence syndrome severity that is recognized by the American Academy of Pediatrics, or a nationally recognized organization with expertise in neonatal abstinence syndrome.

2.53. Variance — means a formal agreement between the Office of Health Facility Licensure and Certification and the neonatal abstinence syndrome center that allows the program to comply with the intent of the regulatory rule, policy or standard in a manner not otherwise permitted by this rule, policy or standard. A variance may not be obtained based solely on the inability to achieve compliance.

2.54. Volunteer — means individuals who perform services without pay.

§71-16-3. Licensure, Approval, and Exemption.

3.1. The intent of the neonatal abstinence syndrome center, or center is to:

3.1.1. Treat symptoms of withdrawal in patients who have been prenatally exposed to drugs using both pharmacological and non-pharmacological interventions;

3.1.2. Educate families, legal representatives, and/or foster families in the appropriate care needs of a patient with neonatal abstinence syndrome; and

3.1.3. Support families through the recovery process.

3.2. Unless otherwise exempted by this rule, all individuals or other entities operating as a neonatal abstinence syndrome center shall meet the requirements of applicable state statutes and rules and shall be licensed by the designated state oversight agency.

3.3. Hospitals licensed under W. Va. Code §§16B-3-1, *et seq.*, and W. Va. Code R. §§71-12-1, *et seq.*; behavioral health centers licensed under W. Va. Code R. §§71-25-1, *et seq.*; and opioid treatment facilities licensed under W. Va. Code §§16B-13-1, *et seq.*, and W. Va. Code R. §§71-27-1, *et seq.*, and which provide opioid treatment to adults, 18 years or older, are exempt from this rule.

3.4. Licensed neonatal abstinence syndrome centers are exempt from state licensure regulating hospitals (W. Va. Code §§16B-3-1, *et seq.* and W. Va. Code R. §§71-12-1, *et seq.*), behavioral health centers (W. Va. Code R. §§71-25-1, *et seq.*), nursing homes (W. Va. Code §§16B-4-1, *et seq.* and W. Va. Code R. §§71-15-1, *et seq.*), chronic pain management clinics (W. Va. Code §§16B-7-1, *et seq.* and W. Va. Code R. §§71-26-1, *et seq.*) and opioid treatment centers (W. Va. Code §§16B-13-1, *et seq.* and W. Va. Code R. §§71-27-1, *et seq.*).

3.5. Licensure Process.

3.5.1. Before establishing, operating, maintaining or advertising a neonatal abstinence syndrome center within the state of West Virginia, the center shall:

3.5.1.a. Have an approved certificate of need pursuant to W. Va. Code §§16-2D-1, *et seq.*; and

3.5.1.b. Obtain from the Office of Health Facility Licensure and Certification a license authorizing the operation of the neonatal abstinence syndrome center.

3.6. License Application.

3.6.1. All applications for an initial or renewed license for a neonatal abstinence syndrome center shall include:

3.6.1.a. A completed application as established by the Office of Health Facility Licensure and Certification;

3.6.1.b. A copy of the approved certificate of need pursuant to W. Va. Code §§16-2D-1, *et seq.*;

3.6.1.c. Copies of all required policies and procedures; and

3.6.1.d. The applicable filing fee.

3.6.2. The program sponsor shall submit all required information for the initial application not less than 30 days and not more than 60 days prior to the anticipated initiation of services.

3.7. License Fees and Inspection Costs.

3.7.1. All initial and renewal fees shall be assessed by the Director and shall include a non-refundable license fee in the amount of $250, and an application fee of $400. The license and application fee must be paid to the Office of Inspector General in full prior to the issuance of the license.

3.7.2. The neonatal abstinence syndrome center shall pay for the cost of the initial inspection made by the Office of Health Facility Licensure and Certification prior to issuing a license. The cost of the initial inspection shall be billed to the applicant within five business days after the inspection. The cost of the initial inspection fee must be paid in full by the applicant before a license may be issued.

3.8. Initial Inspection and Issuance of License.

3.8.1. Upon receipt of an application for an initial license to operate as a neonatal abstinence syndrome center, the Office of Health Facility Licensure and Certification shall make an unannounced inspection of the center. This inspection will determine whether the program has satisfied all of the state requirements for licensure.

3.8.2. If the inspection reveals violations, deficiencies or shortcomings on the part of the neonatal abstinence center, the Office of Health Facility Licensure and Certification shall advise the program sponsor. The program sponsor may submit a written plan of correction demonstrating compliance with the cited deficiencies or request a variance. The Director may conduct follow-up inspections, if required.

3.8.3. Following an application review, onsite inspection or inspections, approval of any subsequent written plans of correction, or the granting of a variance, if there is substantial compliance with the requirements of this rule and the cost of the inspection and license has been paid in full, the Office of Health Facility Licensure and Certification shall issue a license in one of three categories:

3.8.3.a. An initial license, valid for six months from the date of issuance, shall be issued to the program establishing a new unlicensed program found to be in substantial compliance on initial review with regard the provisions of this rule.

3.8.3.b. A provisional license shall be issued when a program seeks a renewal license and is not in substantial compliance with this rule but does not pose a significant risk to the rights, health and safety of the patient. A provisional license expires not more than six months from the date of issuance and shall be consecutively reissued upon action of the Office of Health Facility Licensure and Certification for a period not to exceed 12 months, unless the provisional determination is that of the state fire marshal.

3.8.3.c. A renewal license shall be issued annually when a neonatal abstinence syndrome center has successfully completed the survey process. Renewal licenses expire not more than one year from the date of issuance.

3.9. Denial of License.

3.9.1. The Director, in consultation with the Inspector General, may deny an application for an initial or renewed license when:

3.9.1.a. The state oversight agency determines the application is deficient in any respect;

3.9.1.b. The neonatal abstinence syndrome center will not be or is not operated in accordance with state standards, rules, and procedures;

3.9.1.c. The neonatal abstinence syndrome center will not permit an inspection or survey to proceed or will not permit access to relevant records or information in a timely manner; or

3.9.1.d. The neonatal abstinence syndrome center has made misrepresentations in obtaining certification or licensure.

3.9.2. If the state oversight agency determines not to issue a license, the Director shall notify the applicant in writing by regular mail of the denial and the basis for the decision.

3.9.3. A neonatal abstinence syndrome center may protest the denial of a new or renewed license pursuant to the administrative procedures in section 3.11. of this rule.

3.10. Renewal or Modified License.

3.10.1. Renewal License. The program sponsor of a neonatal abstinence syndrome center shall submit an application for a renewed license to the Director not less than 60 days prior to the expiration of the current license.

3.10.1.a. After the Director receives a complete renewal application with the required fee, the existing license shall not expire until the new license has been issued or denied.

3.10.2. Modified License. The program sponsor shall notify the Director 30 days prior to a change in name, a change in the geographic location or services, or a change in the substantial nature of the center and shall simultaneously apply for modification of the license.

3.11. Administrative Due Process.

3.11.1. Any person aggrieved by an order by the Director based on this rule may request in writing a hearing by the Board of Review.

3.11.2. All hearings shall be conducted in accordance with the Office of Inspector General Procedural Rule, "Rules of Procedure for Contested Case Hearings and Declaratory Rulings", W. Va. Code R. §§69-1-1, *et seq.*, a copy of which may be obtained from the Secretary of State.

3.12. Variances.

3.12.1. The Director, in consultation with the Inspector General, may grant a variance from any provision of this rule if he or she determines:

3.12.1.a. Strict compliance would impose a substantial hardship on the licensee;

3.12.1.b. The licensee will otherwise meet the intent of the rule; and

3.12.1.c. A variance will not result in less protection of the health, safety and welfare of the patients.

3.12.2. A variance shall not be granted from a provision pertaining to patients' rights.

3.12.3. Requests for variances from the West Virginia fire safety and building construction requirements shall be addressed with the appropriate authorities.

§71-16-4. Office of Health Facility Licensure and Certification Authority; Powers and Duties.

4.1. The Office of Health Facility Licensure and Certification shall provide regulatory oversight, licensing and inspection of neonatal abstinence syndrome centers.

4.2. The duties and powers of the Inspector General, as delegated to the Director, include, but are not limited to, the following:

4.2.1. Develop and implement rules, standards, and best practice guidelines regarding the licensure and oversight of neonatal abstinence syndrome centers;

4.2.2. Accept applications and fees for the licensure of neonatal abstinence syndrome centers;

4.2.3. Conduct all necessary reviews, inspections or investigations in order to determine whether a license should be issued or renewed;

4.2.4. Issue initial, amended and renewed licenses to neonatal abstinence syndrome centers upon a determination that the program is qualified;

4.2.5. Deny initial, amended and renewed licenses to neonatal abstinence centers upon the determination that the program is not qualified;

4.2.6. Perform annual inspections, revisits and complaint investigations as unannounced surveys when necessary and appropriate;

4.2.7. Monitor activities of all neonatal abstinence syndrome centers to ensure compliance with all state requirements;

4.2.8. Receive and act upon patient complaints, appeals and grievances;

4.2.9. Inspect all allegations of misconduct, rule or regulation violations, unauthorized activities or other conduct that may affect the health, safety or well-being of patients or employees of a neonatal abstinence syndrome center;

4.2.10. Issue a directed plan of correction when a neonatal abstinence syndrome center fails to develop an acceptable plan of correction;

4.2.11. Revoke or suspend the license of a neonatal abstinence syndrome center in accordance with the applicable administrative proceedings; and

4.2.12. Perform all other necessary actions related to the licensing, monitoring, investigatory and oversight of neonatal abstinence syndrome centers.

4.3. Annual Inspections.

4.3.1. Each neonatal abstinence syndrome center shall be inspected annually by the Director. Inspections shall include, but are not limited to:

4.3.1.a. Observations of service delivery;

4.3.1.b. Review of life safety and environmental conditions;

4.3.1.c. Review of clinical and administrative records;

4.3.1.d. Review of policies and procedures;

4.3.1.e. Review of employee and volunteer personnel files, criminal background checks, qualifications, staff education and staff training; and

4.3.1.f. Interviews with staff, administrators, volunteers, families, and legal representatives.

4.3.2. The neonatal abstinence syndrome center shall comply with any reasonable requirements from the Director with access, in a timely manner, to the facility, personnel, records, patients, and/or family/legal representatives to conduct annual inspection activities.

4.3.3. Within ten working days of the completion of the inspection, the Director shall issue a written report to the center. The written report or statement of deficiencies will detail the findings of the annual inspection, and a determination of compliance.

4.3.4. The Director may permit the neonatal abstinence syndrome center to develop a plan of correction based on the finding of the statement of deficiencies.

4.3.5. Based upon the neonatal abstinence syndrome center's previous substantial compliance with this rule, and the current inspection report, the Director may waive the requirement for an onsite inspection for issuance of an amended license.

4.4. For Cause Inspections and Complaints.

4.4.1. The Director may at any time inspect a neonatal abstinence syndrome center for cause upon a complaint or a reasonable suspicion the facility is operating in violation of this rule.

4.4.2. Any person may file a complaint with the Office of Health Facility Licensure and Certification alleging a violation of applicable laws, rules, or policies by a neonatal abstinence syndrome center.

4.4.3. The Director may conduct unannounced inspections of a neonatal abstinence syndrome center named in a complaint and any other inquiries deemed necessary to determine the validity of a complaint.

4.4.4. At the time of any on-site investigation activities, the Director shall notify the program sponsor or administrator of the general reason for the investigation.

4.4.5. Within ten working days of the completion of the investigation, the Director shall provide the program sponsor or administrator a written report of the results of the investigation. The report shall specify any deficiency found and the provisions of this rule that forms the basis for the violation.

4.4.6. The Director may permit the neonatal abstinence center to develop a plan of correction to address any cited violations or deficiencies.

4.4.7. The Director may issue a directed plan of correction to the center for implementation by the neonatal abstinence center to correct any violations or deficiencies.

4.4.8. The Director shall keep confidential any information that could reasonably lead to the identification of a complainant and of any patient involved in the complaint or investigation. The Director shall not disclose such information without the written consent of the complainant. Any identifying information shall be deleted before disclosure of the investigative information to the public.

4.5. Plans of Correction.

4.5.1. Within ten working days of the completion of the inspection, the Director shall issue a written report to the center. The written report or statement of deficiencies will detail the findings of the annual inspection, and a determination of compliance.

4.5.2. The Director may permit the neonatal abstinence syndrome center to develop a plan of correction based on the finding of the statement of deficiencies.

4.5.3. The Director may issue a directed plan of correction for implementation by the neonatal abstinence syndrome center to correct any violations or deficiencies.

4.5.4. Within ten working days after receipt of the inspection report, program sponsor or administrator shall submit to the Director for approval a written plan of correction for all deficiencies cited in an initial, provisional, renewal, complaint, or revisit survey. The plan of correction shall specify:

4.5.4.a. Any action taken or procedures proposed to correct the deficiencies and prevent their reoccurrence;

4.5.4.b. The date of completion of each action taken or to be taken; and

4.5.4.c. The signature of the head of the governing body or his or her designee.

4.5.5. The neonatal abstinence syndrome center shall correct all deficient practices cited during a survey.

4.5.5.a. The facility must take immediate steps to correct a deficient practice that poses an immediate jeopardy to the health or safety of a patient or other person.

4.5.5.b. The facility must identify a completion date for each correction. This completion date shall be within a time period that allows for the correction of the deficient practice.

4.5.6. The proposed plan of correction shall be approved, modified or rejected by the Director in writing.

4.5.6.a. The Director shall determine if the satisfactory corrections have been made and advise the program sponsor in writing of any compliance or continued deficiencies.

4.5.6.b. The Director shall state the reasons for rejection or modification of any plan of correction.

4.5.7. The neonatal abstinence syndrome center shall submit a revised plan of correction to the Director within ten working days of receipt of a rejection by the Director.

4.5.8. The Director may conduct an onsite revisit to determine compliance with the plan of correction.

4.6. Penalties.

4.6.1. The Director, in consultation with the Inspector General, may impose a fine, suspend or revoke a license or take other action as deemed appropriate to address any violations or deficiencies.

4.6.2. The Director, in consultation with the Inspector General, may suspend or revoke a license of any neonatal abstinence syndrome center for violating the prohibition of this rule.

4.6.3. The Director, in consultation with the Inspector General, may deny any application for licensure or licensure renewal as a neonatal abstinence syndrome center; revoke or suspend a license; and/or order an admissions ban or reduction in patient census for one or more of the following reasons:

4.6.3.a. The Director makes a determination that fraud or other illegal action has been committed;

4.6.3.b. The Director has violated federal, state or local law relating to building, health, fire protection, safety, sanitation or zoning;

4.6.3.c. The neonatal abstinence syndrome center conducts practices that jeopardize the health, safety, welfare or clinical treatment of a patient;

4.6.3.d. The neonatal abstinence syndrome center has failed or refused to submit reports or make records available as requested by the Director; or

4.6.3.e. The neonatal abstinence syndrome center has refused to provide access to its facility or records as requested by the Director.

4.6.4. If a license for a neonatal abstinence syndrome center has been revoked, the Director, in consultation with the Inspector General, may stay the effective date of the revocation if the program can show that the stay is necessary to ensure appropriate referral and placement of patients.

4.7. Informal Dispute Resolution.

4.7.1. The Director shall offer a neonatal abstinence syndrome center an opportunity for an informal dispute resolution process to contest a cited deficiency.

4.7.2. The neonatal abstinence syndrome center shall submit a request for an informal dispute resolution to the Director with the plan of correction.

4.7.3. The request for an informal dispute resolution must be received within ten working days of receipt of the inspection or investigation report.

4.7.4. The Director will maintain policies and procedures for conducting informal dispute resolutions.

4.7.5. If the neonatal abstinence syndrome center is successful in demonstrating the disputed deficiencies should not have been cited, the Director shall remove the deficiencies from the inspection or investigation report, and rescind any penalties imposed solely as a result of those disputed deficiencies.

4.7.6. All communications during an informal dispute resolution are confidential and cannot be used by or against the licensee or the Director in the event a formal hearing takes place.

4.7.7. Neither party is entitled to representation during the informal dispute resolution process.

4.8. Inspection Reports and Records.

4.8.1. Neonatal Abstinence Center Responsibilities.

4.8.1.a. The center shall make the results of the surveys and inspections, as well as plans of correction, available for examination in a place readily accessible.

4.8.1.b. The center shall post a notice of the availability of the survey and inspection reports in a place readily accessible to patients and visitors.

4.8.1.c. Any person shall have the right to review the most recent and past state inspection and complaint reports with the plan of correction.

4.8.2. Office of Health Facility Licensure and Certification Responsibilities.

4.8.2.a. The Director shall keep on file a report of any inspection, survey, investigation of any neonatal abstinence syndrome center or any program sponsor, owner, employee, volunteer or patient thereof in accordance with the Office of Inspector's record retention policy.

4.8.2.b. The information in reports or records shall be available to the public except for the following:

4.8.2.b.1. Information regarding complaints and subsequent investigations that is deemed confidential by any provision of this rule or applicable state or federal laws;

4.8.2.b.2. Information of a personal nature from a patient or personnel file; or

4.8.2.b.3. Information required to be kept confidential by state or federal law.

4.8.2.c. The Director shall make available for public inspection and, upon request, provide hard copies at a cost of $0.25 per page or electronically at a nominal cost, of the following documents:

4.8.2.c.1. Applications and exhibits;

4.8.2.c.2. Inspection reports;

4.8.2.c.3. Reports of investigations conducted in response to complaints; and

4.8.2.c.4. Any other report filed with or issued by the Director pertaining to the compliance of a neonatal abstinence syndrome center with applicable laws and rules.

4.8.2.d. If the Director determines it is in the best interest of the public, the Director may provide copies of records and reports free of charge to nonprofit community organizations upon written request.

4.8.2.e. The Director shall treat a report of inspection of a center as public information from the time an acceptable plan of correction is submitted.

4.8.2.f. If the center does not submit a written plan of correction, or a written plan of correction is not required within the time specified by the Director pursuant to this rule, reports pertaining to the center shall be made public at the expiration of the specified time.

4.8.2.g. Other records and reports shall be treated as public information from the time they are submitted to or issued by the Director.

4.8.2.h. Nothing contained in this section shall be construed to require or permit the public disclosure of confidential medical, social, personal, or financial records of any patient.

4.10. Interpretive Guidelines. The Director, in consultation with the Inspector General, may issue interpretive guidelines related to this rule and prior to the adoption and implementation of the guidelines, shall provide notice of a public comment period to all affected parties.

§71-16-5. Administrative Organization.

5.1. Each neonatal abstinence syndrome center shall identify a program sponsor, a governing body, an administrator, an advisory council, and a quality improvement committee.

5.2. Each member of the administrative organization, including staff, shall not have any actual or perceived conflict of interest.

5.3. Program Sponsor.

5.3.1. The program sponsor is the person named in the application for certification and licensure of a neonatal abstinence syndrome center.

5.3.2. The program sponsor shall agree on behalf of the center to adhere to all requirements set forth in federal and state laws, rules or regulations regarding the use of pharmacological medications in the treatment of neonatal abstinence syndrome.

5.3.3. The program sponsor is responsible for the general establishment, certification, licensure and operation of the neonatal abstinence syndrome center.

5.3.4. The program sponsor need not be a licensed physician. If the program sponsor is not a licensed physician, the center shall employ a licensed physician for the position of medical director. The medical director shall meet all requirements as specified in this rule.

5.4. Governing Body. The governing body is one or more persons identified by the program sponsor as being legally responsible for the operation of the neonatal abstinence syndrome center.

5.5. Administrator.

5.5.1. The administrator of the center shall have:

5.5.1.a. A minimum of a bachelor's degree in an appropriate area of study and a minimum of four years of management or administrative experience with programs for neonatal abstinence syndrome,

neonatal care, pediatric care, substance abuse, mental health, or other related field at the discretion of the governing body, or

5.5.1.b. A minimum of a master's degree in an appropriate area of study and a minimum of two years of management or administrative experience with programs for neonatal abstinence syndrome, neonatal care, pediatric care, substance abuse, mental health, or other related field at the discretion of the governing body.

5.5.2. The administrator is responsible for the day-to-day operation of the center in a manner consistent with all applicable federal and state laws and regulations.

5.5.3. The duties of the administrator include, but are not limited to:

5.5.3.a. Development of policies and procedures for operation of the center;

5.5.3.b. Maintenance and security of the center;

5.5.3.c. Employment, credentialing, evaluation, scheduling, training and management of staff;

5.5.3.d. Protection of patient rights;

5.5.3.e. Conformity of the program with confidentiality laws and regulations;

5.5.3.f. Security of medication storage and safe handling of medications;

5.5.3.g. Management of the facility budget;

5.5.3.h. Implementation of a quality improvement committee;

5.5.3.i. Implementation of governing body policy; and

5.5.3.j. Communication with the governing body.

5.6. Advisory Council.

5.6.1. Each center shall have an advisory council comprised of a designated group of individuals to serve in a non-managerial advisory capacity to the administrator and governing body.

5.6.2. The advisory council shall consist of individuals previously served by the program, at least one staff representative and interested community members and/or advocates. "Individuals previously served by the program" includes but is not limited to, parents, grandparents, foster parents, adoptive parents, and legal representatives. Individuals who were previously served by the program who have or have had addiction disorders shall be in recovery or have completed a recovery program to participate on the advisory council.

5.6.3. The advisory council shall not have access to any patient medical records unless personally identifying information has been redacted.

5.6.4. The advisory council shall meet at least quarterly in an area of the center where there are no patients present.

5.6.5. The advisory council shall:

5.6.5.a. Review program policies and procedures annually, or as proposed for revision;

5.6.5.b. Make recommendations for operational changes or improvements;

5.6.5.c. Be trained in patient confidentiality laws and regulations;

5.6.5.d. Keep records of meetings and describe business conducted, members present, and members absent; and

5.6.5.e. Work to assist the neonatal abstinence center in identifying, addressing and resolving problems.

5.6.6. The advisory council shall not review information related to specific patients, staffing, security, and medication storage and security.

5.6.7. The advisory council shall report any recommendations for the Quality Improvement Committee.

5.7. Quality Improvement Committee.

5.7.1. A member of the Quality Improvement Committee shall report to the governing board on an annual basis with regard to safety, case review, compliance and quality measures.

5.7.2. The Quality Improvement Committee shall consist of, at a minimum, the:

5.7.2.a. Administrator;

5.7.2.b. Medical Director;

5.7.2.c. Director of Nursing;

5.7.2.d. Registered Professional Nurse; and

5.7.2.e. Patient Care Assistant.

5.7.3. The Quality Improvement Committee will meet at least quarterly to:

5.7.3.a. Review both critical and noncritical incidents;

5.7.3.b. Address reports of and allegations of abuse and neglect;

5.7.3.c. Conduct case review;

5.7.3.d. Address grievances;

5.7.3.e. Establish standards and measurable outcomes, analyze outcome data as self-assessment;

5.7.3.f. Review of any recommendations submitted by the Advisory Council;

5.7.3.g. Provide feedback to the governing board; and

5.7.3.h. Identify problems or service deficits and develop plans to correct areas of concern.

5.7.4. The Quality Improvement Committee will conduct, at least quarterly, the following reviews:

5.7.4.a. Safety review;

5.7.4.b. Medication administration review; and

5.7.4.c. Security review.

5.8. Contractual Relationships.

5.8.1. The organization shall use written purchase of service agreements or written contracts with both general contractors and/or vendors and professional contractors of clinical services.

5.8.2. Purchase of non-clinical service or material contracts shall describe all significant terms and conditions including as appropriate:

5.8.2.a. Roles and responsibilities of participants;

5.8.2.b. Services to be provided;

5.8.2.c. Provisions for training and technical support as necessary;

5.8.2.d. Duration of the contract, including delineation of follow up services;

5.8.2.e. Methods for resolving disputes;

5.8.2.f. Documentation necessary for, and means of reporting to, funding or oversight bodies;

5.8.2.g. Conditions for termination; and

5.8.2.h. Expected outcomes as appropriate.

5.8.3. If the organization arranges externally or contractually for the provision of clinical services, the organization shall have a written agreement which specifies:

5.8.3.a. Roles and responsibilities of the organization and the contracting party;

5.8.3.b. Documentation required of the contracting individual or service with timelines for provision of the documentation;

5.8.3.c. Services to be provided;

5.8.3.d. Provision of appropriate liability or malpractice insurance either by the contractor or contracting party;

5.8.3.e. Procedures for exchange of information;

5.8.3.f. Definition of the patients to be served and the services to be provided;

5.8.3.g. Timelines for provision of service;

5.8.3.h. Methods for resolving disputes;

5.8.3.i. Terms of payment;

5.8.3.j. Assurances that the contracting party shall adhere to state and federal requirements of confidentiality; and

5.8.3.k. Expected outcomes as appropriate.

5.8.4. The organization shall ensure a complete personnel file on each contracted clinical employee and consultant who provides direct services to patients on site, including:

5.8.4.a. Evidence of clinical training;

5.8.4.b. Evidence of appropriate licensure or certification;

5.8.4.c. Evidence of malpractice or liability insurance as specified in the contract;

5.8.4.d. Evidence of ability to conduct business in the state of West Virginia; and

5.8.4.e. Evidence of state and federal fingerprint-based criminal background check.

5.8.5. If the organization contracts for professional services with a licensed practitioner who serves patients in his or her own location, the organization shall have a personnel file containing the following:

5.8.5.a. Evidence of clinical training;

5.8.5.b. Evidence of licensure;

5.8.5.c. Evidence of state and federal fingerprint-based criminal background check;

5.8.5.d. Evidence of liability insurance; and

5.8.5.e. Evidence of a license to operate a business in the State of West Virginia.

5.8.6. The organization shall ensure that contractual vendors are oriented to and adhere to the organization's policies and procedures regarding professional practices and confidentiality.

§71-16-6. Physical Facility.

6.1. Facility Construction and Renovation.

6.1.1. Before construction or extensive renovation of a neonatal abstinence syndrome center begins, the program sponsor shall submit for approval a complete set of plans for the project to the state oversight agency.

6.1.2. The plans shall include the drawings and specifications for the architectural, structural, and mechanical design for the construction or renovation.

6.1.3. The Director shall advise the program sponsor in writing delivered by regular mail whether approval has been granted within 30 days from the date of receipt of the plans.

6.1.4. In the event the plans for the project are not approved, the Director shall set forth in writing the reasons for the disapproval and provide the program sponsor the opportunity to correct any deficiencies.

6.1.5. Construction or extensive renovation of a facility may not begin until the Director has issued final approval of the plans in writing delivered by regular mail.

6.1.6. All centers must meet all other requirements of applicable federal or state agencies.

6.2. Facility Security Requirements.

6.2.1. Only persons who are employed by the neonatal abstinence syndrome center, volunteers, patients, parents, legal representatives, or other persons designated as approved contractors or visitors are permitted entrance to the neonatal abstinence syndrome center.

6.2.2. All employees and volunteers must wear an identity badge with a picture and first name listed while on the premises;

6.2.3. All doors providing entrance and exit to the center and secure areas of the center must use mechanical and/or electronic locking mechanisms to best ensure the safety of the patients and staff;

6.2.4. Visitation hours must be established by the center for all visitors other than parents and/or the legal representative;

6.2.5. All visitors must present valid government-issued photo identification to be permitted entrance into the facility;

6.2.6. Facilities must have policies and procedures addressing what visitors may or may not bring into the center;

6.2.7. Visitors are not permitted in any area of the facility not specifically identified for visitors; and

6.2.8. Visitors are not permitted to be in any area of the facility without an escort.

6.3. Service Environment.

6.3.1. The center shall ensure all patients have the necessities to meet their basic daily needs.

6.3.2. The center shall provide each patient with a nursery room including at a minimum, a baby bed and a rocking chair to accommodate his or her individual needs.

6.3.3. The center shall provide adequate storage space to accommodate clothing and personal items.

6.3.4. The facility shall have a sprinkler system in accordance with state fire marshal requirements.

6.3.5. The facility shall have a fire alarm system installed in accordance with state fire marshal requirements.

6.3.6. The center shall ensure the basic needs of the patient are consistently met.

6.3.7. The center shall ensure the overall environment is clean, pleasant in appearance, and conducive to the development and treatment of the patient.

6.3.8. All temporary walls or items being used as physical barriers shall be firmly anchored so they pose no threat to the safety of the patient, personnel, or visitors.

6.3.9. The center shall ensure no strings, cords and hanging items are of no threat to the patients.

6.4. Laundry and Linens.

6.4.1. The center shall have written policies for handling, storing, processing, and transporting linens and other laundered goods in a manner to prevent the spread of infection.

6.4.2. The soiled linen room shall be one hour fire rated, have negative air that discharges directly to the outside, and have a hand wash sink in the room.

6.4.3. The center shall provide clean waterproof mattresses or mattress covers that are non-absorbent.

6.4.4. Sufficient supplies shall be available to center personnel to assure the cleanliness and comfort of each patient.

6.4.5. The center shall provide each patient with individual towels, washcloths, and bedding.

6.5. Nursing Equipment and Sterile Supplies.

6.5.1. The center shall have sufficient quantity and type of nursing equipment to meet the individual care needs for each patient.

6.5.2. All electrical patient care equipment shall be maintained, inspected and tested in accordance with the manufacture recommendations, and the applicable sections of the "National Fire Protection Association NFPA 99 Standard for Health Care Facilities."

6.5.3. The generator and all life safety and critical branch electrical circuits shall comply with the standards as identified in the "National Fire Protection Association NFPA 99 Standard for Health Care Facilities."

6.5.4. All equipment shall be maintained in accordance with the provisions of this rule.

6.5.5. Clean nursing equipment and sterile supplies shall be stored in a clean workroom or storeroom that does not permit patient or visitor access.

6.5.6. Sterile supplies shall not be stored under sink drains, in soiled utility rooms or in areas where contamination may occur.

6.5.7. Sterile supplies shall not be stored nor used beyond their dated shelf life.

6.5.8. Damaged supplies and utensils shall not be used and shall be disposed of properly.

6.6. Housekeeping and Maintenance.

6.6.1. The facility shall be constructed, maintained and equipped to protect the health and safety of patients, personnel, and the public.

6.6.2. The center shall establish and implement a maintenance program that assures that:

6.6.2.a. All equipment is operable and in safe working condition;

6.6.2.b. The interior and exterior of the building is safe; and

6.6.2.c. The grounds are maintained in a presentable condition free from rubbish and other health hazards of a similar nature.

6.6.3. The center shall establish and implement a housekeeping program and services that assures a clean, sanitary environment.

6.6.4. The center shall be kept free of insects, rodents and vermin by an effective pest control program.

6.6.5. Pesticides shall be applied only by an applicator certified by the West Virginia Department of Agriculture.

6.6.6. The center shall have sufficient supplies for housekeeping and maintenance properly stored and conveniently located to permit frequent cleaning of floors, walls, woodwork, windows, and screens, and to facilitate building and grounds maintenance. These supplies shall be stored in such a way as to prevent contact with patients or visitors.

6.7. Storage of Supplies.

6.7.1. All cleaning and maintenance supplies must be kept in their original package or container with their labels intact.

6.7.2. All cleaning and maintenance supplies must be kept sealed and locked in an area separate from patient care areas.

6.7.3. All cleaning and maintenance supplies must be used according to the manufacturer's instructions.

6.8. Construction, Additions, Renovations, and Other Standards.

6.8.1. The center shall be located within fifteen minutes of a hospital.

6.8.2. The center shall comply with the most current edition of the National Fire Protection Association (NFPA) standards for limited health care facilities.

6.8.3. The center shall comply with the most current edition of the state building code.

6.8.4. The center shall comply with all applicable provisions of the Americans with Disabilities Act (ADA).

6.8.5. The center shall submit a complete set of architectural, structural, and mechanical drawings, drawn to scale not less than one-eighth inch equals one foot, and shall be approved by the Director before construction begins.

6.8.5.a. This requirement applies to new construction, additions, renovations, or alterations to an existing center.

6.8.5.b. This requirement applies to alterations, renovations, and equipment modifications or additions which may necessitate changes to the center's floor plan, impact on safety, or require the services of a design professional

6.8.5.c. The Director shall approval all plans prior to beginning construction.

6.8.5.d. The submitted drawing and specifications shall be prepared, signed, and sealed by a person registered to practice architecture in the state of West Virginia.

6.8.5.e. The project shall be inspected during the construction phase by a registered professional architect or his or her representative.

6.8.5.f. The requirement for a registered architect may be waived by the Director depending on the scope of the project.

6.8.5.g. The center shall submit complete architectural drawings and specifications for any alterations, renovations, and equipment modifications or additions which may necessitate changes to the center's floor plan, impact on safety, or require the services of a design professional, and shall be approved by the Director prior to beginning any construction.

6.8.5.h. Minor renovations that do not alter floor plans, impact on safety or require the services of a design professional may not require the approval of the Director.

6.8.5.i. A performance statement shall be obtained by the owner from the builder and design professional of a proposed center stating the builder has followed the plans which are on file with and approved by the Director.

6.8.6. All new facilities, additions, and alterations shall be inspected by the Director and shall have the Director's approval in writing prior to admitting patients.

6.8.7. The center shall request in writing a pre-opening inspection no less than 30 days prior to the proposed opening date.

6.8.8. Unless substantial construction is started within one year of the date of approval of final drawings, the owner or architect shall secure written notification from the Director that the plan approval for construction is still valid and in compliance with this rule.

6.9. Site Characteristics.

6.9.1. Sites for all centers and sites for additions to existing centers shall be inspected by the Director prior to site development and the completion of final drawings and specifications.

6.9.2. The site shall be located in an environment that is free from flooding and excessive noise.

6.9.3. The site shall not be exposed to excessive smoke, foul odors or dust.

6.9.4. The site shall have good drainage, approved sewage disposal, an approved potable water supply, electricity, telephone and other necessary utilities available on or near the site.

6.9.5. The site shall be accessible to physicians, emergency services and other necessary services.

6.9.6. Accessibility and transportation to the site and the center shall be facilitated by paved, hard-surfaced, all-weather roads which are kept passable at all times.

6.9.7. The road shall connect directly to a paved hard surface highway.

6.9.8. Grades to all sites shall permit access for emergency vehicles and firefighting equipment in all weather conditions.

6.9.9. Parking areas shall be sufficient according to the latest edition of the Guidelines for Design and Construction of Health Care Facilities according to the Facilities Guidelines Institute and published by the American Society for Healthcare Engineering at http://fgiguidelines.org/.

6.9.10. Local building codes and zoning restrictions shall be followed.

6.9.11. The owner, or his or her designee, shall maintain documentation certifying compliance signed by local fire, building and zoning officials, and this documentation shall be available for review.

6.9.12. Bed capacity may only be increased after the Director has determined the center's physical facilities will support the increase and there is compliance with other requirements, including certificate of need requirements.

6.10. Infection Control.

6.10.1. The neonatal abstinence syndrome center shall establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

6.10.2. The center shall establish and implement an infection control program to:

6.10.2.a. Investigate, control, and prevent infection in the center;

6.10.2.b. Determine what procedures, such as isolation, shall be applied to a patient, and only to the extent required to protect the patient and others; and

6.10.2.c. Maintain a record of incidents, investigations, and corrective actions related to infections. This record shall provide analysis of causal factors and identification of preventative actions to be implemented.

6.10.3. The center shall prohibit employees, volunteer and contracted personnel with a communicable disease or infected skin lesions from direct contact with patients and their food, if direct contact will transmit the disease.

6.10.4. The center shall require staff to wash or sanitize their hands after each direct contact and after engaging in any activity for which hand washing or sanitizing is indicated by accepted standards of professional practice.

6.10.5. Personnel shall handle, store, process and transport linens in order to prevent the spread of infection.

6.10.6. Infections, including culture results, shall be reported to applicable county health departments according to local, county or state laws, rules, and regulations.

6.11. Solid Waste and Bio-Hazard Waste Disposal.

6.11.1. The center shall have procedures and contracts for disposing of bio-hazardous waste.

6.11.2. Chain of custody receipts and forms shall be maintained by the center for one year.

6.11.3. The center shall have procedures for disposing of non-hazardous medical waste and similar waste that is not considered hazardous in a safe sanitary manner.

6.11.4. Solid waste, including garbage and refuse, shall be removed from the building daily or more often as necessary.

6.11.5. All garbage and refuse shall be stored in durable, covered, leak-proof and vermin-proof containers or dumpsters.

6.11.6. The containers and dumpsters shall be kept clean of all residue accumulation.

6.11.7. All garbage and refuse shall be disposed of in accordance with the applicable provisions of state and local law and rules governing the management of garbage and refuse.

6.12. Water Supply.

6.12.1. The facility shall have a water supply that is safe and of sufficient capacity to meet the patients' needs and the requirements of the sprinkler system.

6.12.2. The facility shall have as its source of water and a public water system that complies with West Virginia Department of Health Legislative Rule, Public Water Systems, W. Va. Code R. §§64-3-1, *et seq.*, or water well that complies with West Virginia Department of Health Legislative Rule, Water Well Regulations, W. Va. Code §§64-19-1, *et seq.* and Water Well Design Standards Legislative Rule, W. Va. Code §§64-46-1, *et seq.*

6.12.3. The facility shall have hot and cold running water in sufficient supply to meet the needs of the patients.

6.12.4. Hot water distribution systems serving patient care areas shall be recirculating to provide continuous hot water at each hot water outlet.

6.12.5. The temperatures shall be appropriate for comfortable use but shall not exceed 110° Fahrenheit.

6.12.6. The center shall have written agreements with water suppliers to deliver water when there is a loss of the normal supply.

6.13. Sewage Disposal.

6.13.1. Sewage disposal shall be in accordance with West Virginia Department of Health Legislative Rule, Sewage Systems, Sewage Treatment Systems, and Sewage Tank Cleaners Legislative Rule, W. Va. Code §§64-9-1, *et seq.*, and West Virginia Department of Health Legislative Rule, Sewage Treatment and Collection System Design Standards Legislative Rule, W. Va. Code §§64-47-1, *et seq.*

6.13.2. The sewage system shall be adequate to meet the center's needs.

6.13.3. Sewage systems shall be kept in good working order and shall be properly operated and maintained.

6.14. Fire Safety, Disaster and Emergency Preparedness.

6.14.1. The administrator shall provide evidence of the center's compliance with applicable rules of the State Fire Commission.

6.14.2. Any variation to compliance with the fire code shall be coordinated with the state oversight agency and approved in writing by the State Fire Marshal.

6.14.3. The center shall have a written internal and external disaster and emergency preparedness plan approved by the Director that sets forth procedures to be followed in the event of an internal or external disaster or emergency that could severely affect the operation of the center.

6.14.4. The disaster and emergency preparedness plan shall have procedures to be followed in the event of the following: fire, missing patient, high winds, tornadoes, bomb threats, utility failure, flood and severe winter weather.

6.14.5. The disaster and emergency preparedness plan shall include at least an alternate shelter agreement, an emergency transportation policy, and an emergency food supply list that will provide nutrition for all patients residing in the center for a minimum 72 hours.

6.14.6. The disaster and emergency preparedness plan shall be developed and maintained with the assistance of qualified fire safety and other emergency response teams.

6.14.7. There shall be copies of the disaster and emergency preparedness plan at all staff stations or emergency control stations.

6.14.8. The disaster and emergency preparedness plan shall be located in an area that allows visual contact at all times. The center staff shall know the location of the plan at all times.

6.14.9. The local fire department shall be provided with a floor and disaster plan and be given opportunities to become familiar with the center.

6.14.10. The center shall have a written plan and procedures for transferring casualties and uninjured patients.

6.14.11. These procedures shall include the transfer of pertinent patient records including identification information, diagnoses, allergies, advance directives, medications and treatments, and other records needed to ensure continuity of care.

6.14.12. The center shall have written instructions regarding the location and use of alarm systems, signals and firefighting equipment.

6.14.13. The center shall have information regarding methods of fire containment.

6.14.14. The center shall have written instructions regarding accessibility for evacuation routes.

6.14.15. The disaster and emergency preparedness plan shall be reviewed and updated by the administrator or his or her designee on an annual basis and signed and dated by the administrator or his or her designee to verify the plan was reviewed.

6.14.16. Emergency call information shall be conspicuously posted near each telephone in the center, exclusive of telephones in patient rooms. This information shall include at least the telephone numbers of the fire department, the police, and ambulance service and other appropriate emergency services; and key personnel telephone numbers, including at least the following:

6.14.16.a. The administrator;

6.14.16.b. The Director of Nursing or the registered professional nurse on duty;

6.14.16.c. The maintenance director or safety director;

6.14.16.d. The physician on-site or on-call; and

6.14.16.e. Other appropriate personnel.

6.14.17. The center shall have at least one non-coin-operated telephone or one extension on each distinct unit, section or wing of the center and additional telephones and extensions if needed to summon help in case of an emergency.

6.14.18. The facility shall include an area of sufficient space to hold the congregate population with a heat source that is supplied with emergency electrical power from the emergency power source.

6.14.19. The center shall operate an internal disaster preparedness program that includes orientation and ongoing training and drills in procedures and specific assignments.

6.14.20. The internal disaster plan shall be rehearsed at least annually.

6.14.21. Fire drills shall be held at least quarterly for each shift.

6.14.22. The center shall keep on file for at least two years, a dated written report and an evaluation of each disaster rehearsal and fire drill conducted on the premises.

§71-16-7. Patient Rights and Parent/Legal Representative Rights and Responsibilities.

7.1. Policies and Procedures.

7.1.1. The governing body of the center shall establish written policies and procedures regarding the rights and responsibilities of patients and legal representatives. The policies adopted shall be consistent with the provisions of this rule.

7.1.2. Through the administrator, the governing body is responsible for on-going development of and adherence to procedures implementing policies regarding the rights and responsibilities of patients.

7.1.3. The center shall make its policies and procedures available upon request.

7.1.4. The center shall have a non-discrimination policy, a patient bill of rights and a family bill of rights.

7.1.5. Prominently display a copy of the patient's rights and responsibilities, the names, addresses, and telephone numbers of all associated state agencies including licensing agencies.

7.2. Civil Rights.

7.2.1. A center shall not segregate a patient, give separate treatment, restrict the enjoyment of any advantage or privilege enjoyed by others in the center, or provide any aid, care services, or other benefits that are different from or are provided in a different manner from those provided to others in the center on the grounds of race, color, religion or national origin, age, disability, gender or other protected class.

7.2.2. A center shall not deny admission to a prospective patient on the grounds of race, religion or national origin, age, disability, gender or other protected class.

7.3. Abuse, Neglect, and Misappropriation of Property.

7.3.1. All patients have the right to be free from verbal, sexual, physical, and mental abuse, financial exploitation, discrimination, denial of privileges, corporal punishment, and involuntary seclusion.

7.3.2. The center shall develop and implement written policies and procedures that prohibit neglect, abuse of patients, and misappropriation of patient property. The policy and procedures shall address the screening, training, prevention, identification, investigation, protection, reporting and response of allegations of patient neglect, abuse, and misappropriation of patient property.

7.3.3. The center shall ensure all alleged violations involving mistreatment, abuse, neglect, and misappropriation of property, including injuries of unknown origin are reported in accordance with State law.

7.3.4. The center shall ensure all alleged violations involving mistreatment, abuse, neglect, and misappropriation of property, including injuries of unknown origin are reported to the Director

immediately, and no later than within 24 hours. In addition, the facility shall submit a five-day follow-up report. These shall be submitted on the form developed by the Director.

7.3.5. The center shall document that all alleged violations are thoroughly investigated and shall take appropriate steps to prevent further potential abuse while the investigation is in progress.

7.3.6. The results of all investigations shall be reported to the administrator or his or her designated representative and to other officials in accordance with State law, including the Director, within five working days of the incident, and if the alleged violation is verified appropriate corrective action shall be taken.

7.3.7. The center provides all employees with information regarding abuse, neglect, and misappropriation of property and related reporting requirements, including prevention, intervention and detection. This shall occur during orientation and annually as a continuous staff development program.

7.3.8. The center shall protect patients from abuse, neglect and misappropriation of property during the investigation of any allegations.

7.3.9. The center must have policies and procedures in place to protect patients from abuse, neglect, and misappropriation of property of all forms, whether from staff, visitors, or any other persons.

7.3.10. The center must have policies and procedures in place to identify the mandatory reporting requirements of abuse and neglect in accordance with state law and regulations.

7.4. Legal Representatives.

7.4.1. The center shall maintain in the patients' medical record verification of the authority of the legal representative and shall provide the legal representative with a general description of the scope of the legal representative's decision-making authority.

7.4.2. The center shall inform the parents and/or legal representative of his or her rights and responsibilities under the provisions of this rule. All rules governing parental and/or legal representative conduct must be fully explained prior to or at the time of admission and within 30 days of any changes. The parent and/or legal representative must acknowledge receipt of this information in writing and shall be permanently retained by the center in accordance with this rule.

7.4.3. Parents and/or legal representative must have the right to be informed of the patient's medical condition, care and treatment.

7.4.4. Parents and/or legal representatives have the right to voice all grievances without discrimination or reprisal and have prompt resolution.

7.5. Duties of Staff.

7.5.1. All staff and personnel of the center shall ensure that every patient under their care is accorded with all rights set forth in this rule.

7.5.2. The center staff shall at least annually receive training in the proper implementation of patient rights policies under the provisions of this rule.

7.5.3. When the center's staff limits or restricts the rights of a patient for medical reasons, the staff will document the specific reasons for the limitation or restriction in the patient's medical record, and the specific period of time the limitation or restriction will be in place. The patient or the patient's legal representative shall be notified of the limitation or restriction.

7.6. Informed Consent.

7.6.1. The center must have a policy to address how and when informed consent will be provided to the parents and/or legal representative.

7.6.2. Legal representatives shall be informed of their rights and responsibilities in writing, prior to admission.

7.6.3. Legal representatives shall be informed of the policies and procedures governing the facility.

7.6.4. Legal representatives shall be clearly informed of the responsibilities of the neonatal abstinence center for the care of the patient.

7.6.5. Legal representatives shall be clearly informed in writing of the costs of services to be provided and of any required services or procedures not included in the charge of the center.

7.7. Participate in Care Planning.

7.7.1. Legal representatives shall have the right to participate in the development of the patients' care plans.

7.7.2. Efforts shall be made by the center to accommodate the family and/or legal representative when scheduling all care planning meetings and reviews.

7.8. Confidentiality and Access to Records and Information.

7.8.1. The center shall ensure confidential treatment of each patient's personal and medical records. The center may approve or deny their release to any person outside the center, except in the case of his or her transfer to another health care institution, as required by law, or for a third-party payment contract.

7.8.2. Upon request, the center shall provide to each patient and legal representative access to all of his or her records, including current clinical records, within 24 hours of the request. Records may only be available during normal business operating hours, excluding weekends and holidays.

7.8.3. The center may charge a fee for providing copies of the patient's medical record in accordance with W. Va. Code §§16-29-1, *et seq*. The facility will provide the photocopied materials to the patient or legal representative within two working days of the request.

7.8.4. Any person shall have the right to review the most recent and past state and federal inspection and complaint reports with the center's plan of correction.

7.8.5. The center shall make the results of surveys and inspections, as well as plans of correction, available for examination in a place readily accessible to patients and legal representatives and shall post a notice of their availability.

7.8.6. The center may charge an amount not to exceed $0.25 per page for copies of reports requested by any person.

7.8.7. The center shall adopt policies and procedures that will protect the confidentiality of the patient as it relates to use of the patient's name and photographs.

7.9. Visitation.

7.9.1. The neonatal abstinence center shall have a policy that addresses visitation responsibilities and requirements for parents, legal representatives, and family. The policy must address, at a minimum, the following:

7.9.1.a. Regular visitation hours;

7.9.1.b. Off-hours visitation to accommodate working parents;

7.9.1.c. Visitor identification;

7.9.1.d. Monitoring and documenting the visitation;

7.9.1.e. Hand washing and protective clothing covers for visitors when handling patients;

7.9.1.f. Limiting the items (bags, purses, jackets) visitors may take into the center and/or into the visitation area;

7.9.1.g. Prohibiting illegal substances on the premises of the center;

7.9.1.h. Prohibiting prescription and non-prescription medications and supplements on the premises of the center;

7.9.1.i. Prohibiting weapons of any kind on the premises of the center;

7.9.1.j. Identifying where visitation is permitted within the center;

7.9.1.k. Identifying circumstances that may prohibit or limit visitation rights of parents, legal representatives and/or family;

7.9.1.l. Detailing how visitors will be identified, logged in and monitored;

7.9.1.m. Informing and educating visitors of the visitation policy and other relevant policies;

7.9.1.n. Handling visitors that do not abide by the visitation policies and other relevant policies of the center.; and

7.9.1.o. Addressing any medical needs of parents or guardians who stay overnight with their infant.

7.9.2. The center shall provide all parents, legal representatives, and family with a copy of the center's visitation policy.

7.9.3. All visitors have the responsibility to abide by the center's visitation policy.

7.9.4. The center shall have posted and consistent visitation hours with the exception of working parents who may visit during off hours set by the center.

7.9.5. The center must set hours for quiet time to maintain dimmed lights and a quiet environment.

7.9.6. Parents and/or the legal representative must be given a form of identification that matches their baby's identification wrist or ankle band.

7.10. Refusal of Treatment and of Experimental Research.

7.10.1. A parent and/or legal representative have the right to refuse treatment and to refuse to participate in experimental research unless mandated by court order.

7.10.2. When a refusal of treatment occurs, the center shall assess the reasons for the refusal, clarify and educate the parent and/or legal representative as to the consequences of the refusal, offer alternative treatments, and continue to provide all other services.

7.10.3. When refusal of treatment is assessed by the physician to place or potentially place the patient in immediate jeopardy or harm, the patient shall be transported to the hospital. The Director and child protective services shall be notified.

7.10.4. The center shall maintain documentation in the patient's medical record of the treatment refusal and the actions taken.

7.10.5. The parent and/or legal representative shall have the opportunity to refuse to participate in experimental research prior to the start of the research. The center shall inform a parent and/or legal representative of the patient being considered for participation in experimental research of the nature of the experiment and of the possible consequences for participation.

7.10.6. The center shall not transfer or discharge a patient for refusing treatment unless criteria for transfer or discharge are met under the provisions of this rule.

7.11. Complaint or Grievance Procedures.

7.11.1. The center must have a complaint and grievance policy in place to ensure parents, legal representatives and/or family have a procedure to resolve grievances and complaints in a timely manner.

7.11.2. The policy must address how the center will manage the complaint or grievance process in a timely and objective manner.

7.11.3. The policy must address how the center will inform the parents, legal representatives and/or family on the process for filing a complaint with the Office of Health Facility Licensure and Certification.

7.11.4. The policy must address how the center will inform the parents, legal representatives and/or family on the process to report suspected or alleged abuse and neglect to the child protective services and the Office of Health Facility Licensure and Certification, including address and phone number for filing complaints.

7.11.5. Information about how to file a complaint with the child protective services and the Office of Health Facility Licensure and Certification shall be posted in locations easily accessible by staff and visitors.

7.11.6. The policy must address how the center will inform parents, legal representatives and/or family on the process to report fraud, waste and abuse to the appropriate state agencies.

7.11.7. The policy must address how the center will inform parents, legal representatives and/or family on the process to report suspected crimes to law enforcement.

7.11.8. The policy must be posted in a location that is accessible to visitors.

7.12. Issues with Parental Participation.

7.12.1. If a biological mother is unwilling or refuses to visit or participate in the care of her baby, the center's staff will document each attempt to reach the biological mother, work to include other family members, and report all attempts and documentation to the protective services agency. The staff must document their attempts to assist the biological mother, including linkage and referral to necessary services and supports, including addiction treatment.

7.12.2. If the biological mother is unable to care for her baby, the center will investigate to determine the underlying cause of her inability and take appropriate steps to help her if it is her desire to participate in the care of her patient. This may include factors such as transportation issues, employment during visitation, disability, or other mitigating factors.

7.12.3. If a parent arrives at the center, and he or she is clearly under the influence of drugs or alcohol, the parent will be escorted from the facility, and the case record will be documented. This requirement is applicable to any visitor to the center. The center must have policies and procedures to identify how these situations will be handled.

§71-16-8. Incidents and Incident Reporting.

8.1. Critical Incidents.

8.1.1. The center shall provide an environment that remains free from accident hazards as possible.

8.1.2. The center shall provide an environment where each patient receives adequate supervision.

8.1.3. Critical incidents are incidents resulting in or the potential for significant harm or death to a patient. Critical incidents include, but are not limited to:

8.1.3.a. Allegations of abuse, neglect, mistreatment, misappropriation;

8.1.3.b. Medication errors;

8.1.3.c. Removal of a staff member from duty pending an investigation;

8.1.3.d. Behavior likely to lead to serious injury or significant property damage;

8.1.3.e. Involvement with law enforcement;

8.1.3.f. Possession of illicit substances, including alcohol, by anyone entering the facility;

8.1.3.g. Possession of a weapon by anyone entering the facility;

8.1.3.h. Injuries requiring medical treatment;

8.1.3.i. Reaction to medication or food requiring medical treatment;

8.1.3.j. Dietary errors with a negative outcome;

8.1.3.k. Removal of a patient from the nursery without authorization;

8.1.3.l. Fire;

8.1.3.m. Drug diversion;

8.1.3.n. Incident due to a lack of employee oversight;

8.1.3.o. Injuries of unknown origin;

8.1.3.p. Unusual occurrences, or

8.1.3.q. Any incident that has a significant and negative impact on the patient.

8.2. Critical Incident Reporting and Investigation.

8.2.1. The center shall submit a written report to the state oversight agency within 24 hours of any critical incident or accident in which a patient is involved, either inside or outside of the center. The report shall be documented on a form provided by the Director.

8.2.2. The report shall include the:

8.2.2.a. Date of the occurrence;

8.2.2.b. Time of the occurrence;

8.2.2.c. Place of the occurrence;

8.2.2.d. Details of the occurrence; and

8.2.2.e. Date and signature of the reviewing physician.

8.2.3. Maintains a record of critical incidents, investigations, and corrective actions related to infections. The records shall provide for analysis of causal factors and identification of preventative actions to be implemented.

8.2.4. Non-critical incidents that do not rise to the level of a critical incident shall be documented and monitored by the facility for trends and quality improvement opportunities.

§71-16-9. Staffing.

9.1. Medical Director.

9.1.1. The center shall designate, in writing, a physician accountable to the governing body to serve as medical director.

9.1.2. The center shall have a medical director to ensure medical care provided to patients is adequate and appropriate.

9.1.3. The medical director shall be certified by the American Academy of Pediatrics with a specialty in Pediatrics with at least three years of experience in the medical care of patients with neonatal abstinence syndrome.

9.1.4. The medical director is responsible for:

9.1.4.a. Reviewing policies, procedures, and guidelines to ensure adequate, comprehensive services;

9.1.4.b. Coordinating medical care provided in the center, so it is adequate and appropriate;

9.1.4.c. Assisting in the evaluation of credentialing and re-credentialing of licensed practitioners to determine whether they will be authorized to practice within the organization by recommendation;

9.1.4.d. Approving in-service training programs; and

9.1.4.e. Reviewing and evaluating incident reports or summaries of incident reports, identifying hazards to health and safety, and making recommendations as needed.

9.2. Director of Nursing.

9.2.1. The neonatal abstinence syndrome center shall employ a Director of Nursing with the following minimum qualifications:

9.2.1.a. The Director of Nursing shall hold a current and unencumbered license from the West Virginia Board of Examiners for Registered Professional Nurses; and

9.2.1.b. The Director of Nursing shall have at least two years of experience in the medical care of neonatal or pediatric patients.

9.2.2. The Director of Nursing shall be responsible for:

9.2.2.a. Assisting in the development of performance evaluations for all staff reporting to the Director of Nursing;

9.2.2.b. Supervising day-to-day clinical operations of the center, including but not limited to practice standards and quality improvement;

9.2.2.c. Developing and implementing programs and related materials based on best practices in collaboration with the Medical Director;

9.2.2.d. Assure competency and consistency in care and guide clinical practice through resource development, educational opportunities, consultation and research;

9.2.2.e. Developing and monitoring benchmark standards and tools to evaluate and achieve success in clinical objectives;

9.2.2.f. Reviewing the effectiveness of practice modalities and developing performance measures and indicators to assess success.

9.2.2.g. Continuously monitoring outcomes and approaches to ensure quality performance and outcomes;

9.2.2.h. Assisting in the development of educational materials to address deficiencies in the operation of the center; and

9.2.2.i. Coordinating outreach and education to referring centers or entities.

9.3. Registered Professional Nurse.

9.3.1. The center shall employ registered professional nurses to oversee and manage the care of patients being assessed and treated for neonatal abstinence syndrome.

9.3.2. There shall be one registered professional nurse per every four patients at all times. There must be a minimum of two licensed nurses on each shift, one of which must be a registered professional nurse.

9.3.3. Registered professional nurses shall hold a current and unencumbered license from the West Virginia Board of Examiner's for Registered Professional Nurses.

9.3.4. Registered professional nurses shall have a current cardiopulmonary resuscitation (CPR) certification.

9.3.5. Registered professional nurses shall have Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E. certification (https://stableprogram.org/) within one year of employment.

9.3.6. Registered professional nurses shall be responsible for:

9.3.6.a. Overseeing care and treatment of patients provided by personal care assistants;

9.3.6.b. Checking neonatal abstinence syndrome symptoms score once per shift, and as needed;

9.3.6.c. Participating in physician rounds for all assigned patients;

9.3.6.d. Administering medications according to physician's orders;

9.3.6.e. Verifying and documenting administration and dosage of all medications, including opiates, administered by another registered professional nurse;

9.3.6.f. Monitoring for adherence to feeding and treatment protocols;

9.3.6.g. Reporting all patient medical concerns to the physician;

9.3.6.h. Reporting all social concerns to the social worker;

9.3.6.i. Assuming care and treatment of patients requiring closer monitoring;

9.3.6.j. Communicating with parents and caregivers in a non-judgmental environment;

9.3.6.k. Maintaining confidentiality in all matters pertaining to patient and family care and treatment;

9.3.6.l. Providing education and support to parents and caregivers; and

9.3.6.m. Initiating and updating the plan of care.

9.4. Social Worker.

9.4.1. Social worker educational requirements must hold an unencumbered and valid West Virginia Social Work license.

9.4.2. Social worker must have three years of experience in working with people with substance abuse disorders and/or patient welfare.

9.4.3. Social worker shall be responsible to:

9.4.3.a. Coordinate and collaborate with the social work departments at all admitting hospitals;

9.4.3.b. Visit with and provide information to parents about the center;

9.4.3.c. Coordinate and give tours of the center to parents;

9.4.3.d. Work with the registered professional nurse during the admission process;

9.4.3.e. Review the center rules with parents;

9.4.3.f. Work with families to identify the existing needs and strengths for providing care;

9.4.3.g. Introduce the family to the clinical team at the center;

9.4.3.h. Ensure all families receive necessary training;

9.4.3.i. Provide parent and family training for non-medical issues;

9.4.3.j. Gather and record information regarding the family and patient social status;

9.4.3.k. Be the liaison to Patient Protective Services;

9.4.3.l. Help identify patients who should be remanded into state custody;

9.4.3.m. Coordinate local substance abuse prevention programs;

9.4.3.n. Prepares and maintains records for the patient's chart regarding social and parental strengths and needs; and

9.4.3.o. Meet regularly with the Director of Nursing and registered professional nurses to discuss patient and family care needs.

9.5. Personal Care Assistants.

9.5.1. The facility may employ personal care assistants to care for patients, including bathing, feeding, diapering, therapeutic handling and scoring neonatal abstinence syndrome symptoms that do not require an assessment.

9.5.2. Personal care assistants shall not be assigned to more than three patients.

9.5.3. Personal care assistants shall meet the following educational requirements:

9.5.3.a. A high school diploma, or equivalent; and

9.5.3.b. A current Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E. certification within one year of employment.

9.5.4. The center shall provide comprehensive orientation to each personal care assistant at a minimum to:

9.5.4.a. Provide an in-depth understanding of all policies and procedures of the center;

9.5.4.b. Report allegations abuse, neglect, misappropriation and fraud;

9.5.4.c. Report drug diversion concerns;

9.5.4.d. Become proficient in therapeutic handling; and

9.5.4.e. Become proficient in neonatal abstinence syndrome symptom scoring.

9.5.5. Personal care assistants shall be responsible for:

9.5.5.a. Caring for patients with neonatal abstinence syndrome under the direct supervision of a registered professional nurse;

9.5.5.b. Providing general patient care including, vital signs, bathing, feeding, and diapering.

9.5.5.c. Maintaining a low stimulus environment at all times;

9.5.5.d. Scoring patients using a neonatal abstinence syndrome scoring method;

9.5.5.e. Using therapeutic handling to comfort and decrease stimulus;

9.5.5.f. Directing any concerns to the registered professional nurse immediately;

9.5.5.g. Maintaining confidentiality in all matters pertaining to patient and family care and treatment;

9.5.5.h. Documenting care provided in the patient's chart; and

9.5.5.i. Reporting end of shift status to the registered professional nurse.

9.6. Volunteers.

9.6.1. All volunteers are subject to the criminal background check requirements under the provisions of this rule.

9.6.2. No one under the age of 18 may volunteer.

9.6.3. Each volunteer shall receive training in therapeutic handling and the characteristics of neonatal abstinence syndrome.

9.6.4. Volunteers may only perform tasks related to therapeutic handling, housekeeping, and clerical duties.

9.7. Staffing Ratios.

9.7.1. The center shall maintain a personal care assistant staffing ratio to meet the needs of the patients.

9.7.2. Employees assigned to provide care to patients on a specified unit, including nursing staff, may be included in the employee to patient ratio.

9.7.3. Employees assigned to supervisory duties, including nursing supervisor, or those duties that cause them to be away from the unit may not be included in the count.

9.7.4. There shall be one registered professional nurse per every four patients at all times. There must be a minimum of two licensed nurses on each shift, one of which must be a registered professional nurse, with the ability to increase the ratio when needed.

9.8. Staff Training and Development.

9.8.1. The center shall ensure all patient care employees are specifically trained to meet the needs of the patients with neonatal abstinence syndrome.

9.8.2. All patient care employees shall be trained within the first 30 days of employment on basic patient care, and on an ongoing annual basis.

9.8.3. At a minimum, all patient care employees shall be trained in:

9.8.3.a. Patient development;

9.8.3.b. Neonatal Advanced Life Support (NALS) or S.T.A.B.L.E. within one year of employment;

9.8.3.c. First aid;

9.8.3.d. Basic patient care; and

9.8.3.e. The effects of neonatal abstinence syndrome on the patient.

9.8.4. Prior to completion of the training, the new patient care employees shall be scheduled to work with only fully trained employees.

9.9. Personnel Records.

9.9.1. The center shall maintain a confidential personnel record for each employee containing the following information:

9.9.1.a. A dated application;

9.9.1.b. Reference verification;

9.9.1.c. Evaluations of work performance;

9.9.1.d. Tuberculosis screening prior to hire and every five years;

9.9.1.e. Current license, registration, or certification status if applicable to the job;

9.9.1.f. A summary of the employees' in-service training for the previous two years;

9.9.1.g. Any center specific required forms;

9.9.1.h. A job description signed by the employee; and

9.9.1.i. Records required to be retained for criminal background checks as defined by the provisions of this rule.

9.9.2. The center shall maintain a confidential personnel record for each volunteer containing the following information:

9.9.2.a. A dated application;

9.9.2.b. Reference verification;

9.9.2.c. Evaluations of work performance;

9.9.2.d. Tuberculosis screening prior to hire and every five years;

9.9.2.e. Current license, registration, or certification status, if applicable to the job;

9.9.2.f. A summary of the volunteer's in-service training for the previous two years;

9.9.2.g. Any center specific required forms;

9.9.2.h. A job description signed by the volunteer; and

9.9.2.i. Records required to be retained for criminal background checks as defined by the provisions of this rule.

9.10. Criminal Background Checks. The neonatal abstinence syndrome center shall be subject to the provisions of the W. Va. Code §§16B-15-1, *et seq.*, and W. Va. Code R. §§71-11-1, *et seq*.

§71-16-10. Admission, Discharge, and Transition.

10.1. Admission.

10.1.1. A center may accept admission under the following criteria:

10.1.1.a. The patient is recommended or referred by physician;

10.1.1.b. The patient is in stable condition;

10.1.1.c. The patient has a diagnosis of neonatal abstinence syndrome without other unrelated health conditions; and

10.1.1.d. The patient has an adjusted age of 36 weeks of gestation if born prematurely and is under the age of four months old.

10.1.2. The center shall have policies and procedures detailing the admission process.

10.1.3. The center shall have policies and procedures detailing the eligibility criteria for admission to the facility.

10.1.4. Each parent must sign a discharge preparation agreement upon admission acknowledging the understanding their responsibilities for working towards discharge of their baby. Parents must agree to, including but not limited to, the following:

10.1.4.a. Visit their patient at a frequency determined by the physician and the parents;

10.1.4.b. Participate in the care of the patient while present;

10.1.4.c. Learn the patient's stress cues and how to address them;

10.1.4.d. Learn and practice the minimal stress protocol for the patient experiencing withdrawal;

10.1.4.e. Attends parenting classes provided or arranged for by the center;

10.1.4.f. Attends weekly or bi-weekly meetings with the social worker, nursing staff and, when necessary, the physician.

10.1.4.g. Participate in education provided regarding discharge; and

10.1.4.h. Provide contact information where they can be reached at any time.

10.2. Discharge.

10.2.1. The social worker will oversee the discharge process with protective services or the legal representative with the appropriate legal documentation.

10.2.2. Discharge planning shall begin upon admission.

10.2.3. The family and/or legal representative shall be actively involved in the discharge planning.

10.2.4. Discharges must have a physician's order.

10.2.5. Situations for Appropriate Discharge.

10.2.5.a. The patient achieves the goals of his or her plan of care and no longer needs care and treatment outside of the home;

10.2.5.b. The patient reaches the maximum benefit from the services of the center;

10.2.5.c. The patient no longer meets the eligibility criteria; or

10.2.5.d. The patient has needs exceeding the resources of the center.

10.2.6. Discharge Criteria:

10.2.6.a. The patient must meet the following criteria prior to discharge from the center:

10.2.6.a.1. The patient shall be weaned off pharmacological interventions for at least 72 hours;

10.2.6.a.2. The patient shall have a neonatal abstinence syndrome score on an average of less than 8 or may be discharged with a higher average score at the discretion of the physician; and

10.2.6.a.3. Clearance by child protective services, if applicable.

10.2.6.b. Parents and/or legal representatives will meet criteria on the Parental Discharge Agreement and receive clearance from protective services for discharge.

10.2.6.c. Parents and/or legal representatives will receive instruction for therapeutic handling.

10.2.6.d. Parental education will be an ongoing process throughout the patient's hospitalization treatment.

10.2.6.e. All caregivers are required to receive training on the:

10.2.6.e.1. Period of excessive crying;

10.2.6.e.2. Caring for drug exposed patients;

10.2.6.e.3. Therapeutic handling; and

10.2.6.e.4. Discharge and aftercare.

10.2.7. Discharge Needs and Aftercare.

10.2.7.a. An assessment shall be completed by the center to determine whether the patient has access to appropriate baby items for daily care in the home.

10.2.7.b. An assessment shall be completed by the center to determine whether the patient has access to health, medical, nutritional, social, crisis, and emergency support in the home.

10.2.7.c. Referrals shall be made to connect the patient and their caregiver with the needed in-home care and support to meet their needs.

10.2.7.d. Patients shall be referred to all appropriate community-based support by the date of discharge as part of the after-care plan.

10.2.8. Discharge for Going Home with a Person other than a Biological Parent.

10.2.8.a. The legal representative must sign a Discharge Authorization form. The form must state the name of the person the patient is to be released to (including the father or other relative), date, and a form of identification (copied). The completion of the form must be witnessed.

10.2.8.b. Check the identification of the person picking up the patient. Identification must correspond with the name given on the Discharge Authorization form. If the patient is being held in custody of protective services, there must be an additional release form in the chart and the protective services representative must be present.

10.2.8.c. No patient is to be discharged to any person, other than the biological parent or legal representative, without signed consent unless the patient is in custody of the Department of Human Services.

10.2.8.d. The person picking up the patient must have all the appropriate legal documents deemed appropriate by the social worker of the facility.

10.2.8.e. Removal of the patient from the center shall only take place after all legal documents are signed and approved by the social worker of the facility.

10.2.8.f. The center's registered professional nurse will accompany the patient to the motor vehicle of the person picking up the patient and document patient was secure in an approved rear-facing car seat.

10.2.8.g. Document to whom the patient was discharged and complete any state required minor release reports.

10.3. Transfer.

10.3.1. The center shall have in effect a transfer agreement with one or more hospitals to reasonably assure timely admission of a patient to the hospital when transfer is medically appropriate as determined by a physician; and

10.3.2. The center shall have in effect a transfer agreement with one or more hospitals to reasonably assure medical and other information needed for the care and treatment of patients is exchanged between the institutions.

§71-16-11. Plan of Care.

11.1. Preventive health examinations shall occur at two-to-four-week intervals up to 24 weeks.

11.2. Thorough medical supervision and testing shall be done by an appropriately licensed health care professional with a specialization in neonatal abstinence syndrome.

11.3. Standing medical orders for conditions other than neonatal abstinence syndrome shall be carefully evaluated and shall take into consideration cautions necessary for neonatal abstinence syndrome.

11.4. The center shall have policies and procedures to assess and treat patients who show signs of illness, which include but are not limited to diarrhea, vomiting, and fever.

11.5. Each patient shall have an initial comprehensive assessment within 24 hours of admission that will result in the development of the initial plan of care. The initial plan of care will include a comprehensive summary of findings. The initial plan of care and implementation of services must begin at the earliest opportunity immediately after the initial assessment.

11.6. Comprehensive Assessment. The assessment will result in the development of the summary of findings and the plan of care.

11.6.1. The comprehensive assessment shall include:

11.6.1.a. Physical and medical assessment;

11.6.1.b. Demographic information and custody status;

11.6.1.c. Presenting problems and reason for referral;

11.6.1.d. Medical history;

11.6.1.e. Social history;

11.6.1.f. Developmental history;

11.6.1.g. Exposure history;

11.6.1.h. Summary of family strengths and weaknesses;

11.6.1.i. Treatment and medication orders;

11.6.1.j. Nutritional and dietary needs;

11.6.1.k. Summary of presenting problems and focus for treatment;

11.6.1.l. Behavioral status and needs; and

11.6.1.m. Any other special needs or accommodations.

11.6.2. When appropriate to the needs of the patient, the assessment should include:

11.6.2.a. Review of adaptive behavior;

11.6.2.b. Review of need for special accommodation or adaptive technology; and

11.6.2.c. Special or unique behavioral issues.

11.6.3. Each assessment will consider any unique aspects of the patient's racial, ethnic and cultural backgrounds and the need for any special service approaches resulting from the assessment.

11.6.4. The results of the initial assessment will be included in a written summary included in the patient's chart. This summary must include:

11.6.4.a. Recommendations for health screenings or treatment;

11.6.4.b. A diagnosis;

11.6.4.c. Recommendations for further assessment;

11.6.4.d. Recommendations for clinical behavioral health treatment;

11.6.4.e. Recommendations for interventions to be made in the home environment;

11.6.4.f. Recommendations for placement and aftercare upon discharge; and

11.6.4.g. Recommendations for family visitation unless contraindicated clinically or legally.

11.6.5. Medical and Physical Assessments.

11.6.5.a. Medical and physical assessments must occur upon admission and ongoing assessments must occur at various times throughout the day, week and month.

11.6.5.b. Medical and physical assessments must include, at a minimum, the following:

11.6.5.b.1. A head-to-toe physical assessment must be completed upon admission;

11.6.5.b.2. Vital signs and temperature must be completed upon admission and daily once per shift;

11.6.5.b.3. Scoring of neonatal abstinence syndrome symptoms, while the infant is on medication and during the observation period, is to be completed upon admission and every three to four hours thereafter;

11.6.5.b.4. Skin integrity for mottling or breakdown;

11.6.5.b.5. Respiratory status;

11.6.5.b.6. Breathing sounds;

11.6.5.b.7. Cardiovascular system;

11.6.5.b.8. Brief neurological exam; and

11.6.5.b.9. Weight and length of infant, and circumference of head.

11.6.5.c. Twice Daily Assessment.

11.6.5.c.1. Each patient will undergo a comprehensive head-to-toe assessment by a registered professional nurse every 12 hours. A patient care assistant may assist the nurse and observe the assessment.

11.6.5.c.2. Coordination of at least one of the twice daily assessments should take place during visitation hours, when possible, to provide an opportunity for parental participation.

11.7. Comprehensive Summary of Findings. The comprehensive summary of findings shall be developed as a result of the comprehensive assessment, and shall include:

11.7.1. A diagnosis;

11.7.2. A prognosis;

11.7.3. Recommendations for health screenings, pharmacological interventions, and non-pharmacological interventions;

11.7.4. Recommendations for continued assessment;

11.7.5. Recommendations for behavioral health treatment;

11.7.6. Recommendations for interventions needed in the home environment;

11.7.7. Recommendations for placement and aftercare upon discharge;

11.7.8. Recommendations for family visitation unless contraindicated clinically or legally; and

11.7.9. Recommendations for rights restrictions.

11.8. Plan of Care.

11.8.1. The Plan of Care will be developed based on the Comprehensive Summary of Findings.

11.8.2. The Plan of Care shall include the type, frequency, responsible party and justification or rationale for the following:

11.8.2.a. Treatment to be provided for health screenings, pharmacological interventions, and non-pharmacological interventions;

11.8.2.b. Nutritional interventions;

11.8.2.c. Continued assessment needs and schedule;

11.8.2.d. Behavioral health treatment and interventions;

11.8.2.e. Interventions for in the home environment;

11.8.2.f. Interventions for any other underlying medical problems;

11.8.2.g. Description of all services to be provided;

11.8.2.h. Family visitation schedule unless contraindicated clinically or legally; and

11.8.2.i. Consent and approval of the parent or legal representative, as appropriate.

11.8.3. The Plan of Care shall be developed by a team consisting of, at a minimum, the Medical Director, Director of Nursing, the patient's nurse, and the parents or legal representative of the patient.

11.8.4. A weekly review and update to the Plan of Care shall be conducted for the initial 30 days. All data from the weekly reviews shall be compiled to develop the Comprehensive Care Plan.

11.8.5. Development of the Plan of Care. The Plan of Care shall include, at a minimum, the following:

11.8.5.a. Plan to strengthen the relationship between patient and family, if clinically and legally appropriate;

11.8.5.b. Identify the goals of each service to be provided;

11.8.5.c. Identify the services to be provided to achieve all identified goals;

11.8.5.d. Identify pharmacological and non-pharmacological treatments and interventions prescribed by the physician;

11.8.5.e. Identify therapeutic and other behavioral health interventions to be provided;

11.8.5.f. Identify dietary and other health services to be provided;

11.8.5.g. Identify services provided by outside providers or entities;

11.8.5.h. Discharge and permanency plan;

11.8.5.i. Identify the person(s) responsible for all services and interventions provided; and

11.8.5.j. Identify the frequency for all services and interventions provided.

11.8.6. Review of the Plan of Care. The Plan of Care will be reviewed and updated on a weekly basis and at all critical junctures. The review shall be conducted by Medical Director, Director of Nursing, patient's family and/or legal representative. The review shall include, at a minimum, the following:

11.8.6.a. Review of each goal and its current status;

11.8.6.b. Identification of problems preventing progress and strategies to address these problems;

11.8.6.c. Modifications to the made to the plan;

11.8.6.d. Summary of interventions provided to date; and

11.8.6.e. Review of discharge plan.

§71-16-12. Pharmacological Interventions.

12.1. Pharmacological interventions used shall be those recognized as appropriate to treat neonatal abstinence syndrome in an inpatient community-based setting.

12.2. Medication, including over-the-counter medicine, will be prescribed and monitored by a licensed physician, physician's assistant or advanced practice registered professional nurse.

12.3. Patients admitted to the facility with properly labeled and bottled medications may continue those medications with appropriate consent until the center obtains a current physician's order. At no time shall this period exceed 24 hours.

12.4. Only the person with prescriptive authority may order medications and dosages; only the program physician may approve changes in dosage.

12.5. The parent and/or legal representative shall be advised of any change in medication dosage or administration.

12.6. Each neonatal abstinence syndrome center shall have policies and procedures to comply with all relevant federal and state laws, rules and regulations regarding the storage, management and administration of medications kept at the facility. The policies and procedures shall include measures to:

12.6.1. Ensure responsible handling and secure storage of all medications kept at the facility;

12.6.2. Ensure responsible documentation of all medications received, stored, administered and dispensed at the facility;

12.6.3. Ensure only authorized personnel may access the storage areas where any medications are kept;

12.6.4. Ensure the security of medications to prevent diversion;

12.6.5. Ensure the proper recording keeping of all medications, including but not limited to, the:

12.6.5.a. Receipt of medication records;

12.6.5.b. Initial inventory;

12.6.5.c. Monthly inventory;

12.6.5.d. Counting of all controlled substances;

12.6.5.e. Perpetual logs;

12.6.5.f. Administration;

12.6.5.g. Documenting wastage;

12.6.5.h. Documentation of patient charts;

12.6.5.i. Disposal of controlled substances; and

12.6.5.j. Transferring of controlled substances among registrants.

12.6.6. Ensure all personnel administering medications to adhere to federal and state laws, rules, regulations, and protocols or guidelines from approved authorities;

12.6.7. Ensure medications are administered only by a practitioner who is qualified to do so by his or her scope of practice, is licensed under the appropriate state law, and is registered under the appropriate state and federal laws to administer opioid drugs; and

12.6.8. Ensure all medication is administered in accordance with its approved product labeling.

12.7. Medication Errors.

12.7.1. In the event of a medication error, a registered professional nurse shall:

12.7.1.a. Complete a physical assessment of the patient's condition;

12.7.1.b. Provide any and all first aid, and contact emergency medical services;

12.7.1.c. Place patient on cardio-respiratory monitor, if opiate error;

12.7.1.d. Notify the attending physician immediately;

12.7.1.e. Document and read back physician orders; and

12.7.1.f. Once patients are stable, notify the Administrator, Director of Nursing, child protective services, and the Office of Health Facility Licensure and Certification.

12.7.2. Medication errors are considered a critical incident and must be reported to the Office of Health Facility Licensure and Certification.

12.8. Medication Storage and Handling.

12.8.1. Each and every time-controlled substances change hands or are used, documentation must be generated and maintained at the center.

12.8.2. Controlled substance records shall be maintained according to W. Va. Code §§60A-1-101, *et seq*.

12.8.3. Controlled substance records must be maintained at the center and must be readily retrievable and open to inspection and copying by the appropriate federal and state authorities.

12.8.4. The neonatal abstinence center shall conduct and submit a regular narcotics inventory and log review to the governing board on a quarterly basis.

12.8.5. On a regular monthly basis, and no longer than a 30-day interval, a narcotics log review shall be conducted by the Director of Nursing and one other professional staff member selected by the facility or the Governing Body.

12.8.6. The center shall provide training for all employees handling controlled substances in the proper procedures for storage and handling. This training shall be in accordance with the provisions of this rule.

12.8.7. All centers are required to have adequate controls in place to detect and prevent diversion of controlled substances.

12.8.8. All centers must follow proper storage requirements for ensuring security of medications, according to W. Va. Code §§60A-1-101, *et seq.*, including but not limited to:

12.8.8.a. All controlled substances in a building must be stored in a permanently affixed, securely double locked and substantially built safe or cabinet;

12.8.8.b. The process or system for security of controlled substances must be commensurate with the quantity and types of controlled substances stocked; and

12.8.8.c. Controlled substances must not be left out or unattended at any time.

12.9. Handling Diversion, Loss and Theft.

12.9.1. A loss or theft must be immediately reported to the Drug Enforcement Administration, Board of Pharmacy, the West Virginia State Police, and the Office of Health Facility Licensure and Certification.

12.9.2. All reports of loss or theft must be completed on the required forms or methods as indicated by state and federal law, regulation or protocol.

12.9.3. All centers shall have a diversion control plan to address the prevention, intervention, investigation and quality control measures for the safeguarding of medications.

12.10. Administration of Narcotic Medications. When administering narcotic medication:

12.10.1. Two licensed nurses, one of which shall be a registered professional nurse, shall count the number of vials belonging to the patient;

12.10.2. The registered nurses shall remove the prescribed amount of the medication and record the remaining number of vials;

12.10.3. The unused (excess) amount shall be wasted and disposed of in accordance with state and federal law and within the provisions of this rule; and

12.10.4. Both licensed nurses shall sign the individual narcotic record book.

12.11. Medication Disposal.

12.11.1. Any medication that is unused, outdated, discontinued, expired or contaminated as wastage must be disposed of or destroyed according to local, state and federal laws and regulations.

12.11.2. When controlled substances are disposed of or destroyed, the following documentation must occur:

12.11.2.a. Log must have the center's name and address indicated;

12.11.2.b. Date of disposal or destruction;

12.11.2.c. Time of disposal or destruction;

12.11.2.d. Patient's name;

12.11.2.e. Drug name, drug dosage, and quantity disposed of or destroyed;

12.11.2.f. Reason for disposal or destruction;

12.11.2.g. Signature of the person, who shall be a licensed professional, preparing the report and performing the disposal or destruction; and

12.11.2.h. Signature of the witness, who shall be a licensed professional, as to the report and disposal or destruction.

12.11.3. Controlled substances must be disposed of or destroyed beyond reclamation.

12.11.4. All other medications shall be disposed of according to federal and state laws, regulations and protocols.

§71-16-13. Non-Pharmacological Interventions.

13.1. The center shall provide patients a low stimulus environment to go through the withdrawal process in a safe manner without additional discomfort.

13.2. The center shall use therapeutic handling techniques, as tolerated, upon admission. Therapeutic handling consists of the following techniques:

13.2.1. Swaddling;

13.2.2. C-Position;

13.2.3. Head-to-Toe Movement;

13.2.4. Vertical Rocking;

13.2.5. Clapping;

13.2.6 Feeding;

13.2.7. Controlling the Environment; and

13.2.8. Introducing Stimuli.

13.3. The center shall ensure all caregivers will use soft voices and slow movements when handling patients.

13.4. The center shall provide an environment with low lighting, as needed by the patient.

13.5. The center shall maintain a quiet environment at all times.

13.6. The center shall educate parents and/or legal representative on the first visit about the low stimulus environment.

13.7. The center shall provide a consistent routine for all patients.

13.8. The center shall increase the amount of stimuli, including visual, auditory and tactile, as tolerated by the patient and according to the plan of care.

13.9. Feeding.

13.9.1. Prepared bottles shall be capped and clearly labeled with the patient's name, contents and the date prepared;

13.9.2. Prepared bottles shall be refrigerated in a separate section of the refrigerator and accessible only to employees;

13.9.3. Formula shall be stored in containers specific to the purpose;

13.9.4. Formula that remains at a temperature greater than 41 degrees Fahrenheit for more than one hour shall be discarded;

13.9.5. Formula bottles shall be used within timeframes established by the manufacturer and listed on the package; and

13.9.6. A microwave oven is not permitted for the heating of formula bottles under any circumstances.

13.9.7. A center shall have a planned three-day emergency food and water supply, and this may be incorporated with the regular stock of supplies.

13.10. Bathing.

13.10.1. The facility shall have a policy outlining the center's procedure for bathing patients in their care.

13.10.2. The center shall have a policy outlining the center's procedure for cleaning and disinfecting patient bathtubs.

13.11. Transportation.

13.11.1. The center shall have a policy to ensure the safety of the patient during transportation.

13.11.2. Qualified employees shall ensure each patient is secured in an approved rear-facing car seat.

13.12. Physician and Physician Services.

13.12.1. A physician shall approve, in writing, a recommendation for a person to be admitted to a neonatal abstinence center. Each patient shall remain under the care of an attending physician.

13.12.2. Physician supervision. A center shall ensure the medical care of each patient is supervised by a physician.

13.12.3. Physician visits. The physician shall:

13.12.3.a. Review the patient's plan of care, including medications and treatments, and examine the patient personally at each visit required under the provision of this rule;

13.12.3.b. Write, sign and date progress notes at each visit; and

13.12.3.c. Sign and date all orders.

13.12.4. Frequency of physician visits. The patient shall be seen face-to-face by a physician:

13.12.4.a. Within 24 hours of admission; and

13.12.4.b. At least twice per week, or more frequently as indicated by the needs of the patient.

13.12.5. Except as provided under the provisions of this rule, all required physician visits shall be made by the physician personally.

13.12.6. Availability of physician for emergency care. A center shall provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

13.12.7. Physician delegation of tasks. Except as specified under the provisions of this rule, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who:

13.12.7.a. Is licensed by the State;

13.12.7.b. Is acting within their scope of practice; and

13.12.7.c. Is under the supervision of the physician.

§71-16-14. Parent Education and Counseling.

14.1. The center shall provide or arrange for engagement, assessment, therapeutic services, and link to community support and services as part of the discharge and transition planning. Primary focus will be parents, families, and legal representatives of patients.

14.2. The parent education and counseling essential duties and responsibilities include but are not limited to:

14.2.1. Meet, or document attempts to meet, with parents, families, and/or legal representatives while patient is in the hospital and prior to admission to the neonatal abstinence syndrome center for the purpose of engaging and initiating admission process;

14.2.2. Complete biopsychosocial assessment of parents, family, and/or the legal representative that includes the use of drugs and alcohol;

14.2.3. Provide access to individual and group therapy, individual and group supportive intervention, and psychoeducational services to parents, families, and/or legal representatives;

14.2.4. Assist parents in obtaining needed support by establishing linkage, including but not limited to, employment, housing, and social service benefits;

14.2.5. Develop and arrange services and support for the parents, family, and/or legal representative upon discharge, including but not limited to behavioral and physical health services and recovery support; and

14.2.6. Coordinate linkage with, and support by, peer support and recovery coaches.

§71-16-15. Medical Records and Retention.

15.1. A medical record must be maintained for every individual evaluated or treated in the facility.

15.2. The center must employ adequate personnel to ensure prompt completion, filing and retrieval of records.

15.3. Medical records must be accurately written, promptly completed, properly filed and retained.

15.4. The center must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

15.5. Medical records must be retained in their original or legally reproduced form until the patient reaches 24 years of age.

15.6. The center must have a procedure for ensuring the confidentiality of patient records.

15.6.1. Information from or copies of records may be released only to authorized individuals and the facility must ensure that unauthorized individuals cannot gain access to or alter patient records.

15.6.2. Original medical records must be released by the facility only in accordance with federal or state laws, court orders or subpoenas.

15.7. All patient medical record entries must be legible, complete, dated, timed and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with policies and procedures of the center.

15.8. The clinical or medical record must contain, at a minimum, the following:

15.8.1. Biographical information;

15.8.2. Copies of the custody and/or guardianship records;

15.8.3. Court ordered restrictions for the patient;

15.8.4. Reason for the referral;

15.8.5. Admission intake forms;

15.8.6. Discharge plan;

15.8.7. Aftercare plan for ongoing and future service needs;

15.8.8. Psychological, medical, toxicological, diagnostic and psychosocial evaluations;

15.8.9. Assessment information;

15.8.10. Plan of care, including goals of service;

15.8.11. Reports from outside and contracted providers of service to the patient;

15.8.12. Copies of all signed, written consent forms;

15.8.13. Routine documentation of ongoing services;

15.8.14. Documentation of incidents;

15.8.15. Documentation of medication administration records;

15.8.16. Documentation of treatment administration records;

15.8.17. Copies of all written orders for medications or special treatment procedures; and

15.8.18. Closing summary of discharge.

15.9. Medical records shall be maintained, handled and stored in a confidential manner to comply with all state and federal laws.

15.10. Access to the medical record is limited to the:

15.10.1. Patient;

15.10.2. His or her parents, as legally appropriate;

15.10.3. Legal representative;

15.10.4. Attorney, as legally appropriate;

15.10.5. Employees, as needed to provide care; and

15.10.6. Others as permitted by state or federal law.